## The Lifetime Prevention Schedule For Children and Youth

Establishing Priorities among Effective Clinical Prevention Services in British Columbia For Children and Youth

Summary and Technical Report July 2014 Update







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### Establishing Priorities among Effective Clinical Prevention Services in British Columbia for Children and Youth

#### **Executive Summary**

The report, *A Lifetime of Prevention*, which was published by the Clinical Prevention Policy Review Committee (CPPRC) in December of 2009,<sup>1</sup> outlined which clinical prevention services were considered to be effective, had a significant impact on population health, and were cost-effective. It has been several years since the proposed Lifetime Prevention Schedule (LPS) was published, therefore it is time to update and potentially expand the number of clinical prevention services based on new evidence of effectiveness, clinically preventable burden and cost effectiveness. The purpose of the current project is to update and potentially expand the number of clinical prevention services included on the LPS. To do so, the following questions were addressed:

Is there new evidence which calls into question the effectiveness of any of the clinical prevention services currently on the LPS?

Are there additional clinical prevention services which are effective and should be considered for inclusion on an expanded LPS? The process by which this question was addressed is the topic of two companion documents.<sup>2,3</sup>

Based on currently available data, what is the clinically preventable burden (CPB) associated with the clinical prevention service? CPB is defined as "the total quality-adjusted life years (QALYs) that could be gained if the clinical preventive service were delivered at recommended intervals to a B.C. birth cohort of 40,000 individuals over the years of life that a service is recommended."

Based on currently available data, what is the cost-effectiveness (CE) associated with the clinical prevention service? CE is defined as "the average net cost per QALY gained in typical practice by offering the clinical preventive service at recommended intervals to a B.C. birth cohort over the recommended age range."

Through a collaborative process and the application of consistent methodology, the Lifetime Prevention Schedule Expert Advisory Committee completed a process in which additional clinically effective prevention maneuvres were considered for inclusion in the previous LPS. The updated list is shown below. Nine of the 19 maneuvers (highlighted in *italics*) are particularly relevant to children and youth.

<sup>&</sup>lt;sup>1</sup> Clinical Prevention Policy Review Committee. A Lifetime of Prevention: A Report of the Clinical Prevention Policy Review Committee. 2009. Available at

http://www.health.gov.bc.ca/library/publications/year/2009/CPPR\_Lifetime\_of\_Prevention\_Report.pdf. Accessed August 2013.

<sup>&</sup>lt;sup>2</sup> H. Krueger & Associates Inc. *Evidence Review and Economic Modelling of Preventive Health Maneuvers to Update the BC Lifetime Prevention Schedule: Methodology Report.* October 21, 2013.

<sup>&</sup>lt;sup>3</sup> H. Krueger & Associates Inc. Evidence Review and Economic Modelling of Preventive Health Maneuvers to Update the BC Lifetime Prevention Schedule: Determining Which Maneuvers to Prioritize. November 4, 2013.

#### Screening for Asymptomatic Disease or Risk Factors - Children/Youth

- Newborn screening for hearing
- Vision (amblyopia) screening

#### **Behavioural Counseling Interventions – Children/Youth**

• Preventing tobacco use

- **Preventive Medication Children/Youth** 
  - Fluoride varnish and sealants to prevent dental caries

Screening for Asymptomatic Disease or Risk Factors – Adults

- Breast cancer screening women 50-74
- Cervical cancer screening women 25-69
- Colorectal cancer screening adults 50-74
- Hypertension screening and treatment adults 18+
- Cholesterol screening and treatment men 35+, women 45+

• Screening for Hepatitis C Virus - adults born between 1945 and 1965

#### Routine Offer of Screening for STIs in Sexually Active Young Adults

- Screening for Human Immunodeficiency Virus (HIV) adolescents/adults 15-65
- Screening for Gonorrhea females 15-29
- Screening for Chlamydia females 15-29
- Screening for Syphilis

#### **Behavioural Counseling Interventions – Adults**

- Smoking cessation advice and help to quit
- Alcohol screening and brief counseling
- Prevention of Fetal Alcohol Spectrum Disorder (FASD)

#### **Preventive Medication – Adults**

- Discuss daily aspirin use men 45-79, women 55-79
- Preventing falls in community-dwelling elderly adults 65+

# This document provides the details supporting the estimated CPB and CE associated with each of the 9 maneuvers that are particularly relevant to children and youth. Each section of the document will focus on a specific maneuver, including the most current recommendations from the Canadian Task Force on Preventive Health Care (CTFPHC) or the US Preventive Services Task Force (USPSTF), information on the utilization of the maneuver in British Columbia and best practices elsewhere in the world (to determine the *potential* utilization of the maneuver in BC) and an estimate of Clinically Preventable Burden (CPB) and Cost Effectiveness (CE), including a sensitivity analysis.

In order not to duplicate evidence reviews, the Lifetime Prevention Schedule Expert Advisory Committee decided to refer any recommendations regarding immunizations to the BC Immunization Schedule and any recommendations regarding prenatal care, intrapartum care and immediate postpartum care to the Perinatal Services BC (PSBC) or other relevant Provincial Health Services (PHSA) guidelines. A listing of these is included in the appendices.

The following summary tables and figures are based on the analysis of the 9 clinical prevention services particularly relevant to children and youth being considered for inclusion on the LPS.

Table ES-1 provides an overview of the results. The *estimated coverage* columns include information on current coverage in BC for a specific maneuver as well as information indicating the best coverage in the world (BiW). For example, an estimated 30% of children

in BC have dental sealants. Evidence from other jurisdictions suggests that this coverage could be increased to 70%.

The *CPB* columns identify the clinically preventable burden (in terms of quality adjusted life years or QALYs) that is being achieved in BC based on current coverage and the potential CPB if BiW coverage is achieved. For example, with BiW coverage for dental sealants of 70%, we would expect a CPB of 558 QALYs. Since BC's coverage is at 30%, a CPB of 239 QALYs is being achieved. This is 319 QALYs short of the potential 558 QALYs achievable based on BiW coverage, as identified in the *Gap* column.

The *CE* columns identify the cost-effectiveness ratio associated with a maneuver based on a cost per QALY. The ratio is given based on the use of a 3% and a 0% discount rate. In the economic appraisal of health programs or interventions, costs and benefits that are spread over time are usually weighted according to when they are experienced. The further in the future, the less heavily they are weighted or the more they are discounted. This can be particularly challenging for interventions in which costs are current and benefits are further in the future (e.g. prevention). The impact of discounting is most noticeable for preventive services in children and youth, given that costs are generally current while benefits and potential costs avoided may stretch over the lifetime of the individual.

From a health economics perspective, the usual approach is to discount both costs and benefits when calculating cost-effectiveness. However, discounting may fail to reflect a value we as a society might hold for the future of our children. It would thus be important to explicitly understand the impact of discounting in the current project. To do so, we will use both a 3% discount rate as well as a 0% discount rate. A 0% discount rate is equivalent to not discounting.

As an example of the application of a 3% and a 0% discount rate, the cost/QALY associated with dental sealants in BC is estimated at -\$15,140, based on using a discount rate of 3%. If a 0% discount rate is used, then the cost/QALY would be reduced to -\$18,917.

Summary (Not incl	luding Immun	izations or P	erinatal Ca	re)			
			CPB(2	) <b>(0% Disco</b>	unt)	CE(3) (% I	Discount)
	Estimated	Coverage		QALYs		Cost	/QALY
Clinical Prevention Services	B.C.	'BiW'(1)	B.C.	'BiW'(1)	Gap	3%	0%
Screening for Asymptomatic Disease or Risk Factors - Children							
Screening for hearing - newborn		Ра	rt of immed	diate postpa	rtum care		
Vision screening for amblyopia - children, 3-5	93%	93%	25	25	-	\$879,199	\$179,901
Behavioural Counseling Interventions - Children/Youth							
Preventing tobacco use - children/youth	Unknown, assume 0%	65%	-	1,299	1,299	(\$7,262)	(\$16,750
Preventive Medication - Children							
Fluoride varnish - children	92%	92%	407	407	-	\$19,292	\$19,292
Dental sealants - children/youth	30%	70%	239	558	319	(\$15,140)	(\$18,917
Routine Offer of Screening for Sexually Transmitted Infections	- Adults						
Screening for Human Immunodeficiency Virus - adults 15-65	20%	70%	111	387	276	\$43,846	\$43,846
Screening for Chlamydia/Gonorrhea - women 15-29	29%	50%	647	1,115	468	\$9,900	\$7,980
Behavioural Counseling Interventions - Adults							
Alcohol screening and brief counseling - adults	Unknown, assume 0%	35%	-	1,136	1,136	\$1,175	(\$12,636
LARC(4) and screening/counseling to reduce Fetal Alcohol Spectrum Disorder (FASD)	Unknown, assume 0%	70%	-	3,752	3,752	(\$2,829)	(\$4,980

Figure ES-1 provides a summary of the CPB associated with each service. Results are displayed based on using a 0% discount rate. Results based on a 3% discount rate are available in the body of the report. The results are organized from left to right based on the maneuvers with the highest to lowest potential CPB. For example, fully implementing the maneuver *long acting reversible contraception and screening/counseling to reduce Fetal Alcohol Spectrum Disorder* (FASD) (i.e. achieving levels that are comparable to the best in the world) would result in a CPB of 3,281 QALYs, the highest of any maneuver reviewed. We have assumed that this maneuver is not currently available in any systematic way in BC so the gap between current results in BC and the potential full implementation of this maneuver in the province would be 3,281 QALYs.

The black error bars / whiskers associated with each maneuver represent a potential range in CPB based on one-way sensitivity analysis. That is, the range is based on varying (over a plausible range) the one assumption that has the largest effect on the model results. Simultaneously varying more than one assumption would increase the potential range. A larger range suggests a higher sensitivity in the model to the assumptions used.

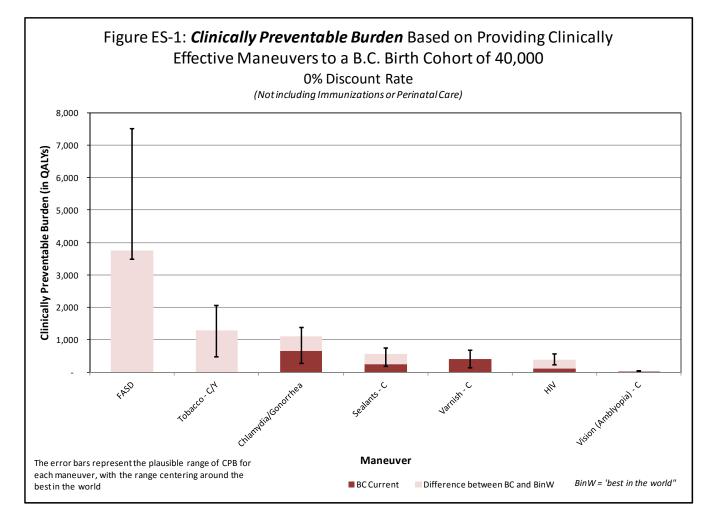
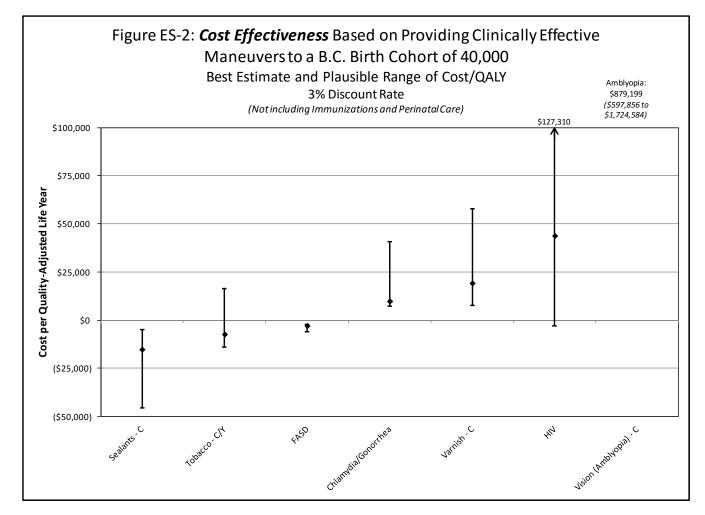


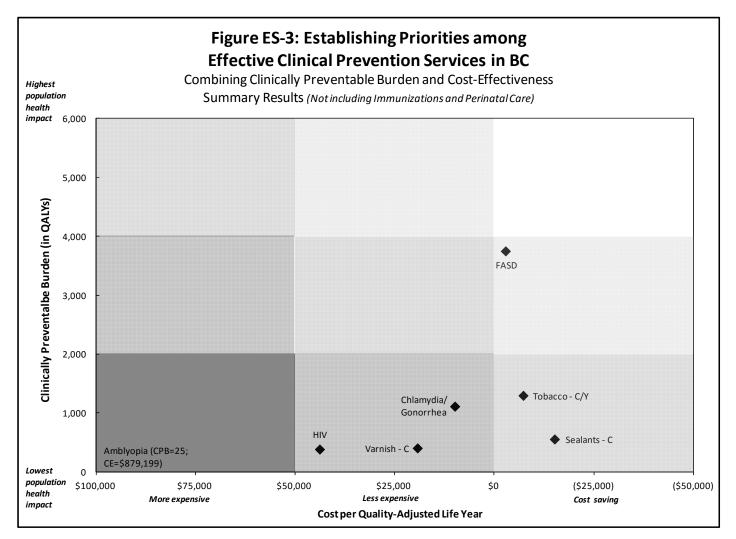
Figure ES-2 provides a summary of the CE associated with each service. Results are displayed based on using a 3% discount rate. Results based on a 0% discount rate are available in the body of the report. The results are organized from left to right based on the maneuvers with the best to worst potential CE, including a plausible range for each maneuver based on sensitivity analysis. The use of *dental sealants for the prevention of caries in permanent teeth* has the best CE result of any maneuver reviewed. That is, this maneuver is considered to be cost-saving with a cost per QALY of -\$15,140 (with a potential range from -45,421 to -\$4,706).

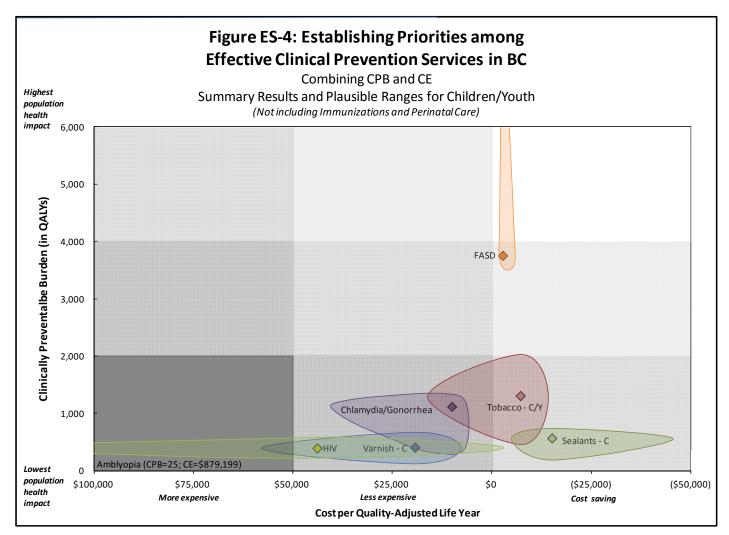
The black error bars / whiskers associated with each maneuver represent a potential range in CE based on one-way sensitivity analysis. That is, the range is based on varying (over a plausible range) the one assumption that has the largest effect on the model results. Simultaneously varying more than one assumption would increase the potential range. A larger range suggests a higher sensitivity in the model to the assumptions used.



The results for CPB and CE are combined in Figure ES-3. CPB is on the vertical axis, ranging from 0 to 6,000 QALYs. CE is on the horizontal axis, ranging from \$100,000/QALY at the intersection of the x- and y-axis to -\$50,000 at the far right of the x-axis. By arranging CPB and CE in this manner, the most positive results are on the upper right of the chart and the least positive results are in the lower left of the chart. We also divided CPB into three equal segments as follows; 0 to 2000 CPB, 2000 to 4000 CPB and 4000 to 6000 CPB. CE was also divided into three equal segments as follows; \$100000 to \$50000 per QALY, \$50000 to \$0 per QALY and \$0 to -\$50000 per QALY.

The result is nine equivalent segments in Figure ES-3. Maneuvers in the upper right segment have the most favourable combination of CPB and CE while maneuvers in the lower left segment have the least favourable combination of CPB and CE.





In Figure ES-4, we have incorporated visual information on plausible ranges (based on one-way sensitivity analysis) with the point estimates for each maneuver.

#### Introduction

The report, *A Lifetime of Prevention*, was published by the Clinical Prevention Policy Review Committee (CPPRC) in December of 2009.<sup>4</sup> A key goal of the CPPRC was to determine which clinical prevention services are worth doing in British Columbia, culminating in a proposed Lifetime Prevention Schedule (LPS).

Clinical prevention services (CPS) are defined as:

Maneuvres pertaining to primary and early secondary prevention (i.e., immunization, screening, counselling and preventive medication) offered to the general population (asymptomatic) based on age, sex, and risk factors for disease, and delivered on a one-provider-to-one-client basis, with two qualifications:

(i) the provider could work as a member of a care team, or as part of a system tasked with providing, for instance, a screening service; and

(ii) the client could belong to a small group (e.g., a family, a group of smokers) that is jointly benefiting from the service.

This definition does not refer to the type of provider or the type of funding. This allows for the evaluation of the appropriate implementation of the service as a separate program planning matter. For example, a childhood immunization is considered effective regardless of whether a public health nurse or a family physician administers the dose.

In writing *A Lifetime of Prevention*, the CPPRC recognized that the proposed LPS was an initial step in enhancing the provision of CPS within the province. Indeed, the report made the following recommendations related to potential updates of the LPS:

- 1. Ensure subsequent changes to the LPS are recommended by the Clinical Prevention System Working Group with representatives from across the system. New services will be identified on the basis of their:
  - clinical effectiveness;
  - potential population health impact (as measured by the clinically preventable burden of disease or other suitable measure) and
  - cost-effectiveness.
- 2. Assess as a priority, for possible inclusion in the LPS, four potential new services:
  - Alcohol screening and brief counselling in adults;
  - Screening for STIs in sexually active young adults;
  - Vision screening in adults 65+ and
  - Well-baby care.
- 3. Assess as a priority, for possible inclusion in the LPS, services reviewed by the US Preventive Services Task Force (USPSTF) since 2008, the date of the material found in the appendices. Particular attention should also be paid to services reviewed since 2004, since the HealthPartners analysis of clinically preventable burden and costeffectiveness only included items prior to that date. Additionally, as the Canadian

<sup>&</sup>lt;sup>4</sup> Clinical Prevention Policy Review Committee. A Lifetime of Prevention: A Report of the Clinical Prevention Policy Review Committee. 2009. Available at

 $http://www.health.gov.bc.ca/library/publications/year/2009/CPPR\_Lifetime\_of\_Prevention\_Report.pdf.\ Accessed\ August\ 2013.$ 

Task Force on Preventive Health Care becomes re-established and begins to develop new or updated guidelines and recommendations, their "A" graded guidelines and recommendations will also need to be assessed for inclusion in the LPS.<sup>5</sup> (p 41)

Since 2004, the UPSTF has conducted or updated 81 evidence reviews while the Canadian Task Force on Preventive Health Care (CTFPHC) has conducted or updated 10 evidence reviews.

In preparing the current update, the Lifetime Prevention Schedule Expert Advisory Committee refined the methodology involved<sup>6</sup> and then completed a process in which additional clinically effective prevention maneuvers were included on a list together with the maneuvers currently on the Lifetime Prevention Schedule.<sup>7</sup> The updated list is shown below. Nine of the 19 maneuvers (highlighted in *italics*) are particularly relevant to children and youth.

#### Screening for Asymptomatic Disease or Risk Factors – Children/Youth

- Newborn screening for hearing
- Vision (amblyopia) screening

#### **Behavioural Counseling Interventions – Children/Youth**

• Preventing tobacco use

#### **Preventive Medication – Children/Youth**

• Fluoride varnish and sealants to prevent dental caries

#### Screening for Asymptomatic Disease or Risk Factors – Adults

- Breast cancer screening women 50-74
- Cervical cancer screening women 25-69
- Colorectal cancer screening adults 50-74
- Hypertension screening and treatment adults 18+
- Cholesterol screening and treatment men 35+, women 45+
- Screening for Hepatitis C Virus adults born between 1945 and 1965

#### Routine Offer of Screening for STIs in Sexually Active Young Adults

- Screening for Human Immunodeficiency Virus (HIV) adolescents/adults 15-65
- Screening for Gonorrhea females 15-29
- Screening for Chlamydia females 15-29
- Screening for Syphilis

#### **Behavioural Counseling Interventions – Adults**

- Smoking cessation advice and help to quit
- Alcohol screening and brief counseling
- Prevention of Fetal Alcohol Spectrum Disorder (FASD)

#### **Preventive Medication – Adults**

- Discuss daily aspirin use men 45-79, women 55-79
- Preventing falls in community-dwelling elderly adults 65+

<sup>&</sup>lt;sup>5</sup> Clinical Prevention Policy Review Committee. A Lifetime of Prevention: A Report of the Clinical Prevention Policy Review Committee. 2009. Available at

http://www.health.gov.bc.ca/library/publications/year/2009/CPPR\_Lifetime\_of\_Prevention\_Report.pdf. Accessed August 2013.

<sup>&</sup>lt;sup>6</sup> H. Krueger & Associates Inc. Evidence Review and Economic Modelling of Preventive Health Maneuvers to Update the BC Lifetime Prevention Schedule: Methodology Report. October 21, 2013.

<sup>&</sup>lt;sup>7</sup> H. Krueger & Associates Inc. *Evidence Review and Economic Modelling of Preventive Health Maneuvers to Update the BC Lifetime Prevention Schedule: Determining Which Maneuvers to Prioritize*. November 4, 2013.

Each maneuver on this list was then assessed for the clinically preventable burden (CPB) and cost-effectiveness (CE) associated with the maneuver. CPB is defined as "the total quality-adjusted life years (QALYs) that could be gained if the clinical preventive service were delivered at recommended intervals to a B.C. birth cohort of 40,000 individuals over the years of life that a service is recommended." CE is defined as "the average net cost per QALY gained in typical practice by offering the clinical preventive service at recommended intervals to a B.C. birth cohort over the recommended age range."

This document provides the details supporting the estimated CPB and CE associated with each of the 9 maneuvers that are particularly relevant to children and youth. Each section of the document will focus on a specific maneuver, including the most current recommendations from the CTFPHC or the USPSTF, information on the utilization of the maneuver in British Columbia and best practices elsewhere in the world (to determine the *potential* utilization of the maneuver in B.C.) and an estimate of CPB and CE, including a sensitivity analysis.

#### **Key Assumptions**

The following key assumptions have been made throughout this project.

#### **Duplication of Effort**

In order not to duplicate evidence reviews, the Lifetime Prevention Schedule Expert Advisory Committee decided to refer any recommendations regarding immunizations to the B.C. Immunization Schedule and any recommendations regarding prenatal care, intrapartum care and immediate postpartum care to the Perinatal Services B.C. (PSBC) guidelines or to other agencies responsible for specific recommendations.<sup>8</sup> This document includes an overview of the current B.C. Immunization Schedule in Appendix B and an overview of guidelines regarding prenatal care, intrapartum care and immediate postpartum care that are relevant to clinical prevention in children and youth in Appendix C. Many of these guidelines in Appendix C have not gone through the same rigor or economic modelling as the maneuvers being considered for the Lifetime Prevention Schedule.

#### **Delivery Mechanism(s)**

The definition of clinical prevention is independent of delivery mechanism(s). In estimating cost-effectiveness, however, we had to make assumptions about delivery mechanisms in order to estimate the costs of providing the service. For purposes of consistency and comparability between the various preventive services, we chose to use a general physician's office as the delivery mechanism whenever appropriate. That is, if an established delivery mechanism is not in place, then we assumed, for costing purposes, that it would take place in a general physician's office. For example, no clinical prevention program currently exists in B.C. for the prevention of tobacco use in children and youth so we assumed this would take place in a general physician's office. Determining which delivery mechanism would be most suitable for each service will be assessed in a subsequent phase of this project.

#### **Patient Costs**

Clinical prevention services are offered to the asymptomatic general population. As such, people are being asked to give up some of their time for a service which has a (relatively small) chance of detecting a clinically relevant issue. Or, they may be asked to give up some of their time for a behavioural counselling intervention that has a modest potential for success. As such, it is important to value this time in an assessment of the cost-effectiveness of the intervention. For the purposes of consistency and comparability, we have assessed this time by including travel time to and from the intervention as well as time during the intervention and then valued this total time based on average wage rates for the B.C. population. We have also identified the proportion of costs attributable to patient costs for each maneuver.

#### Discounting

In the economic appraisal of health programs or interventions, costs and benefits that are spread over time are usually weighted according to when they are experienced. The further in the future, the less heavily they are weighted or the more they are discounted. This can be particularly challenging for interventions in which costs are current and benefits are further in the future (e.g. prevention). The impact of discounting is most noticeable for preventive

<sup>&</sup>lt;sup>8</sup> H. Krueger & Associates Inc. Evidence Review and Economic Modelling of Preventive Health Maneuvers to Update the BC Lifetime Prevention Schedule: Methodology Report. October 21, 2013.

services in children and youth, given that costs are generally current while benefits and potential costs avoided may stretch over the lifetime of the individual.<sup>9,10,11,12</sup>

From a health economics perspective, the usual approach is to discount both costs and benefits when calculating cost-effectiveness. However, discounting may fail to reflect a value we as a society might hold for the future of our children. It would thus be important to explicitly understand the impact of discounting in the current project. To do so, we will use both a 3% discount rate as well as a 0% discount rate. A 0% discount rate is equivalent to not discounting.

#### Incorporating Information on Current Coverage

A number of the preventive services assessed in this project have an established history in the province while others may only be provided in a limited, fairly random approach (as 'random acts of kind prevention'). With this in mind, we set out to assess CPB and CE from two perspectives. First, assuming that the service had no current coverage in the province (i.e. that the service had not yet been established in the province). Second, assessing the gap between current coverage in the province and what arguably could be considered the best possible coverage (based on information on 'best in the world' coverage for the service).

#### **Incorporating Key Recent Evidence**

The USPSTF is attempting to update their evidence review and recommendations every five years. It is possible that a landmark study (or studies) have been published during the interval between updates and that these studies may alter recommendations. To take this into account, we reviewed evidence reviews from other organizations (e.g. the Cochrane Collaboration and the National Institute for Health and Clinical Excellence [NICE] in the UK) for any USPSTF or CTFPHC recommendations published more than four years ago.

#### Focus on the Best Available Evidence

An important assumption of this project is to focus on the highest level of available evidence. Given the limited capacity in the health care system, it is better to focus on a limited number of preventive interventions that are clearly proven to be effective, will have an important impact on the health of the entire population of B.C. and are likely to be cost-effective. The focus should be on achieving potential coverage and an effective dose for a limited number of preventive services rather than incomplete coverage of a larger number of preventive services.

<sup>&</sup>lt;sup>9</sup> Parsonage M and Neuburger H. Discounting and health benefits. *Health Economics*. 1992; 1(1): 71-6.

<sup>&</sup>lt;sup>10</sup> Brouwer WB, Niessen LW, Postma MJ et al. Need for differential discounting of costs and health effects in cost effectiveness analyses. *British Medical Journal*. 2005; 331(7514): 446-8.

<sup>&</sup>lt;sup>11</sup> Claxton K, Sculpher M, Culyer A et al. Discounting and cost-effectiveness in NICE - stepping back to sort out a confusion. *Health Economics*. 2006; 15(1): 1-4.

<sup>&</sup>lt;sup>12</sup> Gravelle H, Brouwer W, Niessen L et al. Discounting in economic evaluations: stepping forward towards optimal decision rules. *Health Economics*. 2007; 16(3): 307-17.

#### **Challenges in Formulating Evidence-Based Recommendations**

There are a number of challenges associated with formulating evidence-based recommendations with respect to clinical prevention services. In this section, we highlight several of these challenges, with a focus on evidence-based recommendations applicable to children and youth.

A key challenge is that limited high quality research evidence in prevention is available for both adults as well as children/youth. For example, between January 2004 and September 2013 the USPSTF made 117 recommendations regarding preventive services for adults. Of the 117 recommendations, 20 (17%) received an 'A', 21 (18%) received a 'B', 8 (7%) received a 'C', 30 (26%) received a 'D' and 38 (32%) received an 'I'. The 'I' recommendation means that "[t]he USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined."<sup>13</sup>

#### **Evidence Supporting Prevention in Children/Youth**

Our review of current USPSTF recommendations applicable to children and youth found 51 specific recommendations in 38 areas. Of these 51 recommendations, 9 (18%) received an 'A' recommendation, 13 (25%) received a 'B' recommendation, none received a 'C' recommendation, 9 (18%) received a 'D' recommendation and 20 (39%) received an 'I' recommendation (see following table).

<sup>&</sup>lt;sup>13</sup> See <u>http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm</u>. Accessed November 2013.

USPSTF Recommendations for Children and Adolescen	Date of Most Recent Update	Recommendatio
Primary Care Behavioral Interventions to Reduce Illicit Drug and Nonmedical Pharmaceutical	Recent Opdate	Recommendation
Jse in Children and Adolescents The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and		
harms of primary care-based behavioral interventions to prevent or reduce illicit drug or		
nonmedical pharmaceutical use in children and adolescents. This recommendation applies to	Current Draft	I
children or adolescents who are not known to be abusing or addicted to drugs.		
creening for Suicide Risk in Adolescents		
The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and	Current Draft	1
harms of screening for suicide risk in adolescents, adults, and older adults in a primary care setting.		
revention of Dental Caries in Children From Birth Through Age 5 Years		
The USPSTF recommends that primary care clinicians prescribe oral fluoride supplementation		
starting at age 6 months for children whose water supply is deficient in fluoride, and apply fluoride	Current Draft	В
varnish to the primary teeth of infants and children starting at the age of primary tooth eruption.		
The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and		
harms of routine screening for dental caries in children from birth to age 5 years by primary care	Current Draft	I
clinicians.		
creening for Hypertension in Children and Adolescents		
The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and	0.1.1	
harms of screening for hypertension in asymptomatic children and adolescents to prevent	October, 2013	I
subsequent cardiovascular disease in childhood or adulthood. rimary Care–relevant Behavioral Interventions to Prevent Tobacco Use in School-aged Children		
nd Adolescents		
The USPSTF recommends that primary care clinicians provide interventions, including education or		
brief counseling, to prevent initiation of tobacco use among school-aged children and adolescents.	August, 2013	В
rimary Care Interventions to Prevent Child Maltreatment		
The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and		
harms of primary care interventions to prevent child maltreatment.	August, 2013	I
creening for HIV		
The USPSTF recommends that clinicians screen adolescents and adults aged 15 to 65 years for HIV	July 2012	•
infection. Younger adolescents and older adults who are at increased risk should also be screened.	July, 2013	<b>A</b>
creening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse		
The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and		
harms of screening and behavioral counseling interventions in primary care settings to reduce	May, 2013	I.
alcohol misuse in adolescents.		
ehavioral Counseling to Prevent Skin Cancer		
The USPSTF recommends counseling children, adolescents, and young adults aged 10 to 24 years	May 2012	D
who have fair skin about minimizing their exposure to ultraviolet radiation to reduce risk for skin cancer.	May, 2012	В
creening for Cervical Cancer		
The USPSTF recommends against screening for cervical cancer in women younger than age 21 years.	March, 2012	D
The USPSTF recommends against screening for cervical cancer with HPV testing, alone or in	101011, 2012	
combination with cytology, in women younger than age 30 years.	March, 2012	D
cular Prophylaxis for Gonococcal Ophthalmia Neonatorum		
The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention		
of gonococcal ophthalmia neonatorum.	July, 2011	Α
creening for Testicular Cancer		
The USPSTF recommends against screening for testicular cancer in adolescent or adult males.	April, 2011	D
creening for Visual Impairment in Children Ages 1 to 5		
The USPSTF recommends vision screening for all children at least once between the ages of 3 and 5	January 2011	
years, to detect the presence of amblyopia or its risk factors.	January, 2011	В
The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and	January, 2011	I
harms of vision screening for children <3 years of age.	January, 2011	
creening for Obesity in Children and Adolescents		
The USPSTF recommends that clinicians screen children aged 6 years and older for obesity and offer		
them or refer them to intensive counseling and behavioral interventions to promote improvements	January, 2010	В
in weight status.		
reening of Infants for Hyperbilirubinemia to Prevent Chronic Bilirubin Encephalopathy		
The USPSTF concludes that the evidence is insufficient to recommend screening infants for	October, 2009	1
hyperbilirubinemia to prevent chronic bilirubin encephalopathy.		
creening for Hepatitis B Virus Infection in Pregnancy		
Screen for hepatitis B virus infection in pregnant women at their first prenatal visit.	June, 2009	A
creening for Syphilis Infection in Pregnancy	May 2000	Α
Screen all pregnant women for syphilis infection. Jajor Depressive Disorder in Children and Adolescents	May, 2009	A
The USPSTF recommends screening for major depressive disorder (MDD) in adolescents (ages 12 to		
18 years) when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-	March, 2009	В
behavioral or interpersonal), and followup.		5
The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and		
harms of screening for MDD in children (ages 7 to 11 years).	March, 2009	I
ehavioral Counseling to Prevent Sexually Transmitted Infections		
The USPSTF recommends high-intensity behavioral counseling to prevent sexually transmitted		
	October, 2008	В
infections (STIs) for all sexually active adolescents and for adults at increased risk for STIs.		
infections (STIs) for all sexually active adolescents and for adults at increased risk for STIs. The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and		
	October, 2008	1

	ntinued)	
	Date of Most	
	Recent Update	Recommendation
Primary Care Interventions to Promote Breastfeeding The USPSTF recommends interventions during pregnancy and after birth to promote and support		
breastfeeding.	October, 2008	В
Universal Screening for Hearing Loss in Newborns		
The USPSTF recommends screening for hearing loss in all newborn infants.	July, 2008	В
Screening for Phenylketonuria (PKU)		
The USPSTF recommends screening for phenylketonuria (PKU) in newborns.	March, 2008	Α
Screening for Congenital Hypothyroidism The USPSTF recommends screening for congenital hypothyroidism (CH) in newborns.	March, 2008	Α
Screening for Bacterial Vaginosis in Pregnancy to Prevent Preterm Delivery		
Do not screen for bacterial vaginosis in pregnant women at low risk for preterm delivery.	February, 2008	D
Current evidence is insufficient to assess the balance of benefits and harms of screening for	February, 2008	1
bacterial vaginosis in pregnant women at high risk for preterm delivery.		
Screening for Illicit Drug Use		
The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening adolescents, adults, and pregnant women for illicit drug use.	January, 2008	I
Screening for Sickle Cell Disease in Newborns		
The USPSTF recommends screening for sickle cell disease in newborns.	September, 2007	А
Counseling about Proper Use of Motor Vehicle Occupant Restraints and Avoidance of Alcohol		
Use to Prevent Injury		
The USPSTF concludes that the current evidence is insufficient to assess the incremental benefit,		
beyond the efficacy of legislation and community-based interventions, of counseling in the primary care setting, in improving rates of proper use of motor vehicle occupant restraints (child safety	August, 2007	I
seats, booster seats, and lap-and-shoulder belts).		
The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and		
harms of routine counseling of all patients in the primary care setting to reduce driving while under	August, 2007	I
the influence of alcohol or riding with drivers who are alcohol-impaired.		
Screening for Lipid Disorders in Children The USPSTF concludes that the evidence is insufficient to recommend for or against routine		
screening for lipid disorders in infants, children, adolescents, or young adults (up to age 20).	July, 2007	I
Screening for Chlamydial Infection		
The USPSTF recommends screening for chlamydial infection in all sexually active, nonpregnant	June, 2007	Α
young women ages 24 and younger and in older nonpregnant women who are at increased risk.	June, 2007	<u> </u>
The USPSTF recommends screening for chlamydial infection in all pregnant women ages 24 and	June, 2007	В
younger and in older pregnant women who are at increased risk. Screening for Elevated Blood Lead Levels in Children		
The USPSTF concludes that evidence is insufficient to recommend for or against routine screening		
for elevated blood lead levels in asymptomatic children aged 1 to 5 who are at increased risk.	December, 2006	I
The USPSTF recommends against routine screening for elevated blood lead levels in asymptomatic	December, 2006	D
children aged 1 to 5 years who are at average risk. Screening for Iron Deficiency Anemia		
The USPSTF concludes that the evidence is insufficient to recommend for or against routine		
screening for iron deficiency anemia in asymptomatic children ages 6 to 12 months.	May, 2006	I
The USPSTF recommends routine iron supplementation for asymptomatic children ages 6 to 12	May, 2006	В
months who are at increased risk for iron deficiency anemia.	Widy, 2000	
The USPSTF concludes that the evidence is insufficient to recommend for or against routine iron supplementation for asymptomatic children ages 6 to 12 months who are at average risk for iron	May, 2006	I
deficiency anemia.	Way, 2000	I
Screening for Developmental Dysplasia of the Hip		
The USPSTF concludes that evidence is insufficient to recommend routine screening for	March, 2006	
developmental dysplasia of the hip in infants as a means to prevent adverse outcomes.	Warch, 2000	
Screening for Speech and Language Delay in Preschool Children		
The USPSTF concludes that the evidence is insufficient to recommend for or against routine use of	Fabruary 2006	I
brief, formal screening instruments in primary care to detect speech and language delay in children	February, 2006	
brief, formal screening instruments in primary care to detect speech and language delay in children age 5 years or younger.		· · · · · · · · ·
brief, formal screening instruments in primary care to detect speech and language delay in children age 5 years or younger. Screening for Gonorrhea The USPSTF recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young	May, 2005	В
brief, formal screening instruments in primary care to detect speech and language delay in children age 5 years or younger. Screening for Gonorrhea The USPSTF recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors).		В
brief, formal screening instruments in primary care to detect speech and language delay in children age 5 years or younger. Screening for Gonorrhea The USPSTF recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors). Screening for Genital Herpes		В
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brief, formal screening instruments in primary care to detect speech and language delay in children age 5 years or younger. Screening for Gonorrhea The USPSTF recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors). Screening for Genital Herpes The USPSTF recommends against routine serological screening for herpes simplex virus (HSV) in asymptomatic pregnant women at any time during pregnancy to prevent neonatal HSV infection. The USPSTF recommends against routine serological screening for HSV in asymptomatic adolescents and adults. Screening for Idiopathic Scoliosis in Adolescents	May, 2005 March, 2005	D
brief, formal screening instruments in primary care to detect speech and language delay in children age 5 years or younger. Screening for Gonorrhea The USPSTF recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors). Screening for Genital Herpes The USPSTF recommends against routine serological screening for herpes simplex virus (HSV) in asymptomatic pregnant women at any time during pregnancy to prevent neonatal HSV infection. The USPSTF recommends against routine serological screening for HSV in asymptomatic adolescents and adults. Screening for Idiopathic Scoliosis in Adolescents The USPSTF recommends against the routine screening of asymptomatic adolescents for idiopathic	May, 2005 March, 2005	D
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brief, formal screening instruments in primary care to detect speech and language delay in children age 5 years or younger. Screening for Gonorrhea The USPSTF recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors). Screening for Genital Herpes The USPSTF recommends against routine serological screening for herpes simplex virus (HSV) in asymptomatic pregnant women at any time during pregnancy to prevent neonatal HSV infection. The USPSTF recommends against routine serological screening for HSV in asymptomatic adolescents and adults. Screening for Idiopathic Scoliosis in Adolescents The USPSTF recommends against the routine screening of asymptomatic adolescents for idiopathic scoliosis.	May, 2005 March, 2005 March, 2005	D
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brief, formal screening instruments in primary care to detect speech and language delay in children age 5 years or younger. Screening for Gonorrhea The USPSTF recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors). Screening for Genital Herpes The USPSTF recommends against routine serological screening for herpes simplex virus (HSV) in asymptomatic pregnant women at any time during pregnancy to prevent neonatal HSV infection. The USPSTF recommends against routine serological screening for HSV in asymptomatic adolescents and adults. Screening for Idiopathic Scoliosis in Adolescents The USPSTF recommends against the routine screening of asymptomatic adolescents for idiopathic scoliosis. Screening for Hepatitis B Virus Infection in Nonpregnant Adolescents and Adults The USPSTF recommends against routinely screening the general asymptomatic population for chronic hepatitis B virus infection. Screening for Rh(D) Incompatibility The USPSTF strongly recommends Rh(D) blood typing and antibody testing for all pregnant women	May, 2005 March, 2005 March, 2005 June, 2004 February, 2004	D D D D D D D D D D
brief, formal screening instruments in primary care to detect speech and language delay in children age 5 years or younger. Screening for Gonorrhea The USPSTF recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors). Screening for Genital Herpes The USPSTF recommends against routine serological screening for herpes simplex virus (HSV) in asymptomatic pregnant women at any time during pregnancy to prevent neonatal HSV infection. The USPSTF recommends against routine serological screening for HSV in asymptomatic adolescents and adults. Screening for Idiopathic Scoliosis in Adolescents The USPSTF recommends against the routine screening of asymptomatic adolescents for idiopathic scoliosis. Screening for Hepatitis B Virus Infection in Nonpregnant Adolescents and Adults The USPSTF recommends against routinely screening the general asymptomatic population for chronic hepatitis B virus infection. Screening for Rh(D) Incompatibility The USPSTF stongly recommends Rh(D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care.	May, 2005 March, 2005 March, 2005 June, 2004	D D D D
brief, formal screening instruments in primary care to detect speech and language delay in children age 5 years or younger. Screening for Gonorrhea The USPSTF recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors). Screening for Genital Herpes The USPSTF recommends against routine serological screening for herpes simplex virus (HSV) in asymptomatic pregnant women at any time during pregnancy to prevent neonatal HSV infection. The USPSTF recommends against routine serological screening for HSV in asymptomatic adolescents and adults. Screening for Idiopathic Scoliosis in Adolescents The USPSTF recommends against the routine screening of asymptomatic adolescents for idiopathic scoliosis. Screening for Hepatitis B Virus Infection in Nonpregnant Adolescents and Adults The USPSTF recommends against routinely screening the general asymptomatic population for chronic hepatitis B virus infection. Screening for Rh(D) Incompatibility The USPSTF strongly recommends Rh(D) blood typing and antibody testing for all pregnant women	May, 2005 March, 2005 March, 2005 June, 2004 February, 2004	D D D D D

This high proportion of recommendations receiving an 'I' recommendation has been noted by the USPSTF.<sup>14,15</sup> It is important to observe that the limited high quality research evidence for preventive services is applicable to both adults and children/ youth. The proportion of 'I' recommendations for children/youth, however, is somewhat higher (at 39%) than that for adults (at 32%).

#### **Reasons for the Lack of Evidence**

The USPSTF and others<sup>16</sup> have identified the following reasons for the lack of research studies supporting preventive interventions, especially in children and youth:

- Diseases are relatively rare, thus it is more challenging to include a large enough sample of patients to have adequate statistical power
- Significant ethical and regulatory concerns paediatric studies are held to a higher standard that studies in adults
- Restrictions in enrolling children in studies that exceed minimal risk
- The need for both parental permission and, depending on their age, the assent of the child/youth as well
- Challenges in retaining the child throughout the study which may involve discomfort and/or boredom while the parents often face additional costs/issues associated with participating in the study, such as their child's school attendance, their own work schedules and care for siblings
- High costs of rigorous evaluations of preventive services
- Limited research funding for child health, especially in preventive services
- Insufficient numbers of paediatric researchers whose interests lie in these areas

#### Filling the Void in Available Evidence

The void in available research is often filled with recommendations based on 'expert opinion' or 'clinical consensus'. Evidence-based medicine "is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."<sup>17</sup> When assessing preventive interventions in children and youth, the 'current best evidence' is often expert opinion. The American Academy of Pediatrics finds this reliance on expert opinion to be "entirely appropriate" in this situation.

For many situations in pediatric health care, high-quality evidence is not yet available. Because evidence is often absent or conflicting, many statements will inevitably be based largely on expert opinion. This is entirely appropriate, provided the basis is readily apparent to the critical reader. Indeed, it is when evidence is lacking, scant, or conflicting that expert guidance is most often sought. In these situations, policy authors must rely on lower-quality evidence, such as reasoning based on basic principles or expert consensus, to formulate coherent recommendations.<sup>18</sup>

<sup>&</sup>lt;sup>14</sup> Moyer VA and Butler M. Gaps in the evidence for well-child care: a challenge to our profession. *Pediatrics*. 2004; 114(6): 1511-21.

<sup>&</sup>lt;sup>15</sup> Melnyk BM, Grossman DC, Chou R et al. USPSTF perspective on evidence-based preventive recommendations for children. *Pediatrics*. 2012; 130(2): e399-407.

<sup>&</sup>lt;sup>16</sup> Jacobson RM. Pediatrics and evidence-based medicine revisited. *Journal of Pediatrics*. 2007; 150(4): 325-6, Jacobson RM. Pediatrics and evidence-based medicine revisited. *Journal of Pediatrics*. 2007; 150(4): 325-6.

 <sup>&</sup>lt;sup>17</sup> Sackett DL, Rosenberg WM, Gray JA et al. Evidence based medicine: what it is and what it isn't. *British Medical Journal*. 1996; 312(7023): 71-2.

<sup>&</sup>lt;sup>18</sup> Shiffman RN, Marcuse EK, Moyer VA et al. Toward transparent clinical policies. *Pediatrics*. 2008; 121(3): 643-6.

Others, however, are more concerned about this reliance on expert opinion and suggest that it may be one of the reasons for the plethora of conflicting guidelines.<sup>19,20,21,22</sup> Nearly all guidelines are advertised as evidence-based but this includes a wide range of "evidence" including professional consensus. Evidence is open to interpretation. The composition of a panel can influence recommendations and the recommendations may be vulnerable to the panelists' conflicts of interest. As a result, there is increasing concern about the quality of guidelines, especially those produced by professional societies and medical specialty groups (i.e., professional advocacy groups).<sup>23,24</sup>

A primary concern in developing guidelines is the potential for a financial conflict of interest in which the guideline authors may have a financial relationship with industry. For example, the six guideline authors of the American Psychiatric Association's *Practice Guideline for the Treatment of Major Depressive Disorder* each had an average of 20.5 financial ties with industry.<sup>25</sup> A less publicised conflict occurs when clinical investigators place disproportionate weight on the results of studies that they, or members of their institution, co-authored. This intellectual conflict of interest has been defined as "academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgement about a specific recommendation."<sup>26</sup> As a measure of intellectual conflict of interest in the American Psychiatric Association's *Practice Guideline for the Treatment of Major Depressive Disorder*, 13% of references supporting the recommendations were coauthored by one or another of the six guideline authors.<sup>27</sup>

Some time ago, Sackett noted that "experts face an unavoidable temptation to accept or reject new evidence, not on the basis of its scientific merit, but on the extent to which is agrees or disagrees with their own prior public positions on these observations and inferences."<sup>28</sup>

A potential way forward involving three key changes is offered by Guyatt and colleagues:<sup>29</sup>

- 1. Place equal emphasis on intellectual and financial conflicts and provide explicit criteria for each
- 2. A methodologist should have primary responsibility for each guideline chapter

<sup>&</sup>lt;sup>19</sup> Moyer VA and Butler M. Gaps in the evidence for well-child care: a challenge to our profession. *Pediatrics*. 2004; 114(6): 1511-21.

<sup>&</sup>lt;sup>20</sup> Solberg LI, Nordin JD, Bryant TL et al. Clinical preventive services for adolescents. *American Journal of Preventive Medicine*. 2009; 37(5): 445-54.

<sup>&</sup>lt;sup>21</sup> Melnyk BM, Grossman DC, Chou R et al. USPSTF perspective on evidence-based preventive recommendations for children. *Pediatrics*. 2012; 130(2): e399-407.

<sup>&</sup>lt;sup>22</sup> Lenzer J. Why we can't trust clinical guidelines. *British Medical Journal*. 2013; 346: f3830.

<sup>&</sup>lt;sup>23</sup> Grilli R, Magrini N, Penna A et al. Practice guidelines developed by specialty societies: the need for a critical appraisal. *The Lancet.* 2000; 355(9198): 103-6.

<sup>&</sup>lt;sup>24</sup> Norris SL, Holmer HK, Ogden LA et al. Conflict of interest in clinical practice guideline development: a systematic review. *PLOS ONE*. 2011; 6(10): e25153.

<sup>&</sup>lt;sup>25</sup> Cosgrove L, Bursztajn HJ, Erlich DR et al. Conflicts of interest and the quality of recommendations in clinical guidelines. *Journal of Evaluation in Clinical Practice*. 2013; 19(4): 674-81.

<sup>&</sup>lt;sup>26</sup> Guyatt G, Akl EA, Hirsh J et al. The vexing problem of guidelines and conflict of interest: a potential solution. *Annals of Internal Medicine*. 2010; 152: 738-41.

<sup>&</sup>lt;sup>27</sup> Cosgrove L, Bursztajn HJ, Erlich DR et al. Conflicts of interest and the quality of recommendations in clinical guidelines. *Journal of Evaluation in Clinical Practice*. 2013; 19(4): 674-81.

<sup>&</sup>lt;sup>28</sup> Sackett DL. Second thoughts. Proposals for the health sciences--I. Compulsory retirement for experts. *Journal of Chronic Diseases*. 1983; 36(7): 545-7.

<sup>&</sup>lt;sup>29</sup> Guyatt G, Akl EA, Hirsh J et al. The vexing problem of guidelines and conflict of interest: a potential solution. *Annals of Internal Medicine*. 2010; 152: 738-41.

3. Only panel members without important conflicts can be involved in developing the recommendations for a specific question

More recently, the U.S. Institute of Medicine has suggested a set of eight standards for the development of trustworthy clinical practice guidelines.<sup>30</sup> These include:

- 1. Establishing transparency
- 2. Management of conflict of interest
- 3. Guideline development group composition
- 4. Clinical practice guideline-systematic review intersection
- 5. Establishing evidence foundations for and rating strength of recommendations
- 6. Articulation of recommendations
- 7. External Review
- 8. Updating

#### **Potential Harms**

The inclusion of recommendations based on expert opinion can dramatically increase the number of recommendations. The American Academy of Pediatrics, for example, has 162 different health advice directives on which paediatricians should counsel parents and their children throughout childhood.<sup>31</sup> Given the limited number of visits to a physician by children/youth<sup>32</sup> (1.9 visits per year for adolescents)<sup>33</sup> and the short time allocated to these visits (~15 minutes per visit),<sup>34</sup> it would be impossible to deliver this range of services. Indeed, only 1/3 of recommended services for well child/youth care are being provided in the U.S.<sup>35</sup>

Focussing on interventions with limited evidentiary support displaces more effective activities during the all-too-brief clinical encounters. As noted by Moyer and Butler, "[w]hen ineffective or less effective interventions displace more effective interventions, children are deprived of the more effective interventions."<sup>36</sup>

In addition to limited access and time, clinicians often fail to provide preventive care as they may be uncertain or confused about which services to provide.<sup>37</sup> Indeed, none of the 162 health advice directives by the American Academy of Pediatrics included an evidence-based discussion of the efficacy of the suggested advice.<sup>38</sup> One of the potential reasons that Mangione-Smith and colleagues found such a low adherence to recommended services for

<sup>&</sup>lt;sup>30</sup> Institute of Medicine. *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press; 2011.

<sup>&</sup>lt;sup>31</sup> Belamarich PF, Gandica R, Stein RE et al. Drowning in a sea of advice: pediatricians and American Academy of Pediatrics policy statements. *Pediatrics*. 2006; 118(4): e964-e78.

<sup>&</sup>lt;sup>32</sup> Selden TM. Compliance with well-child visit recommendations: evidence from the Medical Expenditure Panel Survey, 2000-2002. *Pediatrics*. 2006; 118(6): e1766-78.

<sup>&</sup>lt;sup>33</sup> Solberg LI, Nordin JD, Bryant TL et al. Clinical preventive services for adolescents. *American Journal of Preventive Medicine*. 2009; 37(5): 445-54.

<sup>&</sup>lt;sup>34</sup> Moyer VA and Butler M. Gaps in the evidence for well-child care: a challenge to our profession. *Pediatrics*. 2004; 114(6): 1511-21.

<sup>&</sup>lt;sup>35</sup> Mangione-Smith R, DeCristofaro AH, Setodji CM et al. The quality of ambulatory care delivered to children in the United States. *New England Journal of Medicine*. 2007; 357(15): 1515-23.

<sup>&</sup>lt;sup>36</sup> Moyer VA and Butler M. Gaps in the evidence for well-child care: a challenge to our profession. *Pediatrics*. 2004; 114(6): 1511-21.

<sup>&</sup>lt;sup>37</sup> Ayres CG and Griffith HM. Perceived barriers to and facilitators of the implementation of priority clinical preventive services guidelines. *American Journal of Managed Care*. 2007; 13(3): 150-5.

<sup>&</sup>lt;sup>38</sup> Belamarich PF, Gandica R, Stein RE et al. Drowning in a sea of advice: pediatricians and American Academy of Pediatrics policy statements. *Pediatrics*. 2006; 118(4): e964-e78.

well child/youth care in the U.S. may be that all of the 33 recommendations for children and 7 of the 8 recommendations for adolescents were based on the lowest level of evidence, namely, expert opinion and/or descriptive studies.<sup>39</sup>

There are other potential costs and adverse effects associated with providing preventive services based on lower quality evidence.<sup>40</sup> These include directs costs for physician and staff time, laboratory examinations and agents used in prophylaxis, as well as costs to parents for transportation and lost time from work. False-positive results from screening can lead to unnecessary patient anxiety and follow-up testing. Finally, there is some evidence of potential increases in unintended negative behaviours.<sup>41,42</sup> The use of Mr. Yuk stickers on poison products in the U.S., for example, increased children's exposure to poisons.<sup>43,44</sup>

#### Summary

In summary, there is limited high quality research evidence supporting preventive maneuvers in adults and children/youth. Reasons for the lack of high-quality research studies include the high costs of rigorous evaluations of preventive services and challenges in using research designs in real-world environments. In 2014, the USPSTF published an article discussing challenges it encounters in aggregating the behavioural counselling intervention literature, including clear descriptions of the study population, intervention protocols, assessment of outcomes, and linking behaviour changes to health outcomes.<sup>45</sup> Researchers are encouraged to pay closer attention to these issues in designing and writing up their behavioural intervention research.

Additional challenges are encountered in research involving children and youth, including significant ethical and regulatory concerns, challenges in retention (especially for longer studies) and a limited number of paediatric researchers whose interests lie in these areas.

This gap in high quality research evidence is often filled with lower quality evidence, including 'expert opinion' or 'clinical consensus'. Evidence from this source is open to financial and intellectual conflict of interest.

Harms associated with disseminating guideline recommendations based on lower quality evidence include a proliferation of suspect recommendations that, at a minimum, result in a waste of time and resources and, on occasion, have the potential to result in physical harm.

<sup>&</sup>lt;sup>39</sup> Mangione-Smith R, DeCristofaro AH, Setodji CM et al. The quality of ambulatory care delivered to children in the United States. *New England Journal of Medicine*. 2007; 357(15): 1515-23.

<sup>&</sup>lt;sup>40</sup> Moyer VA and Butler M. Gaps in the evidence for well-child care: a challenge to our profession. *Pediatrics*. 2004; 114(6): 1511-21.

<sup>&</sup>lt;sup>41</sup> Irvine L, Crombie IK, Clark RA et al. Advising parents of asthmatic children on passive smoking: randomised controlled trial. *British Medical Journal*. 1999; 318(7196): 1456-9.

 <sup>&</sup>lt;sup>42</sup> Stevens MM, Olson AL, Gaffney CA et al. A pediatric, practice-based, randomized trial of drinking and smoking prevention and bicycle helmet, gun, and seatbelt safety promotion. *Pediatrics*. 2002; 109(3): 490-7.
 <sup>43</sup> Fergusson DM, Horwood LJ, Beautrais AL et al. A controlled field trial of a poisoning prevention method. *Pediatrics*. 1982; 69(5): 515-20.

<sup>&</sup>lt;sup>44</sup> Vernberg K, Culver-Dickinson P and Spyker DA. The deterrent effect of poison-warning stickers. *American Journal of Diseases of Children*. 1984; 138(11): 1018-20.

<sup>&</sup>lt;sup>45</sup> Curry S, Grossman D, Whitlock E et al. Behavioral counseling research and evidence-based practice recommendations: U.S. Preventive Services Task Force Perspectives. *Annals of Internal Medicine*. 2014; 160: 407-13.

#### Background

The question of what constitutes well child care has existed since at least the 1970s. The Canadian Task Force on the Periodic Health Examination<sup>46</sup> was established in 1976 and produced its first report in 1979 on the periodic health examination.<sup>47</sup> This report contains a series of 'health protection packages' for infants at birth and during the first week of life; at 2-4 weeks; at 2, 4, 6, 9, 12-15 and 18 months; and at 2-3, 4, 5-6, 10-11 and 12-15 years. A 1990 update focussed on the first two years of life and found sufficient evidence to support the inclusion of the preventive services outlined in Table 1-1.<sup>48</sup>

	In the	First 2 Years of Life 1990	
Effectiveness	Level of Evidence	Maneuver	Recommendation
Incidence of diphtheria, <i>Haemophilus influenzae</i> type b (Hib) infection, measles, mumps, pertussis, poliomyelitis, rubella and tetanus is much reduced in Canada except where there is poor access to health care; low rates indicate control of these diseases	Randomized controlled trials and comparisons between times and places	Vaccination with DPT and polio vaccines at 2, 4, 6 and 18 mo (if oral polio vaccine is used it should be given at 2, 4 and 6 mo), MMR vaccine at 12 mo and Hib vaccine at 18 mo	Good evidence to include in periodic health examination (A)
Families counselled about risk factors for accidental injury in the home have fewer risk factors at follow-up visits than those not counselled	Randomized controlled trails	Counselling to reduce risk factors in the home	Good evidence to include in periodic health examination (A)
Families complying with appropriate counselling have fewer problems with night-time crying than those not counselled	Randomized controlled trails	Anticipatory guidance for night-time crying	Good evidence to include in periodic health examination (A)
Outcome better with early than with late detection and treatment of congenital hip dislocation, amblyopia and hearing impairment	Cohort studies	Repeated examination of hips, eyes and hearing, especially in the first year of life	Good evidence to include in periodic health examination on basis of good detection maneuvers, effective treatment and alleviation of burden of suffering (A)
Other than the prevention of phenylketonuria and hypothyroidism (usually diagnosed in the neonatal period) few preventive measures are available for mental retardation; for environmentally deprived infants an enriched environment may enhance normal mental development	Cohort studies	Enquiries about the achievement of milestones at each visit	Fair evidence to include in periodic health examination (B)
No good evidence that early detection of parenting problems prevents child abuse	Expert opinion	Enquiries about parents' coping ability, stresses and supports; referral to social agency or counsellor	No evidence to include enquiries in periodic health examination, but referral may be beneficial and should be assessed on an individual basis
Canadian Task Force on the Periodic Health Examination. Periodic health	examination, 1990 update:	4. Well-baby care in the first 2 years of life. Canadian	Medical Association Journal . 1990; 143(9): 867-72.

Table 1-1: Canadian Task Force on the Periodic Health Examination's Summary of Well-Baby Care

In addition to early questions about which preventive services to include within well child care, questions were raised about the frequency of visits required. In 1967, the American Academy of Pediatrics recommended 9 well-baby visits to paediatricians during the first year of a child's life, followed by four in the second year, two in the third and annually thereafter.<sup>49</sup> Hoekelman and colleagues assessed the recommendation of 9 visits within the first year of life and found no differences in outcomes associated with 3 or 6 annual visits to either a paediatrician or a paediatric nurse practitioner.<sup>50</sup> A randomized controlled trial in

<sup>&</sup>lt;sup>46</sup> Since renamed as the *Canadian Task Force on Preventive Health Care* 

<sup>&</sup>lt;sup>47</sup> Canadian Task Force on the Periodic Health Examination. The periodic health examination. *Canadian Medical Association Journal*. 1979; 121(9): 1193-254.

<sup>&</sup>lt;sup>48</sup> Canadian Task Force on the Periodic Health Examination. Periodic health examination, 1990 update: 4. Wellbaby care in the first 2 years of life. *Canadian Medical Association Journal*. 1990; 143(9): 867-72.

<sup>&</sup>lt;sup>49</sup> Council on Pediatric Practice. *Standards of Child Health Care*. Evanston, Illinois: American Academy of Pediatrics; 1967.

<sup>&</sup>lt;sup>50</sup> Hoekelman RA. What constitutes adequate well-baby care? *Pediatrics*. 1975; 55(3): 313-26.

Canada found that the goals of well-baby care were achieved equally with 5-6 visits versus 10 visits in the first *two* years.<sup>51</sup>

Since these early efforts at identifying what constitutes well child/youth care, the number of organizations promoting evidence-based guidelines for this care has proliferated. In Canada, this includes the Rourke Baby Record for children aged 0 to 5 years<sup>52</sup> and the Grieg Health Record for children and adolescents aged 6 to 17 years.<sup>53,54</sup> Both of these guidelines have been endorsed by the College of Family Physicians of Canada and the Canadian Paediatric Society.

In the U.S., organizations promoting evidence-based guidelines for preventive services in children/youth include the American Academy of Pediatrics Bright Futures project,<sup>55</sup> the American Medical Association Guidelines for Adolescent Preventive Services,<sup>56</sup> the American Academy of Family Practice,<sup>57</sup> the Institute for Clinical Systems Improvement<sup>58</sup> and the United States Preventive Services Task Force (USPSTF).<sup>59</sup> Ozer and colleagues have also promoted the need for preventive health care guidelines specifically for young adults ages 18-26.<sup>60</sup>

#### **Comparison of Recommendations in North America**

In 2004, Moyer and Butler compared recommendations for well child care from 7 major North American organizations, including the USPSTF.<sup>61</sup> Their comparison is grouped into recommendations for brief counselling (Table 1-2), screening (Table 1-3) and prophylaxis (Table 1-4).

One of the key themes seen in Table 1-2 is that brief, office-based interventions tend to have a limited effectiveness, but that this effectiveness can be enhanced in some areas with more time-intensive, multi-factorial interventions.

<sup>&</sup>lt;sup>51</sup> Gilbert JR, Feldman W, Siegel LS et al. How many well-baby visits are necessary in the first 2 years of life? *Canadian Medical Association Journal*. 1984; 130(7): 857-61.

<sup>&</sup>lt;sup>52</sup> Rourke L, Leduc D, Constantin E et al. Getting it right from birth to kindergarten: what's new in the Rourke Baby Record? *Canadian Family Physician*. 2013; 59(4): 355-9.

<sup>&</sup>lt;sup>53</sup> Greig A, Constantin E, Carsley S et al. Preventive health care visits for children and adolescents aged six to 17 years: The Greig Health Record - Executive Summary. *Paediatrics & Child Health*. 2010; 15(3): 157-62.

<sup>&</sup>lt;sup>54</sup> Greig A, Constantin E, Carsley S et al. Preventive health care visits for children and adolescents aged six to 17 years: The Greig Health Record - Technical Report. *Paediatrics & Child Health*. 2010; 15(3): 157-9.

<sup>&</sup>lt;sup>55</sup> See, for example, the periodicity schedule available at

http://brightfutures.aap.org/pdfs/AAP\_Bright\_Futures\_Periodicity\_Sched\_101107.pdf. Accessed November, 2013.

<sup>&</sup>lt;sup>56</sup> Elster AB, Kuznets NJ. AMA Guidelines for Adolescent Preventive Services (GAPS): Recommendations and Rationale. Williams & Wilkins, Baltimore. 1994.

<sup>&</sup>lt;sup>57</sup> American Academy of Family Physicians. *Summary of Recommendations for Clinical Preventive Services*. October 2013. Available online at

http://www.aafp.org/dam/AAFP/documents/patient\_care/clinical\_recommendations/cps-recommendations.pdf. Accessed November, 2013.

<sup>&</sup>lt;sup>58</sup> See <u>https://www.icsi.org/guidelines\_more/</u>. Accessed November 2013.

<sup>&</sup>lt;sup>59</sup> See <u>http://www.uspreventiveservicestaskforce.org/tfchildcat.htm</u>. Accessed November 2013.

<sup>&</sup>lt;sup>60</sup> Ozer EM, Urquhart JT, Brindis CD et al. Young adult preventive health care guidelines: there but can't be found. *Archives of Pediatrics and Adolescent Medicine*. 2012; 166(3): 240-7.

<sup>&</sup>lt;sup>61</sup> Moyer VA and Butler M. Gaps in the evidence for well-child care: a challenge to our profession. *Pediatrics*. 2004; 114(6): 1511-21.

	Overenizations	Organizations	Evidence-	
Recommended Maneuver	Organizations Recommending	Organizations Recommending Against	Evidence From Trials	Results
Injury prevention (in general)	AAFP, AAP, CTF, GAPS, <b>USPSTF,</b> ICSI, Bright		Yes	Modest decreases in some risk behaviors with counseling; the most effective strategies are
	Futures			multifactorial and time-intensive
Bicycle/motorcycle helmets	CTF,ICSI, Bright Futures		Yes	Conflicting evidence, possible small effect of counseling on bicycle helmet use
Automobile occupant restraints	ICSI, <b>USPSTF,</b> Bright Futures		Yes	Modest increase in automobile restraint use
Poisoning prevention	ICSI, CTF, Bright Futures	Mr Yuk Stickers specifically; AAFP, <b>USPSTF</b>	Yes	No difference in safety behaviors among counseled families; use of Mr Yuk stickers increases exposure to poisons
Choking prevention	ICSI, Bright Futures		No	
Sunburn/skin cancer prevention	ICSI, CTF, <b>USPSTF,</b> Bright Futures		No	
Violence, including child abuse, counseling	AAP, ICSI, Bright Futures		Yes	Interventions in the office setting do not prevent violent behavior; comprehensive and home visit- based programs have some effect
Passive smoke exposure counseling	ICSI, AAFP, <b>USPSTF,</b> Bright Futures		Yes	Brief, office-based interventions not effective; modest effect of intensive counseling
Smoking/tobacco use counseling	ICSI, AAFP, GAPS, <b>USPSTF,</b> Bright Futures		No	Studies of adults find office counseling effective; effectiveness increases with treatment intensity
Drinking and drugs (including drinking and driving) counseling	ICSI, <b>USPSTF,</b> Bright Futures		Yes	Brief, office-based interventions not effective; 1 randomized, clinical trial showed slight increase in drinking in intervention group
STD prevention	AAFP, CTF, GAPS, <b>USPSTF,</b> Bright Futures		Yes	4 trials showed minimal effect of brief, office-based counseling; more intensive intervention resulted in decreased incidence of STDs
Pregnancy prevention	GAPS, ICSI, <b>USPSTF,</b> CTF, Bright Futures		No	No studies of brief, office-based counseling; of othe programs, only intensive, multifaceted programs show an effect
Physical activity	AAFP, GAPS, Bright Futures		Yes	Brief advice does not change physical activity; multimodal interventions have modest effect
Nutrition/diet counseling	AAP, GAPS, ICSI, AAFP, USPSTF, Bright Futures		No	1 randomized, clinical trial underway
Breastfeeding	AAFP, CTF, ICSI, <b>USPSTF,</b> Bright Futures		Yes	One-on-one prenatal education increases breastfeeding, multifaceted programs have greater effect, breastfeeding support programs extend duration, counseling on pacifiers changes pacifier use but not duration of breastfeeding
Infant sleep position counseling	ICSI, AAP, Bright Futures		No	
Oral health counseling	AAP, ICSI, CTF, <b>USPSTF,</b> Bright Futures		No	

Abbreviations: AAP, American Academy of Pediatrics; USPSTF, US Preventive Services Task Force; GAPS, Guidelines for Adolescent Preventive Services; AAFP, American Academy of Family Practice; CTF, Canadian Task Force on Preventive Health Care; ICSI, Institute for Clinical Systems Improvement.

Moyer VA and Butler M. Gaps in the evidence for well-child care: a challenge to our profession. Pediatrics. 2004; 114(6): 1511-21.

In the comparison of the recommendations associated with screening in well child/youth care on Table 1-3, a key theme is the limited availability of evidence from trials. Indeed, just two maneuvers (i.e., amblyopia screening and chlamydia screening in sexually active adolescents) were identified at the time as having evidence from clinical trials.

Recommended Screening Maneuver	Organizations Recommending	Organizations Recommending Against	Evidence From Trials	Results
Periodic complete physical examination	AAP, GAPS, Bright Futures; ICSI (limited recommendation)		No	
Repeated examination of the hips	CTF, Bright Futures		No	
Growth monitoring	AAP, GAPS, Bright Futures, AAFP, ICSI		No	2 trials, patient-important outcomes not considered
Blood pressure monitoring	AAP, Bright Futures, ICSI, GAPS, USPSTF		No	
Scoliosis screening through examination	Bright Futures		No	
Assessment for physical and sexual abuse	Bright Futures, GAPS	CTF	No	
Behavioral risk assessment	AAP, Bright Futures, ICSI, GAPS		No	
Alcohol use assessment	CTF, USPSTF, GAPS, Bright Futures		No	
Developmental assessment	AAP, Bright Futures, CTF, ICSI	CTF (DDST)	No	
Visual acuity screening	AAP, CTF, ICSI, Bright Futures		No	
Amblyopia screening	AAP, CTF, ICSI, USPSTF, Bright Futures		Yes	1 trial of repeated screening by orthoptists in Unite Kingdom resulted in small decrease in amblyopia and improved visual acuity (NNT: 100)
Tuberculosis screening	AAP, Bright Futures, AAFP, ICSI, CTF, USPSTF		No	
Urine screening (infection)	AAP, Bright Futures	AAFP, ICSI, USPSTF, CTF	No	
Hyperlipidemia screening (>2 y)	AAP, AAFP, ICSI, GAPS, Bright Futures	USPSTF (children)	No	
Anemia screening (universal screening)	AAP, ICSI (1 time), Bright Futures (high- risk children)	USPSTF, CTF, AAPF, ICSI (annual screening of older children)	No	
Lead poisoning screening (high-risk children)	AAP, ICSI, CTF, AAFP, <b>USPSTF,</b> Bright Futures		No	
Chlamydia screening (sexually active adolescents)	AAP, ICSI, GAPS, AAFP, CTF, <b>USPSTF,</b> Bright Futures		Yes	Screening reduces the rate of subsequent pelvic inflammatory disease
Gonorrhea and HIV screening (high- risk sexual activity)	AAP, ICSI, GAPS, AAFP, CTF, <b>USPSTF,</b> Bright Futures		No	
Papanicolaou (Pap) smear (18–21 y)	AAP, GAPS, Bright Futures, ICSI	Recommended frequency varies	No	
HPV screening	GAPS, Bright Futures	CTF	No	
Hearing screening after newborn period	AAP, CTF (subjective), ICSI, Bright Futures	CTF (objective), USPSTF (middle childhood)	No	

Moyer VA and Butler M. Gaps in the evidence for well-child care: a challenge to our profession. Pediatrics. 2004; 114(6): 1511-21.

The summary in Table 1-4 identifies just four recommendations regarding prophylaxis in	
well child/youth care.	

Recommended Maneuver	Organizations Recommending	Organizations Recommending Against	Evidence From Trials	Results
Folate supplementation for women of childbearing age	AAP, CTF, <b>USPSTF</b> , AAFP		Yes	4 trials showed substantial decrease in neural tube defects with supplementation
Iron supplementation	AAP, ICSI, <b>USPSTF,</b> CTF (iron- rich foods)	<b>USPSTF</b> (iron supplements)	Yes	Trials showed decreased prevalence of iron deficiency, developmental outcomes did not chang no data on long-term outcome, no increase in infectious illnesses with supplementation
Oral fluoride treatment	USPSTF, CTF, ICSI, AAFP		No	
Newborn ocular prophylaxis	<b>USPSTF,</b> CTF, AAFP		No	Trials compared agents but no trials compared prophylaxis with placebo or no prophylaxis

More recently, Ozer and colleagues compared recommendations of well adolescent care from 3 major North American organizations, including the USPSTF, Bright Futures and the American Congress of Obstetricians and Gynecologists (ACOG) (see Table 1-5).<sup>62</sup>

	USPSTF	Bright Futures	ACOG
	Adolescent, Aged <18 y	Adolescent, Aged 11-21 y	Adolescent, Aged 13-21 y
deline Variable			
Substance Use			
Alcohol (screening and counseling)	No Recommendation	✓	✓
Tobacco (screening and counseling)	No Recommendation	✓	✓
Other illicit drugs (screening and counseling)	No Recommendation	$\checkmark$	$\checkmark$
Reproductive Health			
STI screening (counseling)	✓All sexually active adolescents	✓If sexually active	✓ If sexually active
	and adults at increased risk for STI		
	✓All adolescents and adults at		
HIV	increased risk for HIV infection	✓ If sexually active	✓ If sexually active
Chlamydia (female)	✓ Sexually active at ≤24 y	✓If sexually active	✓ If sexually active
Chlamydia (male)	No Recommendation	✓If sexually active	✓ If sexually active
Syphilis	✓ All persons at increased risk for	✓If sexually active	✓ If sexually active
зурниз	syphilis infection	• Il sexually active	• Il sexually active
Gonorrhea	✓All sexually active women if at	✓If sexually active	✓ If sexually active
	increased risk for infection	· II Schudily delive	· II Sexually active
Birth control methods	····	✓If sexually active	✓If sexually active
Pregnancy		✓ Sexually active females without	
		contraception, late menses, or amenorrhea	
Mental Health/Depression			
Suicide screening	No Recommendation	✓	✓
	✓ 12-18 y when systems are in		
Depression	place to ensure accurate diagnosis,	<b>√</b>	✓
Depression	psychotherapy (cognitive- behavioral or interpersonal), and	v	*
	follow-up		
Nutrition/Exercise/Obesity			
Cholesterol level	No Recommendation	√>20 y	✓
Health diet	No Recommendation	√	
Hypertension/blood pressure	No Recommendation	✓	✓
Obesity/BMI	√>6 y	$\checkmark$	✓
Physical activity counseling	No Recommendation	✓	
Safety/violence			
Family/partner violence	No Recommendation	✓	✓
Fighting		✓	
Helmets		✓ ✓	
Seat belts	No Recommendation	✓ ✓	√
Alcohol while driving Guns	No Recommendation	✓ ✓	
Bullying	··· ···	✓ ✓	
Screening			
Cervical cancer screening	✓ If sexually active	✓If sexually active	√>21 y <sup>b</sup>
Testicular cancer screening	Recommend against		
Vision		After risk assessment	
Anemia		After risk assessment	
Hearing		After risk assessment	
Tuberculosis		After risk assessment	
Physical examination (as defined by		Complete physical examination is included as	Physical examination should be include
Bright Futures)		part of every health supervision visit	1 time during early, middle, and late
Measure blood pressure		✓	adolescence
Calculated and plot BMI	······································	✓ · · · · · · · · · · · · · · · · · · ·	····
Skin		✓ · · · · · · · · · · · · · · · · · · ·	
Spine		✓	
Breast		$\checkmark$	
Genitalia		$\checkmark$	
Breast self-examination	Recommend against	····	
<sup>b</sup> Updated November 20, 2009			

<sup>62</sup> Ozer EM, Urquhart JT, Brindis CD et al. Young adult preventive health care guidelines: there but can't be found. *Archives of Pediatrics and Adolescent Medicine*. 2012; 166(3): 240-7.

#### Well Child/Youth Care in Other Jurisdictions

#### Ontario

In October of 2009, Ontario introduced an enhanced 18-month well-baby visit. In recognition that the 18-month visit is the last regularly scheduled primary care encounter (usually involving immunizations) before school entry, the recommendation was that the focus shift from a well-baby check-up to a pivotal assessment of developmental health.<sup>63</sup> These visits are opportunities for monitoring growth and development, for early identification of risk, and for referral to early intervention and treatment. Of equal importance is the opportunity to support parents, through anticipatory guidance, to enhance parenting skills. The initiative introduces a process, using standardized tools, for health professionals to have a discussion with parents on child development, to identify those children who will require referral to specialized services, and to discuss parenting and local community programs that promote healthy child development and early learning. Furthermore, it is an opportunity to reinforce the importance of literacy, language development, book reading, and other skills required for literacy.

As explained by Williams et al., the 18-month well-baby visit includes the prior completion by the parent of the Nipissing District Developmental Screen. This screen is a checklist designed to monitor a child's progress, including 17 items spanning gross and fine motor skills, communication, speech and language, cognition and emotional domains. "When the child is seen in the physician's office, a 'point-of-prompt' record, i.e. the Rourke Baby Record, which aligns with the Nipissing screen, is to be used to ensure that physicians not only provide the usual history, physical, and immunization, but also an enhanced focus on neurodevelopment, parenting, child care, and literacy." (p. 37)<sup>64</sup>

Key features of the 18-month well baby visit include:

- Using the Rourke Baby Record to screen for developmental delay.
- Asking parents about concerns regarding their child, based on their completion of the Nipissing screen.
- Assessing the state of parent-child interaction, including discipline techniques.
- Promoting reading to/with the child whenever possible.
- Ensuring that parents become familiar with community resources.

The specific recommendations associated with this enhanced visit, as noted above, are based on the Rourke Baby Record (RBR). The RBR is a "system that many Canadian doctors and other healthcare professionals use for well-baby and well-child visits for infants and children from 1 week to 5 years of age. It includes forms (Guides I to V) for charting the well-baby visits as well as supporting resources for healthcare professionals."<sup>65</sup> The RBR was developed and copyrighted by Drs. Leslie Rourke, Denis Leduc and James Rourke, but is freely available for download by health care providers. The Ontario 18 Month Steering Committee providing guidance and direction for the evidence review that was used to make

<sup>&</sup>lt;sup>63</sup> Williams R and Clinton J. Getting it right at 18 months: in support of an enhanced well-baby visit. *Paediatrics & Child Health*. 2011; 16(10): 647-50.

<sup>&</sup>lt;sup>64</sup> Williams R, Biscaro A and Van Lankveld J. Improving early childhood development – part I: proposed enhancements to the 18-month well baby visit, and the critical role of the primary care physician in child development. *Ontario Medical Review*. 2006; 1: 35-46.

<sup>&</sup>lt;sup>65</sup> See <u>http://www.rourkebabyrecord.ca</u>. Accessed December 2013.

specific recommendations for the Ontario enhanced 18-month well-baby visit included Drs. Leslie Rourke and Denis Leduc.<sup>66</sup>

The evidence review and recommendations developed by the Ontario 18 Month Steering Committee formulated "evidence-based clinical recommendations using published evidence levels" previously utilized by the Canadian Task Force on the Periodic Health Examination.<sup>67</sup>

The levels of evidence and their description from the CTFPHC are noted below.<sup>68</sup>

Level I	Evidence obtained from at least one properly randomized trial.
Level II-1	Evidence obtained from a well-designed controlled trial without
	randomization.
Level II-2	Evidence obtained from well-designed cohort or case controlled analytic
	studies, preferably from more than one centre of research.
Level II-3	Evidence obtained from comparisons between times and places, with or
	without the intervention. Dramatic results in uncontrolled experiments could
	also be included in this category.
Level III	Opinions of respected authorities, based on clinical experience, descriptive
	studies or reports of expert committees.
	without the intervention. Dramatic results in uncontrolled experiments could also be included in this category. Opinions of respected authorities, based on clinical experience, descriptive

A summary of the recommendations for the enhanced 18-month well-baby visit in Ontario and the assigned level of evidence are included in Table 1-6.

The Guidelines Advisory Committee in Ontario (Ontario GAC) took "the lead in providing an evidence platform and interpretation of current evidence as the foundation for the development of recommendations for best clinical practices and tools for an enhanced 18 month well baby visit."<sup>69</sup>

Several conclusions might be drawn from the overview in Table 1-6. Of the 37 recommendations made, 4 (11%) are based on Level I evidence, 19 (51%) are based on Level II evidence and 14 (38%) are based on Level III consensus evidence. The four recommendations based on Level I evidence include vision screening, advice about parental brushing of their child's teeth, considering fluoride supplementation and "[referring] children at risk of, or showing signs of, behavioural problems to parent education programs". While the evidence review purported to use the CTFPHC levels of evidence, the sub categories for Level II appear to be used only once.

<sup>&</sup>lt;sup>66</sup> The 18-Month Steering Committee. *Final Report to the OCFP for the Evidence to Support the 18 Month Well Baby Visit* 2006. Available at http://ocfp.on.ca/docs/cme/final-report-for-the-evidence-to-support-the-18-month-well-baby-visit-.pdf. Accessed December 2013.

<sup>&</sup>lt;sup>67</sup> The 18-Month Steering Committee. *Final Report to the OCFP for the Evidence to Support the 18 Month Well Baby Visit* 2006. Available at http://ocfp.on.ca/docs/cme/final-report-for-the-evidence-to-support-the-18-month-well-baby-visit-.pdf. Accessed December 2013.

<sup>&</sup>lt;sup>68</sup> Canadian Task Force on the Periodic Health Examination. The periodic health examination: 2. 1987 update. *Canadian Medical Association Journal*. 1988; 138(7): 618-26.

<sup>&</sup>lt;sup>69</sup> See <u>http://www.gacguidelines.ca/index.cfm?pagepath=Projects/18\_Month\_Well\_Baby\_Visit&id=18867</u>. Accessed February, 2014.

Recommendations         The Steering Committee supports the current RBR practice of measuring         ength, weight and head circumference at 18 months. The Steering Committee         recommends that the clinician optimize accuracy by using specialized         equipment (for 18 month: a scale, a length board, and head circumference         cape) and train the measurer (MD or nurse). Factors that increase accuracy are:         measuring twice, recording the result immediately, calculating the exact age,         and plotting findings on the chart.         The Steering Committee supports the current RBR recommendation that the         clinician ask about parental concerns at the 18 month visit.         The Steering Committee recommends that the clinician follow the principles of         anticipatory guidance, by specifically raising discipline and developmental         ssues at the 18 month visit in order to reduce the likelihood of harmful         parenting practices and increase the likelihood of beneficial parenting         discipline strategies.         The Steering Committee recommends that the clinician:         1. Use interviewing techniques which have been associated with increased         parental disclosure.         2. Consider using validated parent-child interaction assessment tools.         The Steering Committee recommends that the clinician:	Evidence Consensus Level II Level II Level II
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2. Consider using validated parent-child interaction assessment tools. The Steering Committee recommends that the clinician:	1
The Steering Committee recommends that the clinician:	Level II
1. Tailor advice to the behaviour issue of discipline using techniques known to be effective for 18 month old children. Supplement advice judiciously with developmental information directly relevant to the problem. Use written handouts for more complex disciplinary learning.	Levels I and II
2. Reinforce to all parents that there are many resources available to support parenting skills. Encourage all parents to increase their parenting competency by connecting them to available community resources	Consensus
3. Strongly discourage physical punishment even when taking into consideration the families traditional values.	Level II
The Steering Committee recommends that the clinician: 1. Refer children at risk of, or showing signs of, behavioural problems to parent education programs, which have been shown to improve parenting skill and child outcomes.	Level I
2. Be aware that, despite their effectiveness, there are high rates of non- attendance and non-completion of parenting education programs.	Level II
1. Discuss the association of positive discipline techniques on behavioural outcomes.	
<ul> <li>a. Tell parents that warm, responsive, flexible and consistent techniques are associated with positive child outcomes.</li> </ul>	Level II
b. The use of over reactive, inconsistent, cold and coercive techniques is associated with negative child outcomes.	Level II
2. Review the evidence-based CPS statement on maternal depression.	Consensus
The Steering Committee recommends that the clinician provide families with nformation regarding those factors found to enhance quality childcare: 1. Practitioner Education (generally) 2. Practitioner Training (specifically in Early Childhood Education) 3. Group Size 4. Child/staff ratio 5. Licensing and Registration/Accreditation 6. Infection Control and Injury Prevention 7. Emergency Procedures	Consensus
<ol> <li>Be aware that high quality childcare is associated with improved paediatric outcomes in all children.</li> </ol>	Level I (for children in low-income and disadvantaged families) Level II (for general population)
	parenting skills. Encourage all parents to increase their parenting competency by connecting them to available community resources. 3. Strongly discourage physical punishment even when taking into consideration the families traditional values. The Steering Committee recommends that the clinician: 1. Refer children at risk of, or showing signs of, behavioural problems to parent education programs, which have been shown to improve parenting skill and child outcomes. 2. Be aware that, despite their effectiveness, there are high rates of non- tentatendance and non-completion of parenting education programs. The Steering Committee therefore recommends that the clinician: 1. Discuss the association of positive discipline techniques on behavioural outcomes. a. Tell parents that warm, responsive, flexible and consistent techniques are associated with positive child outcomes. b. The use of over reactive, inconsistent, cold and coercive techniques is associated with negative child outcomes. 2. Review the evidence-based CPS statement on maternal depression. The Steering Committee recommends that the clinician provide families with formation regarding those factors found to enhance quality childcare: 1. Practitioner Education (generally) 2. Practitioner Training (specifically in Early Childhood Education) 3. Group Size 4. Child/staff ratio 5. Licensing and Registration/Accreditation 6. Infection Control and Injury Prevention 7. Emergency Procedures the Steering Committee recommends that the clinician: 1. Be aware that high quality childcare is associated with improved paediatric

ntervention	Recommendations	Evidence
Development		
Developmental Surveillance	The Steering Committee recommends that the clinician inform all families of the potential benefits of developmental programs. The Steering Committee recommends that the clinician:	Level II
	<ol> <li>Provide parents with the opportunity to fill out the NDDS as an educational tool, an opportunity for parents to structure their concerns, a chance for clinicians to follow up on highlighted concerns, and as an advisory for parents to help with activities that enhance development. The steering committee emphasizes that it be used as one of many variables to assist clinicians in raising concern for developmental delay, not as a diagnostic tool by itself.</li> </ol>	Consensus
	2. Ask parents explicitly about any developmental concerns during the interview.	Level II
	<ol> <li>Do not rely on clinical judgement alone. Administer use of validated developmental assessment domains at the 18 month visit, such as those listed in the RBR Table.</li> </ol>	Level II
	The Steering Committee recommends that the clinician: Refer patients for further evaluation if either clinician or parental concern of developmental delay exists, especially in the setting of psychosocial risk factors.	Level II
	In patients who have been judged to have been false positive screens, maintain vigilance in their developmental surveillance and refer to universal programs.	Consensus
	The Steering Committee recommends that the clinician: 1. Make early referrals in view of the evidence that early identification and intervention is increasingly recognized as very important in child development. The Steering Committee recommends that among children with identified or	Consensus
	suspected developmental delay the clinician: 1. Provide directed developmental advice while awaiting programmatic interventions.	Level II
	2. Provide support to families.	Consensus
Communication and Literacy	Communication The Steering Committee recommends that: 1. Further study is required to identify whether universal screening for communication skills would be beneficial.	Consensus
	2. Clinicians should administer those aspects of the Rourke Baby Record addressing communication.	Consensus
	<ol> <li>Clinicians should refer a child with identified communication delay or disorder for assessment and treatment if appropriate.</li> <li>Literacy</li> </ol>	Consensus
	1. Clinicians provide advice for parents to read to their children.	Level II
hysical	The Steering Committee recommends that the clinician examine the child's eyes	
Vision Screening	for red reflex, and with cover/uncover test to detect amblyopia, retinoblastoma, and cataract.	Level I
Hearing Screening	The Steering Committee recommended that the clinician: 1. Refer positive parental concern of hearing loss for formal hearing assessment. 2. Refer all children with normal newborn hearing screening who are at high risk of hearing loss (Table 7) for formal audiology/infant hearing assessment.	Consensus Level II
ental Exam and Counselling	The steering committee reviewed the evidence from the 2 identified systematic reviews and the statement on fluoride use from the Canadian Paediatric Society and recommends that the clinician should:	
	1. Determine for each patient, the fluoride content of his or her drinking water.	Consensus
	2. Assess each child for dental carries risk.	Level II
	<ol> <li>After eruption of the first tooth, recommend that parents brush their 18 month old's teeth with a soft toothbrush using only a pea-sized amount of fluoridated dentifrice twice a day.</li> </ol>	Level I
	4. Consider prescribing fluoride supplementation only if 1) fluoride is <0.3 ppm in water supply, 2) the child is not brushing twice a day and 3) the child at high risk for dental caries.	Level I
	<ol> <li>Examine teeth for dental caries and fluorosis, eruption, abscess, missing teeth.</li> </ol>	Level II-3

Furthermore, a more detailed review of the evidence review and recommendations suggests potential issues regarding the use and interpretation of some of the evidence. For example, one of the recommendations under Parent Child Interaction is as follows: "[t]he Steering Committee recommends that the clinician follow the principles of anticipatory guidance, by specifically raising discipline and developmental issues at the 18 month visit in order to reduce the likelihood of harmful parenting practices and increase the likelihood of beneficial parenting discipline strategies."<sup>70</sup> This recommendation is based on Level II evidence. One of the key studies reviewed is the assessment of the Healthy Steps for Young Children Program in the U.S. published by Minkovitz et al.<sup>71</sup> With respect to the Minkovitz et al. study, the Ontario 18 Month Steering Committee notes that:

[l] astly, a large study (N=5565 children) of a practice-based intervention of enhanced developmental, behavioural and psychosocial care via a "Healthy Steps Specialist" found lower rates of spanking and harsh discipline (p=0.01 and p=0.006, respectively) and higher rates of ignoring misbehaviour and likelihood of discussing maternal sadness (p=0.003 and p <0.001) among intervention groups [...]. Of note, these changes were significant only in the quasi-experimental sites, and none of the outcomes reached significance in the randomized sites. As a result, it cannot be said that anticipatory guidance is supported by RCT level evidence, despite promising results with controlled trials and survey data.<sup>72</sup>

We have recreated the key outcomes table from the Minkovitz et al. study below (see Table 1-7), with statistically significant results highlighted in yellow.

	OR (95% CI)		
Outcome	Total	Randomization Sites	Quasi-Experimental Site
Parent Response to Child Misbehavior			
Ever slap child in face/spank with object	0.73 (0.55 to 0.97)	0.82 (0.54 to 1.26)	0.67 (0.46 to 0.97)
Use more harsh discipline	0.78 (0.62 to 0.99)	0.76 (0.53 to 1.09)	0.80 (0.59 to 1.10)
Often or almost always negotiate	1.16 (1.01 to 1.34)	1.18 (0.96 to 1.45)	1.15 (0.95 to 1.39)
Often or almost always ignore misbehavior	1.38 (1.10 to 1.73)	1.20 (0.84 to 1.71)	1.52 (1.13 to 2.04)
Perception of Child's Behavior <sup>1</sup>			
Aggressive behavior	0.40 (0.06 to 0.75)	0.23 (-0.29 to 0.79)	0.54 (0.08 to 1.00)
Anxious or depressed	0.19 (-0.004 to 0.38)	0.13 (-0.16 to 0.43)	0.24 (-0.02 to 0.50)
Problems sleeping	0.20 (0.03 to 0.36)	0.12 (-0.13 to 0.38)	0.26 (0.04 to 0.49)
Promotion of Child Development and Safety			
Discussed sadness with someone in practice <sup>2</sup>	1.60 (1.09 to 2.36)	0.95 (0.56 to 1.63)	2.82 (1.57 to 5.08)
Read or showed picture books every day or more often	0.96 (0.82 to 1.12)	0.94 (0.75 to 1.18)	0.98 (0.80 to 1.21)
Played with child once a day or more	0.91 (0.74 to 1.12)	0.99 (0.72 to 1.35)	0.85 (0.64 to 1.13)
Followed 3 routines <sup>3</sup>	1.03 (0.88 to 1.20)	0.96 (0.76 to 1.21)	1.09 (0.89 to 1.34)
Lowered temperature on water heater	1.03 (0.89 to 1.20)	1.31 (1.05 to 1.65)	0.84 (0.68 to 1.04)
Used covers on electrical outlets	1.17 (0.92 to 1.48)	1.41 (0.98 to 2.03)	1.02 (0.74 to 1.39)
Had safety latches on cabinets	1.09 (0.86 to 1.39)	1.11 (0.90 to 1.38)	0.98 (0.80 to 1.20)
bbreviations: CI, confidence interval; OR, odds ratio			
Difference in mean values from Child Behavior Checklist			
Among subset of respondents (n = 967 total: n = 525 intervention help with sadness since the child was born, and/or those who rest eeling anxious or depressed.			
Same meal time, naptime, and bedtime each day.			

<sup>&</sup>lt;sup>70</sup> The 18-Month Steering Committee. *Final Report to the OCFP for the Evidence to Support the 18 Month Well Baby Visit* 2006. Available at http://ocfp.on.ca/docs/cme/final-report-for-the-evidence-to-support-the-18-month-well-baby-visit-.pdf. Accessed December 2013.

 <sup>&</sup>lt;sup>71</sup> Minkovitz CS, Hughart N, Strobino D et al. A practice-based intervention to enhance quality of care in the first
 3 years of life: the Healthy Steps for Young Children Program. *Journal of the American Medical Association*.
 2003; 290(23): 3081-91.

<sup>&</sup>lt;sup>72</sup> The 18-Month Steering Committee. *Final Report to the OCFP for the Evidence to Support the 18 Month Well Baby Visit* 2006. Available at http://ocfp.on.ca/docs/cme/final-report-for-the-evidence-to-support-the-18-month-well-baby-visit-.pdf. Accessed December 2013.

The results do indicate lower rates of spanking and harsh discipline, higher rates of ignoring misbehaviour and a higher likelihood of discussing maternal sadness with someone in practice. These results tend to be supported by outcomes from the quasi-experimental sites but not the randomized sites. The only outcome that appears to be significant based on the randomized sites is lowering the temperature on the water heater.

In reviewing these results, one could question whether the focus should be on the significant outcomes observed from sites using a quasi-experimental research design (Level II evidence) or the limited significant outcomes observed from sites using a randomization research design (Level I evidence). An appropriate interpretation might be that the available Level I evidence does not provide support for the effectiveness of anticipatory guidance with respect to changes in parental discipline. Furthermore, the Healthy Steps for Young Children Program being reviewed by Minkovitz et al. is a 3-year intervention that involves an average of 11 well child care visits and 2 home visits during that time. The average cost of the intervention is \$402 - \$953 *per year* or \$1,206 - \$2,859 over the 3-year period.<sup>73</sup> Despite this intensity of intervention, minimal evidence of effectiveness was observed, especially when considering the Level I evidence.

Another recommendation under Parent Child Interaction is to "[r]efer children at risk of, or showing signs of, behavioural problems to parent education programs, which have been shown to improve parenting skill and child outcomes."<sup>74</sup> This recommendation is one of the four that is identified as being supported by Level I evidence. What the Ontario GAC found was a review of randomized controlled trials which supported the effectiveness of Group-Based Parent Education programs in reducing behavioural problems in children.<sup>75</sup> In addition, the Ontario GAC noted that "no studies looked at the likelihood that a parent would comply with a physician referral or advice to attend."<sup>76</sup> It is the effectiveness of a physician referral at 18-months in enhancing attendance at a parent education program.

It is important to keep in mind what the goals of the enhanced 18-month well baby visits and the supporting evidence are. The argument should be that this visit enhances outcomes for children (and perhaps their parents), and thus, it is something in which it is worth investing.

New physician fee codes were introduced in Ontario in October of 2009 as an incentive for conducting these enhanced well baby visits at 18 months (A002 for family physicians and A268 for paediatricians, valued at \$62.20 and \$61.00 respectively). In 2011, the Institute for Clinical Evaluative Sciences prepared a preliminary report assessing the utilization of this new fee code.<sup>77</sup> Based on utilization of the fee codes between October 2009 and December

http://www.ices.on.ca/file/Well%20Baby\_final%20report.pdf. Accessed December 2013.

 <sup>&</sup>lt;sup>73</sup> Minkovitz CS, Hughart N, Strobino D et al. A practice-based intervention to enhance quality of care in the first
 3 years of life: the Healthy Steps for Young Children Program. *Journal of the American Medical Association*.
 2003; 290(23): 3081-91.

<sup>&</sup>lt;sup>74</sup> The 18-Month Steering Committee. *Final Report to the OCFP for the Evidence to Support the 18 Month Well Baby Visit* 2006. Available at http://ocfp.on.ca/docs/cme/final-report-for-the-evidence-to-support-the-18-month-well-baby-visit-.pdf. Accessed December 2013.

<sup>&</sup>lt;sup>75</sup> Barlow J and Stewart-Brown S. Behavior problems and group-based parent education programs. *Journal of Developmental & Behavioral Pediatrics*. 2000; 21(5): 356-70.

<sup>&</sup>lt;sup>76</sup> The 18-Month Steering Committee. *Final Report to the OCFP for the Evidence to Support the 18 Month Well Baby Visit* 2006. Available at http://ocfp.on.ca/docs/cme/final-report-for-the-evidence-to-support-the-18-month-well-baby-visit-.pdf. Accessed December 2013.

<sup>&</sup>lt;sup>77</sup> Guttmann A, Klein-Geltink J, Kopp A et al. *Uptake of the New Fee Code for Ontario's Enhanced 18-Month Well Baby Visit: A Preliminary Evaluation.* 2011. Available at

31, 2010, they found that 38.2% of eligible children in Ontario were receiving the enhanced screening. Rates of utilization were higher in children in the highest income quintile (45%) than those in the lowest income quintile (30%). This difference may be at least partially due to the fact that a higher proportion of children in the lowest income quintile are seen in Community Health Centres who may not be tracking this service. Regardless, the Community Health Centres now have a strategy in place to increase utilization of the 18-month Well Baby visit in children in the lowest income quintile.<sup>78</sup> This information will be included in the next evaluation report on the utilization of the service.

### Australia

In July of 2008, the Australian government introduced the *Healthy Kids Check (HKC)*. The HKC targets every 4-year old in Australia for a basic health check before commencing school. Components of the HKC include:

- Administered by child's usual general practitioner or designated practice nurse
- Conducted in conjunction with vaccinations for 4-year-olds
- Provide parents with a copy of the *Get set 4 life habits for healthy kids* guide, an information booklet that includes tips on child health and development
- Checklist of mandatory assessments:
  - Measure height and weight
  - Check eyesight
  - o Check hearing
  - Check oral health
  - Question toilet habits
  - > Note known or suspected allergies

Recent changes will lower the age to 3 and incorporate elements of social and emotional well-being.<sup>79</sup>

A review by Alexander and Mazza of the recommendations associated with the *Healthy Kids Check* found a fairly high reliance on consensus-based recommendations (see Table 1-8).<sup>80</sup> The authors conclude that "the components of the HKC could be refined to better reflect evidence-based guidelines that target health monitoring of preschool children."

<sup>&</sup>lt;sup>78</sup> Dr. Jean Clinton, Associate Professor, Psychiatry and Behavioural Neuroscience, McMaster University, Offord Centre for Child Studies. Personal communication, February, 2014.

<sup>&</sup>lt;sup>79</sup> Daubney MF, Cameron CM and Scuffham PA. Changes to the Healthy Kids Check: will we get it right? *Medical Journal of Australia*. 2013; 198(9): 475-7.

<sup>&</sup>lt;sup>80</sup> Alexander KE and Mazza D. The Healthy Kids Check - is it evidence-based? *Medical Journal of Australia*. 2010; 192(4): 207-10.

Table 1-8: Mandatory Assessment Components of the Healthy Kids Check,with Relevant Guideline Statements				
Mandatory Assessment	Supporting Guideline Statements	Opposing Guideline Statements	Insufficient Evidence for Screening	
Measure height			Screening for short	
			stature	
Measure weight	BMI can identify overweight (EB) BMI-for-age percentile charts should be used (CB)	Screening for overweight (EB)	Screening for overweight	
Conduct a visual inspection	Screening for	Screening for risk	Impact of screening on	
of eyes	amblyopia/strabismus (EB) (CB)	factors for amblyopia (EB)	prevalence of amblyopia	
Check eyesight using LEA	Screening for defects in visual		Preschool visual acuity	
Children's Chart or similar	acuity (EB) (CB)		screening	
Seek parental concerns about child's vision (eg, squint, infection, injury)	Asking parent about positive possible eye or vision problems (CB)		No evidence evaluating screening for parental concern	
Question if child has family	Asking about positive family		No evidence evaluating	
history of eyesight problems	history of strabismus, amblyopia or media opacity (CB)		screening for family history	
Checking hearing, including	Abnormalities of eardrum may		Alternative screening	
conducting an ear examination	indicate hearing impairment (CB)		tests not adequately compared	
			Inadequate evidence for school entry screening	
Seek parental concerns regarding child's hearing, listening, following instructions, or language	Parental concern is of greater predictive value than examination in doctor's office (EB)			
Question if child has any		Screening for otitis		
history of ear infections,		media with effusion		
discharge, recurrent or		(EB)		
chronic otitis media		(LD)		
Check oral health – teeth and		Caries risk	Dental health screening	
gums		assessment should be based in dental practice (EB)	for caries risk assessments	
Question if child has been to dentist			Impact of general practitioner referral to dentist	
Question how often child brushes teeth	Brushing teeth twice daily with fluoride toothpaste (EB)		dentist	
Question whether child is	(==)	Assess after age 5		
independent with toileting		years (CB)		
Question whether child wets the bed		Assess after age 5 years (CB)		
Note suspected allergies	Sensitivity to most food allergens remits later in childhood (EB) (CB)	years (CD)		
Note known allergies	Educate, prescribe and develop management plan for identified children (CB)			

EB = evidence-based guideline, CB = consensus-based guideline

# Current USPSTF 'A' and 'B' Recommendations

For a variety of reasons, limited high-quality evidence exists on the effectiveness of specific preventive maneuvres provided in a clinical setting for children and youth. Numerous organizations have used lower quality evidence and leaned heavily on expert opinion or consensus to fill this void. This reliance on low quality evidence has resulted in numerous conflicting guidelines that recommend so many interventions of unproven effectiveness that it is impossible for clinicians to determine which interventions of unproven effectiveness also carries with patients. This over-reliance on interventions of unproven effectiveness also carries with it significant harms, not the least of which are a potential waste of resources that could be better utilized elsewhere in improving the health and well-being of children and youth.

Despite the limited available high-quality research evidence, there is sufficient information currently available for the USPSTF to conclude that at least 22 preventive maneuvres application to children and youth are, from a clinical perspective, worth doing (i.e. they received an 'A' or 'B' recommendation). We have summarized these maneuvres in Table 1-9. Note that the USPSTF does not review immunizations so these clinically effective maneuvers are not included in Table 1-9.

From the perspective of this current review, nine of these preventive maneuvres have been referred to the Perinatal Services B.C. (PSBC) guidelines. This includes the recommendations for breastfeeding, ocular prophylaxis in newborns, screening for hepatitis B virus infection, syphilis infection and Rh(D) incompatibility in pregnant women and screening for phenylketonuria, congenital hypothyroidism and sickle cell disease.

Four of the 22 preventive maneuvres, all with a 'B' recommendation, were excluded from the current review by the Lifetime Prevention Schedule Expert Advisory Committee based on a selection process involving a modified Delphi process.<sup>81</sup> These exclusions (major depressive disorder in children and adolescents, behavioral counseling to prevent sexually transmitted infections, behavioral counseling to prevent skin cancer and screening for iron deficiency anemia) were considered to be of lower priority at the time being, given the limited availability of resources for this project. Screening for obesity in children and adolescents was deferred pending the outcomes of the major review currently being completed by the CTFPHC.

Three preventive screening maneuvres including adolescents (screening for HIV, gonorrhea and chlamydial infection) will be covered in the adult section(s) of this report. Finally, the remaining three maneuvres (vision screening for amblyopia in children ages 3 to 5, primary care–relevant behavioral interventions to prevent tobacco use in school-aged children and adolescents, and prevention of dental caries in children from birth through age 5 years) will be reviewed in the following sections of this report.

The USPSTF has begun the guideline development process for screening for speech and language delay and disorders in children age 5 year or younger while the CTFPHC has begun the guideline development process for screening for developmental delay. When available, these recommendations would be relevant to this project and will be considered in the next update of the LPS.

<sup>&</sup>lt;sup>81</sup> H. Krueger & Associates Inc. Evidence Review and Economic Modelling of Preventive Health Maneuvers to Update the BC Lifetime Prevention Schedule: Determining Which Maneuvers to Prioritize. November 4, 2013.

Table 1-9: USPSTF Recommendations for Children and Adoleso Based on 'A' and 'B' Recommendations	Date of Most Recent Update	Recommendation
Screening for Asymptomatic Disease or Risk Factors Routine Offer of Screening for Sexually Transmitted Illnesses		
Screening for HIV		
The USPSTF recommends that clinicians screen adolescents and adults aged 15 to 65 years for HIV		
infection. Younger adolescents and older adults who are at increased risk should also be screened.	July, 2013	A
Screening for Chlamydial Infection		
The USPSTF recommends screening for chlamydial infection in all sexually active, nonpregnant		
young women ages 24 and younger and in older nonpregnant women who are at increased risk.	June, 2007	A
The USPSTF recommends screening for chlamydial infection in all pregnant women ages 24 and		
younger and in older pregnant women who are at increased risk.	June, 2007	В
Screening for Gonorrhea		
The USPSTF recommends that clinicians screen all sexually active women, including those who are		_
pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young	May, 2005	В
or have other individual or population risk factors).		
Recommendations Deferred to PSBC		
Screening for Hepatitis B Virus Infection in Pregnancy		
Screen for hepatitis B virus infection in pregnant women at their first prenatal visit.	June, 2009	A
Screening for Syphilis Infection in Pregnancy		
Screen all pregnant women for syphilis infection.	May, 2009	А
Screening for Phenylketonuria (PKU)		
The USPSTF recommends screening for phenylketonuria (PKU) in newborns.	March, 2008	А
Screening for Congenital Hypothyroidism		
The USPSTF recommends screening for congenital hypothyroidism (CH) in newborns.	March, 2008	А
Screening for Sickle Cell Disease in Newborns		
The USPSTF recommends screening for sickle cell disease in newborns.	September, 2007	А
Screening for Rh(D) Incompatibility	September, 2007	
The USPSTF strongly recommends Rh(D) blood typing and antibody testing for all pregnant women	February, 2004	А
during their first visit for pregnancy-related care.		
The USPSTF recommends repeated Rh (D) antibody testing for all unsensitized Rh (D)-negative	February, 2004	В
women at 24-28 weeks' gestation, unless the biological father is known to be Rh (D)-negative.	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Universal Screening for Hearing Loss in Newborns		
The USPSTF recommends screening for hearing loss in all newborn infants.	July, 2008	В
Excluded from Current Review		
Major Depressive Disorder in Children and Adolescents		
The USPSTF recommends screening for major depressive disorder (MDD) in adolescents (ages 12 to		
18 years) when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-	March, 2009	В
behavioral or interpersonal), and follow-up.		
Included in Current Review		
Screening for Visual Impairment in Children Ages 1 to 5		
The USPSTF recommends vision screening for all children at least once between the ages of 3 and 5		
years, to detect the presence of amblyopia or its risk factors.	January, 2011	В
Behavioural Counseling Interventions		
Recommendations Deferred to PSBC		
Primary Care Interventions to Promote Breastfeeding		
The USPSTF recommends interventions during pregnancy and after birth to promote and support		
	October, 2008	В
breastfeeding.		
Excluded from Current Review		
Screening for Obesity in Children and Adolescents		
The USPSTF recommends that clinicians screen children aged 6 years and older for obesity and offer		
them or refer them to intensive counseling and behavioral interventions to promote improvements	January, 2010	В
in weight status.		
Behavioral Counseling to Prevent Sexually Transmitted Infections		
The USPSTF recommends high-intensity behavioral counseling to prevent sexually transmitted	October 2000	n
infections (STIs) for all sexually active adolescents and for adults at increased risk for STIs.	October, 2008	В
Behavioral Counseling to Prevent Skin Cancer		
The USPSTF recommends counseling children, adolescents, and young adults aged 10 to 24 years		
who have fair skin about minimizing their exposure to ultraviolet radiation to reduce risk for skin	May, 2012	В
	19109, 2012	D
cancer.		
Included in Current Review Primary Core, relevant Rehavioral Interventions to Provent Tabasco Lise in School, and Children and Adole	conto	
Primary Care-relevant Behavioral Interventions to Prevent Tobacco Use in School-aged Children and Adole	scents	
The USPSTF recommends that primary care clinicians provide interventions, including education or	August, 2013	В
brief counseling, to prevent initiation of tobacco use among school-aged children and adolescents.		
Preventive Medication		
Preventive Medication		
Preventive Medication Recommendations Deferred to PSBC	July 2011	
Preventive Medication Recommendations Deferred to PSBC Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum	July, 2011	А
Preventive Medication Recommendations Deferred to PSBC Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention	July, 2011	Α
Preventive Medication Recommendations Deferred to PSBC Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention of gonococcal ophthalmia neonatorum. Excluded from Current Review	July, 2011	Α
Preventive Medication Recommendations Deferred to PSBC Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention of gonococcal ophthalmia neonatorum. Excluded from Current Review Screening for Iron Deficiency Anemia	July, 2011	
Preventive Medication Recommendations Deferred to PSBC     Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum     The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention     of gonococcal ophthalmia neonatorum.     Excluded from Current Review     Screening for Iron Deficiency Anemia     The USPSTF recommends routine iron supplementation for asymptomatic children ages 6 to 12	July, 2011 May, 2006	A B
Preventive Medication Recommendations Deferred to PSBC     Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum     The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention     of gonococcal ophthalmia neonatorum. Excluded from Current Review     Screening for Iron Deficiency Anemia     The USPSTF recommends routine iron supplementation for asymptomatic children ages 6 to 12     months who are at increased risk for iron deficiency anemia.	July, 2011	
Preventive Medication Recommendations Deferred to PSBC     Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum     The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention     of gonococcal ophthalmia neonatorum. Excluded from Current Review     Screening for Iron Deficiency Anemia     The USPSTF recommends routine iron supplementation for asymptomatic children ages 6 to 12     months who are at increased risk for iron deficiency anemia. Included in Current Review	July, 2011	
Preventive Medication     Preventive Medication     Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum     The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention     of gonococcal ophthalmia neonatorum.     Excluded from Current Review     Screening for Iron Deficiency Anemia     The USPSTF recommends routine iron supplementation for asymptomatic children ages 6 to 12     months who are at increased risk for iron deficiency anemia.     Included in Current Review     Prevention of Dental Caries in Children From Birth Through Age 5 Years	July, 2011	
Preventive Medication Recommendations Deferred to PSBC     Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum     The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention     of gonococcal ophthalmia neonatorum. Excluded from Current Review     Screening for Iron Deficiency Anemia     The USPSTF recommends routine iron supplementation for asymptomatic children ages 6 to 12     months who are at increased risk for iron deficiency anemia.     Included in Current Review     Prevention of Dental Caries in Children From Birth Through Age 5 Years     The USPSTF recommends that primary care clinicians prescribe oral fluoride supplementation	July, 2011	
Preventive Medication     Preventive Medication     Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum     The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention     of gonococcal ophthalmia neonatorum.     Scudded from Current Review     Screening for Iron Deficiency Anemia     The USPSTF recommends routine iron supplementation for asymptomatic children ages 6 to 12     months who are at increased risk for iron deficiency anemia.     ncluded in Current Review     Prevention of Dental Caries in Children From Birth Through Age 5 Years	July, 2011	

# Screening for Asymptomatic Disease or Risk Factors

# **Screening for Hearing Loss**

Canadian Task Force on Preventive Health Care Recommendations (1990)

In the 1990 publication on well-baby care in the first 2 years of life, the CTFPHC recommended that there was good evidence to include repeated examination of the hips, eyes and hearing in the first year of life in the periodic health examination. This was given an 'A' recommendation.<sup>82</sup> Based on this information, hearing screening was included in the BC Lifetime Prevention Schedule.<sup>83</sup>

Canadian Task Force on Preventive Health Care Recommendations (1994)

In 1994 the CTFPHC addressed *hearing screening in preschool children* and concluded that there was fair evidence to *exclude* this screening from the periodic health exam (see below).

Hearing problems in preschool children are best divided into short-term, transient problems that resolve and persistent problems. The latter category is composed primarily of persistent middle ear effusion and sensorineural deficits. The prevalence of short-term problems is approximately 15% while for persistent problems it is closer to 3%.

Detection of hearing impairment has not been found to significantly reduce prevalence later.

Fair evidence to exclude from periodic health examination (D).<sup>84</sup>

#### United States Preventive Service Task Force Recommendations (2008)

The focus of the USPSTF recommendations is that hearing screening be completed before 1 month of age (see below).

Children with hearing loss have increased difficulties with verbal and nonverbal communication skills, increased behavioral problems, decreased psychosocial wellbeing, and lower educational attainment compared with children with normal hearing.

Because half of the children with hearing loss have no identifiable risk factors, universal screening (instead of targeted screening) has been proposed to detect children with permanent congenital hearing loss (PCHL). There is good evidence that newborn hearing screening testing is highly accurate and leads to earlier identification and treatment of infants with hearing loss.

*The USPSTF recommends screening for hearing loss in all newborn infants (B recommendation).*<sup>85</sup>

<sup>&</sup>lt;sup>82</sup> Canadian Task Force on the Periodic Health Examination. Periodic health examination, 1990 update: 4. Wellbaby care in the first 2 years of life. *Canadian Medical Association Journal*. 1990; 143(9): 867-72.

<sup>&</sup>lt;sup>83</sup> Clinical Prevention Policy Review Committee. A Lifetime of Prevention: A Report of the Clinical Prevention Policy Review Committee. 2009. Available at

http://www.health.gov.bc.ca/library/publications/year/2009/CPPR\_Lifetime\_of\_Prevention\_Report.pdf. Accessed August 2013.

<sup>&</sup>lt;sup>84</sup> Feightner JW. Canadian Guide to Clinical Preventive Health Care: Chapter 27: Routine Preschool Screening for Visual and Hearing Problems. 1994. Available at http://canadiantaskforce.ca/wp-

content/uploads/2013/03/Chapter27\_preschool\_visualhear94.pdf?0136ff. Accessed November 2013.

Taken together, the recommendations of the USPSTF and the CTFPHC suggest screening early (i.e., within the first month) is clinically effective while screening again later (i.e., in preschool) is not. The overall approach in this process is to refer any recommendations regarding prenatal care, intrapartum care and immediate postpartum care to the agency responsible for recommendations.

<sup>&</sup>lt;sup>85</sup> U.S. Preventive Services Task Force. Universal screening for hearing loss in newborns: US Preventive Services Task Force recommendation statement. *Pediatrics*. 2008; 122(1): 143-8.

# Vision Screening for Amblyopia

United States Preventive Service Task Force Recommendations (2011)

Approximately 2% to 4% of preschool aged children have amblyopia, an alteration in the visual neural pathway in the developing brain that can lead to permanent vision loss in the affected eye. Amblyopia usually occurs unilaterally but can occur bilaterally. Identification of vision impairment before school entry could help identify children who may benefit from early interventions to correct or to improve vision.

The USPSTF recommends vision screening for all children at least once between the ages of 3 and 5 years, to detect the presence of amblyopia or its risk factors (grade B recommendation).

*The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of vision screening for children <3 years of age (I statement).*<sup>86</sup>

#### Canadian Task Force on Preventive Health Care Recommendations (1990)

In the 1990 publication on well-baby care in the first 2 years of life, the CTFPHC recommended that there was good evidence to include repeated examination of the eyes and hearing during the first year of life in the periodic health examination. This was given an 'A' recommendation.<sup>87</sup> Based on this information, vision screening was included in the B.C. Lifetime Prevention Schedule.<sup>88</sup>

#### Canadian Task Force on Preventive Health Care Recommendations (1994)

Once detected, simple refractive errors affecting visual acuity are readily treatable with eye glasses. However, evidence for the treatment of amblyopia is more controversial and inconclusive. It is widely held that for any potential benefit to be realized, amblyopia must be detected during the "sensitive" period, i.e. between birth and about the seventh year.

Systematic screening for visual deficits has been found to decrease prevalence later.

Fair evidence for inclusion in periodic health examination (B Recommendation).<sup>89</sup>

Utilization of This Clinical Preventive Service

#### **Currently in British Columbia**

The B.C. Early Childhood Vision Screening Program, implemented in 2007, targets young children in kindergarten as well as three year olds for vision screening. In British Columbia, children can be enrolled in kindergarten if their fifth birthday is within the calendar year, so a kindergarten class could consist of 4, 5 and 6 year olds. For kindergarten children, vision

<sup>&</sup>lt;sup>86</sup> U.S. Preventive Services Task Force. Vision screening for children 1 to 5 years of age: US Preventive Services Task Force Recommendation statement. *Pediatrics*. 2011; 127(2): 340-6.

<sup>&</sup>lt;sup>87</sup> Canadian Task Force on the Periodic Health Examination. Periodic health examination, 1990 update: 4. Wellbaby care in the first 2 years of life. *Canadian Medical Association Journal*. 1990; 143(9): 867-72.

<sup>&</sup>lt;sup>88</sup> Clinical Prevention Policy Review Committee. A Lifetime of Prevention: A Report of the Clinical Prevention Policy Review Committee. 2009. Available at

http://www.health.gov.bc.ca/library/publications/year/2009/CPPR\_Lifetime\_of\_Prevention\_Report.pdf. Accessed August 2013.

<sup>&</sup>lt;sup>89</sup> Feightner JW. Canadian Guide to Clinical Preventive Health Care: Chapter 27: Routine Preschool Screening for Visual and Hearing Problems. 1994. Available at http://canadiantaskforce.ca/wp-

content/uploads/2013/03/Chapter27\_preschool\_visualhear94.pdf?0136ff. Accessed November 2013.

screening averaged 92.7% between 2007 and 2010, with a high of 94.0% in  $08/09.^{90}$  In three-year-old children, the participation rates are much lower, averaging 9.0% between 2007 and 2010. This rate has increased each year, from 1.9% in the fiscal year 2007/08, to 12.4% in 08/09 and 12.6% in  $09/10.^{91}$ 

#### Best in the World

In Japan, the Maternal and Childhood Health Law requires all children to undergo physical and developmental checkups, including vision screening. In three to four-year-old children, the participation rate in these physical and developmental checkups was 81.9% in 2004.<sup>92</sup>

In South Korea, a large sample of families with children aged 3 to 5 were mailed a home vision screening test in 2001. Of the 36,973 children receiving the invitation to screen, 97.1% (35,894) completed and returned the test with 95.3% (35,226) completing the test correctly.<sup>93</sup>

## Relevant British Columbia Population in 2013

Vision screening can occur at a number of different ages for beneficial effect, but the USPSTF outlines the ages of 3 to 5 in its guidelines. For 2013, BC Stats estimates that there were 137,802 children between the ages of 3 and 5 in British Columbia (see Appendix A).<sup>94</sup> The recommendation is for one time screening between the ages of 3 and 5, and thus the relevant population for vision screening would be 1/3 of 137,802 or approximately 45,500.

# Modelling CPB and CE

No model is available from the Partnership for Prevention and HealthPartners Research Foundation to calculate the CPB and CE of screening for amblyopia in children ages 3 to 5. In this section, we will calculate the CPB and CE associated with screening for amblyopia in children ages 3 to 5 based on the following assumptions for CPB and CE.

Because vision screening is almost universally (93%) applied in kindergarten children in B.C., there would be only minor potential benefits achievable by further improving update of this maneuver. Therefore, in this section we have calculated the total potential CPB in B.C. if screening for amblyopia in children ages 3 to 5 did not exist.

In estimating CPB, we made the following assumptions:

• 99.59% of individuals in a birth cohort of 40,000 would survive to age 4, based on data from the B.C. life tables for 2009 to 2011.<sup>95</sup>

<sup>&</sup>lt;sup>90</sup> Early Childhood Screening Research & Evaluation Unit. *BC Early Childhood Vision Screening Program: Final Evaluation Report.* 2012. Available at http://www.health.gov.bc.ca/women-and-children/pdf/bc-early-childhood-vision-screening-program.pdf. Accessed October 2013.

<sup>&</sup>lt;sup>91</sup> Early Childhood Screening Research & Evaluation Unit. *BC Early Childhood Vision Screening Program: Final Evaluation Report.* 2012. Available at http://www.health.gov.bc.ca/women-and-children/pdf/bc-early-childhood-vision-screening-program.pdf. Accessed October 2013.

<sup>&</sup>lt;sup>92</sup> Matsuo T, Matsuo C, Matsuoka H et al. Detection of strabismus and amblyopia in 1.5- and 3-year-old children by a preschool vision-screening program in Japan. *Acta Medica Okayama*. 2007; 61(1): 9-16.

<sup>&</sup>lt;sup>93</sup> Lim HT, Yu YS, Park SH et al. The Seoul Metropolitan Preschool Vision Screening Programme: results from South Korea. *British Journal of Ophthalmology*. 2004; 88(7): 929-33.

<sup>&</sup>lt;sup>94</sup> BC Stats. Population Projections. 2013. Available at

http://www.bcstats.gov.bc.ca/StatisticsBySubject/Demography/PopulationProjections.aspx. Accessed November 2013.

<sup>&</sup>lt;sup>95</sup> See http://www.statcan.gc.ca/pub/84-537-x/2013005/tbl-eng.htm. Accessed December 2013.

- Estimates of the prevalence of amblyopia ('lazy eye') range from 2.9%<sup>96</sup> to 4.8%.<sup>97</sup> We used the mid-point of this range (3.85%) for the base case (Table 2-1, row *c*) and the range in sensitivity analysis.
- We assumed that 70% of children with amblyopia would be asymptomatic. That is, 30% would be symptomatic and would thus be detected without the need for screening (Table 2-1, row *e*).<sup>98</sup>
- We assumed an average life expectancy for a 4 year-old of 78.7 years (Table 2-1, row *g*), based on data from the B.C. life tables for 2009 to 2011.<sup>99</sup>
- The annual incidence of permanent visual impairment or blindness attributable to loss of vision in the non-amblyopic eye has been estimated at .00004 (.00001 to 0.00006) during the ages of 5 to 15 years, 0.00005 (0.00004 to 0.00007) for ages 16 to 64 and 0.00046 (0.00039 to 0.00052) for ages  $65^{+100}$  (Table 2-1, row *h*, *i* and *j*). In screening a cohort of 40,000, we would expect to find 1,074 four-year olds with amblyopia. Of these, approximately 10 would be expected to have permanent visual impairment or blindness attributable to loss of vision in the non-amblyopic eye. Most of this visual impairment /blindness (64%) would occur after age 65.
- The organization *Prevent Blindness* has reviewed and summarized the available literature on the QALY reduction associated with visual impairment (-0.12) and blindness (-0.28).<sup>101</sup> We used the mid-point of -0.20 in estimating the QALY reduction associated with permanent visual impairment or blindness (Table 2-1, row k).
- The effectiveness of interventions in improving amblyopia is fairly contentious. The USPSTF noted an average improvement of approximately one line on the Snellen eye chart.<sup>102</sup> Others suggest a clinically significant improvement resulting from treatment in between 26% and 75%.<sup>103,104</sup> We have used the mid-point of this range (51%) in our base model and the range in sensitivity analysis (Table 2-1, row *m*).

<sup>&</sup>lt;sup>96</sup> Kemper A, Harris R, Lieu T et al. Screening for visual impairment in children younger than age 5 years: a systematic evidence review for the US Preventive Services Task Force. 2004. Available at

http://www.ncbi.nlm.nih.gov/pubmed/20722123. Accessed January 2014.

<sup>&</sup>lt;sup>97</sup> Carlton J, Karnon J, Czoski-Murray C et al. The clinical effectiveness and cost-effectiveness of screening programmes for amblyopia and strabismus in children up to the age of 4-5 years: a systematic review and economic evaluation. *Health Technology Assessment*. 2008; 12(25): xi-194.

<sup>&</sup>lt;sup>98</sup> Campbell LR and Charney E. Factors associated with delay in diagnosis of childhood amblyopia. *Pediatrics*. 1991; 87(2): 178-85.

<sup>&</sup>lt;sup>99</sup> See <u>http://www.statcan.gc.ca/pub/84-537-x/2013005/tbl-eng.htm</u>. Accessed December 2013.

<sup>&</sup>lt;sup>100</sup> Carlton J, Karnon J, Czoski-Murray C et al. The clinical effectiveness and cost-effectiveness of screening programmes for amblyopia and strabismus in children up to the age of 4-5 years: a systematic review and economic evaluation. *Health Technology Assessment*. 2008; 12(25): xi-194.

<sup>&</sup>lt;sup>101</sup> Prevent Blindness America. *The Economic Burden of Vision Loss and Eye Disorders in the United States: Quality Adjusted Life Years (QALYs).* 2013. Available at http://costofvision.preventblindness.org/costs/loss-of-wellbeing/quality-adjusted-life-years-qalys. Accessed February 2014.

<sup>&</sup>lt;sup>102</sup> U.S. Preventive Services Task Force. Vision screening for children 1 to 5 years of age: US Preventive Services Task Force Recommendation statement. *Pediatrics*. 2011; 127(2): 340-6.

<sup>&</sup>lt;sup>103</sup> Carlton J, Karnon J, Czoski-Murray C et al. The clinical effectiveness and cost-effectiveness of screening programmes for amblyopia and strabismus in children up to the age of 4-5 years: a systematic review and economic evaluation. *Health Technology Assessment*. 2008; 12(25): xi-194.

<sup>&</sup>lt;sup>104</sup> Konig HH and Barry JC. Cost effectiveness of treatment for amblyopia: an analysis based on a probabilistic Markov model. *British Journal of Ophthalmology*. 2004; 88(5): 606-12.

Based on these assumptions, the CPB associated with screening for amblyopia in children ages 3 to 5 is 25 (Table 2-1, row n).

We also modified several major assumptions and recalculated the CPB as follows:

- Assume the prevalence of amblyopia is reduced from 3.85% to 2.9%: CPB = 19
- Assume the prevalence of amblyopia is increased from 3.85% to 4.8%: CPB = 31
- Assume the effectiveness of interventions in improving amblyopia is reduced from 51% to 26%: CPB = 13
- Assume the effectiveness of interventions in improving amblyopia is increased from 51% to 75%: CPB = 37
- Assume the incidence of permanent visual impairment or blindness is at the low end of the range: CPB = 18
- Assume the incidence of permanent visual impairment or blindness is at the high end of the range: CPB = 33

labi	Table 2-1: CPB of Screening for Amblyopia in 3-5 Year-Olds in a Birth Cohort of				
	40,000 (B.C.)				
Row Label	Variable	Base Case	Data Source		
а	% survival at age 4	0.9959	V		
b	4 Year olds in cohort	39,834	= a * 40,000		
с	Prevalence of amblyopia	3.85%	V		
d	4 year-olds with amblyopia in birth cohort	1,534	= b * c		
е	% of amblyopia that are undetected (asymptomatic)	70%	V		
f	4 year-olds with amblyopia in birth cohort detected through screening	1,074	= d * e		
g	Average life expectancy of a 4 year old	78.7	V		
h	Incidence of permanent visual impairment or blindness -5-15 yrs	0.00004	V		
i	Incidence of permanent visual impairment or blindness -16-64 yrs	0.00005	V		
j	Incidence of permanent visual impairment or blindness -65+ yrs	0.00046	V		
k	Change in QoL associated with permanent visual impairment or blindness	0.20	V		
I	Estimated QALYs lost	49			
m	Effectiveness of intervention	51%	V		
n	QALYs gained, CPB	25	= I * m		

√ = Estimates from the literature

. . . . . .

In estimating CE, made the following assumptions:

The estimated cost of screening (Table 2-2, row b) and interventions (Table 2-2, row f) are based on information in the economic evaluation by Carlton et al.<sup>105</sup> They provide costs in British Pounds Sterling (£), which we converted to Canadian Dollars (\$) using a factor of 1.98 \$ per £.<sup>106</sup> The base cost for screening is \$25.54 per screen

<sup>&</sup>lt;sup>105</sup> Carlton J, Karnon J, Czoski-Murray C et al. The clinical effectiveness and cost-effectiveness of screening programmes for amblyopia and strabismus in children up to the age of 4-5 years: a systematic review and economic evaluation. *Health Technology Assessment*. 2008; 12(25): xi-194.

<sup>&</sup>lt;sup>106</sup> See <u>http://www.x-rates.com/average/?from=GBP&to=CAD&amount=1.00&year=2008</u>. Accessed January 2014.

with a range from \$16.59 to \$36.39. The base cost per intervention is \$2,009 with a range from \$1,123 to \$2,891.

- For patient time costs (Table 2-2, row *c*), we assumed an hourly wage of \$24.39 (the B.C. average in 2013)<sup>107</sup> plus 18% benefits applied to the estimated two hours of patient time required for a cost per physician visit of \$57.56.
- Discount rate of 3%.

Based on these assumptions, the CE associated with screening for amblyopia in children ages 3 to 5 is 879,199 per QALY (Table 2-2, row *m*).

We also modified several major assumptions and recalculated the cost per QALY as follows:

- Assume the prevalence of amblyopia is reduced from 3.85% to 2.9% (Table 2-1, row *c*): \$/QALY = \$1,028,370
- Assume the prevalence of amblyopia is increased from 3.85% to 4.8% (Table 2-1, row *c*): \$/QALY = \$789,075
- Assume the effectiveness of interventions in improving amblyopia is reduced from 51% to 26% (Table 2-1, row *m*): \$/QALY = \$1,724,584
- Assume the effectiveness of interventions in improving amblyopia is increased from 51% to 75% (Table 2-1, row *m*): \$/QALY = \$597,856
- Assume the screening cost is reduced from \$25.54 per screen to \$16.59 (Table 2-2, row *b*): \$/QALY = \$830,156
- Assume the screening cost is increased from \$25.54 per screen to \$36.39 (Table 2-2, row *b*): \$/QALY = \$938,654
- Assume the cost per intervention is reduced from \$2,009 to \$1,123 (Table 2-2, row *f*): \$/QALY = \$692,281
- Assume the cost per intervention is increased from \$2,009 to \$2,891 (Table 2-2, row *f*): \$/QALY = \$1,065,274
- Assume the incidence of permanent visual impairment or blindness is at the low end of the range: \$/QALY = \$1,305,171
- Assume the incidence of permanent visual impairment or blindness is at the high end of the range: \$/QALY = \$644,767

<sup>&</sup>lt;sup>107</sup> Statistics Canada. Average Hourly Wages of Employees by Selected Characteristics and Occupation, Unadjusted Data, by Province (Monthly) (British Columbia). 2013. Available at http://www.statcan.gc.ca/tablestableaux/sum-som/l01/cst01/labr69k-eng.htm. Accessed December 2013.

Table	Table 2-2: CE of Screening for Amblyopia in 3-5 Year-Olds in a Birth Cohort of					
	40,000 (B.C.)					
Row						
Label	Variable	Base Case	Data Source			
а	# of 4 Year-olds to screen	27,884	Table 2-1 row b * Table 2-1 row e			
	Costs of screening					
b	Estimated screening cost	\$25.54	٧			
С	Value of patient time and travel for office visit	\$57.56	V			
е	Cost of screening over lifetime of birth cohort	\$2,317,167	=a * (b + c)			
	Costs of interventions					
f	Estimated intervention cost	\$2,009	V			
gg	# of interventions	1,074	Table 2-1 row f			
h	Total cost over lifetime of birth cohort	\$2,156,736	= g * f			
	CE calculation					
··	Cost of screening over lifetime of birth cohort	\$2,317,167	= e			
j	Costs of intervention	\$2,156,736	=h			
k	QALYs saved	25	Table 2-1 row k			
Ι	QALYs saved (3% discount rate)	5				
m	CE (\$/QALY saved)	\$879,199	= (i + j) / I			

√ = Estimates from the literature

# Summary

Table 2-3: Screening for Amblyopia in 3-5 Year-Olds in a Birth Cohort of 40,000						
Summary						
	Base					
	Case	Ra	nge			
<b>CPB</b> (Potential QALYs Gained)						
Assume No Current Service	Assume No Current Service					
3% Discount Rate	5	3	7			
0% Discount Rate	25	13	37			
Gap between B.C. Current	and Best in the V	Norld				
3% Discount Rate	Curront	screening at 93%	Kin B C			
0% Discount Rate	Currents	screening at 95	о III Б.С.			
<b>CE</b> (\$/QALY) <b>including</b> patient	time costs					
3% Discount Rate	\$879,199	\$597,856	\$1,724,584			
0% Discount Rate	\$179,901	\$122,333	\$352,884			
<b>CE</b> (\$/QALY) <b>excluding</b> patient time costs						
3% Discount Rate	\$563 <i>,</i> 788	\$383,376	\$1,105,891			
0% Discount Rate	\$115,362	\$78,446	\$226,287			

#### Routine Offer of Screening for Blood-borne and Sexually Transmitted Infections

Human Immunodeficiency Virus

#### United States Preventive Services Task Force Recommendations (2013)

An estimated 1.2 million persons in the United States are currently living with HIV infection, and the annual incidence of the disease is approximately 50 000 cases. Since the first cases of AIDS were reported in 1981, more than 1.1 million persons have been diagnosed and nearly 595 000 have died from the condition. Approximately 20% to 25% of individuals living with HIV infection are unaware of their positive status.

The USPSTF recommends that clinicians screen adolescents and adults aged 15 to 65 years for HIV infection. Younger adolescents and older adults who are at increased risk should also be screened. (A recommendation)

*The USPSTF recommends that clinicians screen all pregnant women for HIV, including those who present in labor who are untested and whose HIV status is unknown. (A recommendation)*<sup>108</sup>

#### Canadian Task Force on Preventive Health Care Recommendations (1994)

The CTFPHC guidelines in this area have not been updated since 1994 and are significantly out of date. As a result, we have included them as a footnote only (for historical purposes) rather than in the body of the text.<sup>109</sup>

<sup>109</sup> Canadian Task Force on Preventive Health Care. Canadian Guide to Clinical Preventive Health Care: Chapter 58: Screening for HIV Antibody. 1994. Available at http://canadiantaskforce.ca/wp-content/uploads/2013/03/Chapter58 HIV94.pdf?0136ff. Accessed November 2013.

"Obtaining a history of sexual behaviour and injection drug use and offering counselling has limited sensitivity for identifying HIV-positive people in the general population, but is likely to increase detection of risk behaviours. Its inclusion in the periodic health examination of asymptomatic people in the general population is based on expert opinion (C Recommendation).

Recommendations for HIV antibody screening must consider characteristics of the screening maneuver, particularly sensitivity and specificity, and the availability of treatment for asymptomatic seropositive people. There is insufficient evidence to recommend the inclusion or exclusion of HIV antibody screening among pregnant women (C Recommendation). Because the prevalence of HIV infection is lower in Canada than in the U.S. the generalizability of the results of U.S. studies is questionable. Even with excellent test characteristics the positive predictive value cannot be perfect with a low prevalence rate. Screening should be considered for those in large cities because of the low sensitivity of targeted screening and better compliance with routine screening.

HIV antibody screening should be offered to people with high-risk behaviours or those in high-risk groups because of good evidence of the effectiveness of early treatment in delaying the development of AIDS and the efficacy of aerosol pentamidine prophylaxis (A Recommendation). However, labelling is a problem, and there is no information about the long-term effects of treatment.

Cohort studies suggest that testing followed by counselling may reduce the spread of HIV infection among injection drug users and homosexual men.

There is fair evidence to recommend HIV antibody screening for neonates of HIV-positive women (B Recommendation); however, antibody screening is not specific or sensitive for infection, and other diagnostic tests, such as the viral DNA polymerase chain reaction or virus isolation, must be done. Follow-up and vaccinations will be different for seropositive children.

*(footnote continued)* 

<sup>&</sup>lt;sup>108</sup> Moyer VA. Screening for HIV: U.S. Preventive Services Task Force Recommendation Statement. *Annals of Internal Medicine*. 2013; 159(1): 51-60.

#### **Utilization of This Clinical Preventive Service**

#### British Columbia

In 2013 the number of HIV tests performed was 270,971, of which 48,240 were for prenatal HIV testing.<sup>110</sup> In 2011, the uptake of prenatal HIV screening in B.C. reached 95.9%.<sup>111</sup>

241,830 of the 270,971 HIV tests in 2013 were for individuals between the ages of 15-65.112

During the five-year time period from 2009 to 2013, a total of 963,022 HIV tests were provided for 653,417 unique individuals between the ages of 15-65, <sup>113</sup> suggesting a current screening rate in this population of 20.0% (653,417 divided by the 3,267,099 persons aged 15 to 65 living in British Columbia in 2013).

The annual number of new HIV diagnosis in B.C. has declined from a high of 702 in 1996 to 408 by 2003.<sup>114</sup> This decline has continued during the last decade, from 408 in 2003 to 238 in 2012 (see Figure 3-1).<sup>115</sup>

There is insufficient evidence to recommend the inclusion or exclusion of HIV antibody screening in low-risk populations (C Recommendation). The harm caused by false positive results must be weighed against any treatment benefits gained by the few seropositive people identified.

<sup>&</sup>lt;sup>110</sup> British Columbia Centre for Excellence in HIV/AIDS. *HIV Monitoring Quarterly Report for British Columbia, Fourth Quarter 2013.* 2013. Available at

http://www.cfenet.ubc.ca/sites/default/files/uploads/publications/centredocs/BC%20Monitoring%20Report%2013 Q4%20FINAL%20Feb14.pdf. Accessed May 2014.

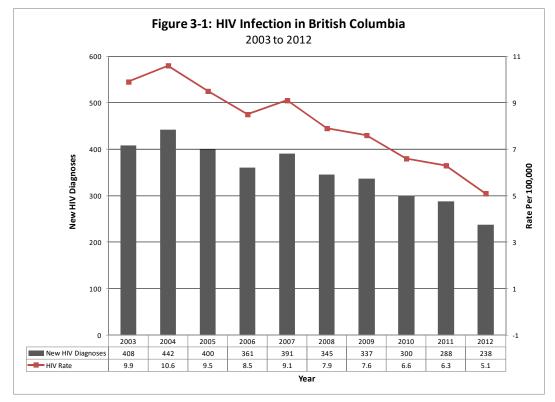
<sup>&</sup>lt;sup>111</sup> Kuo M, Money DM, Alvarez M et al. Test uptake and case detection of syphilis, HIV, and hepatitis C among women undergoing prenatal screening in British Columbia, 2007 to 2011. *Journal of Obstetrics and Gynaecology Canada*. 2014; 36(5): In press.

<sup>&</sup>lt;sup>112</sup> Dr. Mark Gilbert, Surveillance & Online Sexual Health Services, Clinical Prevention Services, BC Centre for Disease Control. Personal communication, May, 2014.

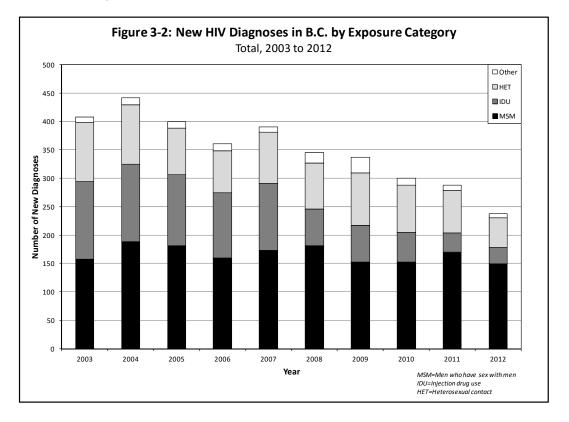
<sup>&</sup>lt;sup>113</sup> Dr. Mark Gilbert, Surveillance & Online Sexual Health Services, Clinical Prevention Services, BC Centre for Disease Control. Personal communication, May, 2014.

<sup>&</sup>lt;sup>114</sup> Montaner JS, Lima VD, Barrios R et al. Association of highly active antiretroviral therapy coverage, population viral load, and yearly new HIV diagnoses in British Columbia, Canada: a population-based study. *The Lancet.* 2010; 376(9740): 532-9.

<sup>&</sup>lt;sup>115</sup> BC Centre for Disease Control. *British Columbia Annual Summary of Reportable Diseases 2012*. 2013. Available at http://www.bccdc.ca/NR/rdonlyres/F30377E3-D33E-4755-B3F4-6844E01BD678/0/FinalAR2012.pdf. Accessed November 2013.



Not only has the number of new HIV diagnoses decreased substantially during the last decade, but the proportion by exposure category has also changed dramatically (see Figure 3-2). In 2003, one-third of new cases were attributable to injection drug use. This proportion has decreased to just 12% in 2011 and 2012.



The number of new HIV diagnoses varies substantially by region within the province, with the highest rate per 100,000 (19.1) being in the Vancouver Health Services Delivery Area (HSDA) and the lowest rates observed in the Northeast HSDA (0.0) and the Thompson Cariboo Shuswap HSDA (0.9) (see Table 3-1).<sup>116</sup> The lower rates in some areas of the province may be at least partially due to inadequate testing.

Table 3-1: New HIV Diagnoses in B.C. By Health Service Delivery Area In 2012				
ID Health Service Delivery Area	# of Cases	Rate / 100,000 Population		
32 Vancouver	131	19.1		
52 Northern Interior	8	5.5		
51 Northwest	4	5.3		
12 Kootenay Boundary	3	3.7		
41 South Vancouver Island	14	3.7		
43 North Vancouver Island	4	3.3		
22 Fraser North	20	3.2		
42 Central Vancouver Island	8	3.0		
23 Fraser South	19	2.6		
11 East Kootenay	2	2.5		
33 North Shore/Coast Garibaldi	7	2.4		
21 Fraser East	6	2.1		
31 Richmond	4	2.0		
13 Okanagan	5	1.4		
14 Thompson Cariboo Shuswap	2	0.9		
53 Northeast	0	0.0		

<sup>&</sup>lt;sup>116</sup> BC Centre for Disease Control. *HIV in British Columbia: Annual Surveillance Report 2012.* 2012. Available at http://www.bccdc.ca/util/about/annreport/default.htm. Accessed November 2013.

The total number of individuals living with HIV infections in B.C. is estimated to be 11,700 (with a range from 9,400 to 14,000) in 2011 (see Table 3-2).<sup>117</sup> This includes both diagnosed and undiagnosed individuals.<sup>118</sup> As noted by the USPSTF earlier, approximately 20% to 25% of individuals living with HIV infection are unaware of their positive status. Canadian estimates suggest that 25% of HIV-infected people are unaware of their HIV status, ranging from 20% of HIV-infected men who have sex with men (MSM) to 25% of HIV-infected injection drug users (IDU) to 34% of HIV-infected heterosexuals.<sup>119</sup>

Table 3-2: Estimated Number of Prevalent HIV Infections         In British Columbia by Exposure Category         2011					
Exposure Category	Number	Ra	nge	% of Total	
MSM	4,950	3,900	6,000	42%	
MSM-IDU	370	260	480	3%	
IDU	3,640	2,780	4,500	31%	
HET (non-endemic	2,240	1,680	2,800	19%	
HET (endemic)	370	240	500	3%	
Other	130	90	170	1%	
All	11,700	9,400	14,000		
MSM - Men who have sex with men IDU - Injection drug use HET (non-endemic) - Heterosexual contact with a person who is either HIV-infected or at risk for HIV or heterosexual as the only identified risk					
HET (endemic) - Heterosexual contact and origin from a country where HIV is endemic Other - Recipients of blood transfusion or clotting factor, perinatal, and occupational					

#### Best in the World

transmission

In the U.S., rates of HIV testing has remained fairly consistent over the last ten years, with 10.5% in 2000 and 10.1% in 2010 of adults aged 18-64 who were tested in the last 12 months. For pregnant women tested in the last 12 months, the proportion was 59.3% in 2000, decreasing to 53.7% in 2010.<sup>120</sup>

In the U.K., 684,510 pregnant women were tested for HIV in 2011, comprising an uptake rate of 97%.<sup>121</sup> In 2012, for citizens of England who had not been previously diagnosed with HIV

- <sup>118</sup> Yang Q, Boulos D, Yan P et al. Estimates of the number of prevalent and incident human immunodeficiency virus (HIV) infections in Canada, 2008. *Canadian Journal of Public Health*. 2010; 101(6): 486-90.
- <sup>119</sup> Public Health Agency of Canada. Summary: Estimates of HIV Prevalence and Incidence in Canada, 2011. 2011. Available at http://www.phac-aspc.gc.ca/aids-sida/publication/survreport/assets/pdf/estimat2011-eng.pdf. Accessed May 2014.

<sup>&</sup>lt;sup>117</sup> BC Centre for Disease Control. *HIV in British Columbia: Annual Surveillance Report 2012.* 2012. Available at http://www.bccdc.ca/util/about/annreport/default.htm. Accessed November 2013.

<sup>&</sup>lt;sup>120</sup> Centers for Disease Control and Prevention. *HIV Testing Trends in the United States, 2000-2011.* 2013. Available at

http://www.cdc.gov/hiv/topics/testing/resources/reports/pdf/Testing%20Trends\_cleared\_01282013.pdf. Accessed November 2013.

<sup>&</sup>lt;sup>121</sup> Health Protection Agency. *HIV in the United Kingdom: 2012 Report.* 2012. Available at http://www.hpa.org.uk/webc/HPAwebFile/HPAweb\_C/1317137200016. Accessed November 2013.

and were accessing STI services in England, 79% (N=1,238,337) were offered HIV screening with an uptake rate of 81% (N=1,003,825).<sup>122</sup> Uptake rates were somewhat lower for women (77%) than men (84%). The uptake rate for MSM was 93% of those offered screening while attending an STI clinic.<sup>123</sup>

Research in the US on the uptake of screening when offered in an Emergency Department suggests a broad range of willingness to accept screening, from approximately 40-90%.<sup>124,125,126,127,128</sup> The large study by Setse and Maxwell in an urban tertiary care facility in Washington, DC found uptake rates of 52.3% in 2007, 88.3% in 2008, 89.3% in 2009, 83.1% in 2010 and 73.1% in 2011.<sup>129</sup>

#### **Relevant British Columbia Population in 2013**

In 2013, BC Stats estimates that there are 3,267,099 persons aged 15 to 65 in British Columbia (see Appendix A).<sup>130</sup>

#### Modelling CPB and CE

No model is available from the Partnership for Prevention and HealthPartners Research for screening adolescents and adults aged 15 to 65 years for HIV infection. In this section, we will calculate the CPB and CE associated with screening adolescents and adults aged 15 to 65 years for HIV infection.

In estimating CPB, we made the following assumptions:

- The total number of individuals living with HIV infections in BC is estimated to be 11,700 (with a range from 9,400 to 14,000) (see Table 3-2).<sup>131</sup>
- 20% of HIV-infected men who have sex with men (MSM), 24% of HIV-infected injection drug users (IDU) and 34% of HIV-infected heterosexuals (HET) are unaware of their HIV status (Table 3-3, rows *c*, *f* & *i*).<sup>132</sup>

http://www.hpa.org.uk/webc/HPAwebFile/HPAweb C/1317137200016. Accessed Novemeber 2013.

<sup>130</sup> BC Stats. *Population Projections*. 2013. Available at

 <sup>&</sup>lt;sup>122</sup> Public Health England. *Table 4a (i): HIV test uptake in England, 2009 - 2012.* 2013. Available at http://www.hpa.org.uk/webc/HPAwebFile/HPAweb\_C/1215589013442. Accessed November 2013.
 <sup>123</sup> Health Protection Agency. *HIV in the United Kingdom: 2012 Report.* 2012. Available at

<sup>&</sup>lt;sup>124</sup> Setse RW and Maxwell CJ. Correlates of HIV testing refusal among emergency department patients in the optout testing era. *AIDS and Behavior*. 2014; 18(5): 966-71.

<sup>&</sup>lt;sup>125</sup> Merchant RC, Seage GR, Mayer KH et al. Emergency department patient acceptance of opt-in, universal, rapid HIV screening. *Public Health Reports*. 2008; 123 Suppl 3: 27-40.

 <sup>&</sup>lt;sup>126</sup> Sattin RW, Wilde JA, Freeman AE et al. Rapid HIV testing in a southeastern emergency department serving a semiurban-semirural adolescent and adult population. *Annals of Emergency Medicine*. 2011; 58(1 Suppl 1): S60-4.
 <sup>127</sup> Lyons MS, Lindsell CJ, Ruffner AH et al. Randomized comparison of universal and targeted HIV screening in the emergency department. *Journal of Acquired Immune Deficiency Syndromes*. 2013; 64(3): 315-23.

<sup>&</sup>lt;sup>128</sup> Bamford L, Ellenberg JH, Hines J et al. Factors associated with a willingness to accept rapid HIV testing in an urban emergency department. *AIDS and Behavior*. 2014; 18(2): 250-3.

<sup>&</sup>lt;sup>129</sup> Setse RW and Maxwell CJ. Correlates of HIV testing refusal among emergency department patients in the optout testing era. *AIDS and Behavior*. 2014; 18(5): 966-71.

http://www.bcstats.gov.bc.ca/StatisticsBySubject/Demography/PopulationProjections.aspx. Accessed November 2013.

<sup>&</sup>lt;sup>131</sup> BC Centre for Disease Control. *HIV in British Columbia: Annual Surveillance Report 2012.* 2012. Available at http://www.bccdc.ca/util/about/annreport/default.htm. Accessed November 2013.

<sup>&</sup>lt;sup>132</sup> Public Health Agency of Canada. Summary: Estimates of HIV Prevalence and Incidence in Canada, 2011. 2011. Available at http://www.phac-aspc.gc.ca/aids-sida/publication/survreport/assets/pdf/estimat2011-eng.pdf. Accessed May 2014.

- Adherence with universal screening was assumed to be 80% for MSM, 70% for HET and 60% for IDU (Table 3-3, rows *u*, *v* & *w*).
- 4.56% of HIV infected individuals die prematurely without early initiation of antiretroviral therapy (ART) (deferring initiation of ART to CD4 levels of 200 cells/µL). This can be reduced to 1.11% with early initiation of ART (Table 3-3, rows y & z).<sup>133</sup>
- The average age at which undiagnosed HIV is detected is 40 (Table 3-3, row bb).<sup>134</sup>
- The gain in quality of life associated with early detection and treatment of an HIV infection is 0.11 (Table 3-3, row *ee*).<sup>135</sup>
- Antiretroviral therapy is a potent intervention for prevention of HIV in discordant couples. The RCT by Cohen, et al. found that just 1 of 28 transmissions occurred in a serodiscordant couple in which the infected partner received early initiation of antiretroviral therapy (a hazard ratio of 0.04; 95% CI from 0.01 to 0.27).<sup>136</sup> The 2013 Cochrane review by Anglemyer and colleagues noted the RCT study by Cohen, et al. as well as nine observational studies. Results from the observational studies suggested that treating the HIV-infected partner in a serodiscordant couple reduces the risk of transmission by 64% (a relative risk of 0.36; 95% CI from 0.17 to 0.75).<sup>137,138</sup> In BC, the expanded utilization of highly active antiretroviral therapy (HAART) between 1996 and 2012 is associated with a 66% decrease in new diagnoses of HIV.<sup>139</sup> To incorporate this information into our model, we first calculated the rate per person year of HIV transmission in HIV-discordant couples if the HIV-positive partner is not treated with ART. This is based on the results from the control arms of the 1 RCT and 9 observational studies included in the Cochrane review by Anglemyer et al. (1,094 transmissions during 42,917 person-years, a transmission rate of 0.0255 per person-year, Table 3-3, row gg). We then assumed a 64% reduction in the transmission rate per person-year if the HIV-positive partner is treated with ART. This results in an annual transmission rate of 0.0092 per personyear (Table 3-3, row hh). In the sensitivity analysis we used results from the Cohen et al study (96% reduction) as the upper bounds and the 95% CI from the 9 observational studies reviewed by Anglemyer et al (RR of 0.75 or a 25% reduction) as the lower bounds.
- We assumed that the 17.82 infections avoided associated with screening and the early treatment with ART (Table 3-3, row *kk*) would lead to an additional 12.80 infections avoided (Table 3-3, row *nn*), due to second order transmission benefits.

 <sup>&</sup>lt;sup>133</sup> Siegfried N, Uthman OA and Rutherford GW. Optimal time for initiation of antiretroviral therapy in asymptomatic, HIV-infected, treatment-naive adults. *Cochrane Database of Systematic Reviews*. 2011; 2.
 <sup>134</sup> Siegfried N, Uthman OA and Rutherford GW. Optimal time for initiation of antiretroviral therapy in asymptomatic, HIV-infected, treatment-naive adults. *Cochrane Database of Systematic Reviews*. 2011; 2.
 <sup>135</sup> Long EF, Brandeau ML and Owens DK. The cost-effectiveness and population outcomes of expanded HIV screening and antiretroviral treatment in the United States. *Annals of Internal Medicine*. 2010; 153(12): 778-89.
 <sup>136</sup> Cohen MS, Chen YQ, McCauley M et al. Prevention of HIV-1 infection with early antiretroviral therapy. *New England Journal of Medicine*. 2011; 365(6): 493-505.

<sup>&</sup>lt;sup>137</sup> Anglemyer A, Rutherford GW, Horvath T et al. Antiretroviral therapy for prevention of HIV transmission in HIV-discordant couples. *Cochrane Database Systematic Reviews*. 2013; 4.

<sup>&</sup>lt;sup>138</sup> Anglemyer A, Horvath T and Rutherford G. Antiretroviral therapy for prevention of HIV transmission in HIVdiscordant couples. *Journal of the American Medical Association*. 2013; 310(15): 1619-20.

<sup>&</sup>lt;sup>139</sup> Montaner JS, Lima VD, Harrigan PR et al. Expansion of HAART coverage is associated with sustained decreases in HIV/AIDS morbidity, mortality and HIV transmission: the "HIV Treatment as Prevention" experience in a Canadian setting. *PLoS One*. 2014; 9(2): e87872.

• The difference in quality of life between avoided infection and symptomatic HIV treated with ART is 0.17 (Table 3-3, row *oo*).<sup>140</sup>

Based on these assumptions, the calculation of CPB (Table 3-3, row qq) is 387 QALYs. This represents the potential CPB moving from no screening to approximately 70% screening uptake. Based on the current 20% screening uptake in the population ages 15-65 in BC, the gap in CPB (between 20% and 70%) would be 276 QALYs (Table 3-3, row *ss*).

We also modified several major assumptions and recalculated the CPB as follows:

- Assume the prevalence of individuals living with HIV infections in BC is decreased from 11,700 to 9,400 (Table 3-3, row *a*): CPB = 311
- Assume the prevalence of individuals living with HIV infections in BC is increased from 11,700 to 14,000 (Table 3-3, row *a*): CPB = 463
- Assume that the early initiation of antiretroviral therapy is associated with a 96% reduction (from 64%) in the transmission rate per person-year (Table 3-3, row *hh*): CPB = 573
- Assume that the early initiation of antiretroviral therapy is associated with a 25% reduction (from 64%) in the transmission rate per person-year (Table 3-3, row *hh*): CPB = 225

<sup>&</sup>lt;sup>140</sup> Long EF, Brandeau ML and Owens DK. The cost-effectiveness and population outcomes of expanded HIV screening and antiretroviral treatment in the United States. *Annals of Internal Medicine*. 2010; 153(12): 778-89.

	40,000 (B.C.)		
Row			
Label	Variable	Base Case	Data Source
a	Prevalence of HIV Infections in B.C.	11,700	V
b	Prevalence of HIV Infections in MSM	5,320	V
C	% Undiagnosed in MSM	20%	V
d	Undiagnosed HIV in MSM	1,064	= b*c
e	Prevalence of HIV Infections in IDU	3,640	V
f	% Undiagnosed in IDU	24%	<u>۷</u>
g	Undiagnosed HIV in IDU	874	= e*f
<u>h</u>	Prevalence of HIV Infections in HET	2,740	V
i	% Undiagnosed in HET	34%	√ ⊾*:
j	Undiagnosed HIV in HET	932	= h*i
k	Undiagnosed HIV in BC	2,869	= d+g+j
1	Diagnosed HIV in BC	8,831	= a-k
m	BC Population Ages 15-65	3,267,099	√
n	Prevalence / 100,000 Diagnosed HIV	270	=l/(m/100,000)
0	Prevalence / 100,000 Undiagnosed HIV	88	=k/(m/100,000
р	Est. diagnosed HIV in BC birth cohort of 40,000	108	= n*0.4
q	Est. undiagnosed HIV in BC birth cohort of 40,000	35	$= 0^{*}0.4$
r	Est. undiagnosed HIV in BC birth cohort of 40,000 - MSM	13	= (d/k)*q
S	Est. undiagnosed HIV in BC birth cohort of 40,000 - IDU	11	= (g/k)*q
t	Est. undiagnosed HIV in BC birth cohort of 40,000 - HET	11	= (j/k)*q
u	Adherence with screening - MSM	80.0%	<u>۷</u>
V	Adherence with screening - IDU	60.0%	٧
W	Adherence with screening - HET	70.0%	٧
х	Previously undiagnosed HIV infections detected by universal screening	24.82	=r*u+s*v+t*w
у	% early death without early initiation of antiretroviral therapy (ART)	4.56%	V
Z	% early death with early initiation of ART	1.11%	٧
аа	Early deaths avoided with early initiation of ART	0.86	=(x*y)-(x*z)
bb	Average age at which undiagnosed HIV infection detected	40	V
СС	Life expectancy of a 40 year-old	44	V
dd	QALYs gained - premature death avoided	37.7	=aa*cc
ee	Gain in QoL associated with early detection and treatment of HIV	0.11	v
ff	QALYs gained - early detection and treatment	120	=x*cc*ee
gg	HIV transmission in HIV-discordant couples, HIV positive partner <b>untreated</b> with ART - rate/person year	0.0255	v
hh	HIV transmission in HIV-discordant couples, HIV positive partner <b>treated</b> with ART - rate/person year	0.0092	v
ii	Potential HIV transmissions, HIV positive partner <b>untreated</b> with ART	27.85	=x*cc*gg
jj	Potential HIV transmissions, HIV positive partner <b>treated</b> with ART	10.03	=x*cc*hh
kk	Infections avoided per early detection associated with ART- first order	17.82	=ii-jj
II	Potential HIV transmissions, HIV positive partner <b>untreated</b> with ART	20.00	=kk*gg*cc
mm	Potential HIV transmissions, HIV positive partner <b>treated</b> with ART	7.20	=kk*hh*cc
nn	Infections avoided per early detection associated with ART- second order	12.80	=ll-mm
00	Difference in QoL associated with no infection vs.	0.17	v
nr	symptomatic infection treated with ART	220	-///
рр	QALYs gained - infections avoided due to ART	229	=(kk+nn)*cc*o
qq	Total QALYs gained, Utilization increasing from 0% to 70%	387	=dd+ff+pp
rr	Estimated current uptake in BC	20%	٧

# Table 3-3: CPB of Screening to Detect and Treat HIV in a Birth Cohort of

√ = Estimates from the literature

In calculating CE, we made the following assumptions:

- Number of screens We have assumed screening between the ages of 15-65 would occur every year in high risk populations and once every 5 years in low-risk populations.<sup>141</sup> Long and colleagues estimated the high-risk population to be 2.85% of the total population ages 15-65 in the US<sup>142</sup> and 1.62% in the UK.<sup>143</sup> We assumed 2.85% for BC (Table 3-4, row *a*). In the sensitivity analysis, we adjusted screening once every five years in the low-risk population to once every 10 years and once per lifetime.
- **True / false positive screens** The ratio of true to false positive test results is 1:1 (Table 3-4, row *i*).<sup>144</sup>
- **Cost of an office visit** We estimated the average cost of a visit to a General Practitioner to be \$34.00 based on information from the BC Medical Services Commission 2013 payment schedule<sup>145</sup> (Table 3-4, row *j*).
- **Patient time costs** For patient time costs (Table 3-4, row *k*), we assumed an hourly wage of \$24.39 (the BC average in 2013)<sup>146</sup> plus 18% benefits applied to the estimated two hours of patient time required for a cost per screening visit of \$57.56.
- Laboratory cost per screen The estimated cost per screen is \$7 (with a range from \$5 to \$9). The estimated cost of confirming true / false positive results is \$400 (with a range from \$300 to \$500) (Table 3-4, rows m & n).<sup>147</sup>
- **Cost of a counselling session** We estimated the average cost of a counselling session associated with a true / false positive result to be \$83.28, based on MSP fee item 13015 (*HIV/AIDS Primary Care Management in or out of office per half hour or major portion thereof*) (Table 3-4, row *o*).<sup>148</sup>
- Average annual cost of antiretrovirals for HIV Calculated based on an estimated average cost per day of treatment in Canada of \$26.00<sup>149</sup> (Table 3-4, row *s*). Costs in

cost-effectiveness analysis for the United Kingdom. *PLoS One*. 2014; 9(4): e95735. <sup>144</sup> Dr. Mel Krajden, Associate Medical Director, BCCDC Public Health Microbiology and Reference Laboratory,

<sup>&</sup>lt;sup>141</sup> Office of the Provincial Health Officer. *HIV Testing Guidelines for the Province of British Columbia* 2014. Available at http://www.bccdc.ca/NR/rdonlyres/B35EDEBD-98CA-48BB-AB7C-

B18A357AC19D/0/HIV\_GUIDE\_051114.pdf. Accessed May 2014.

 <sup>&</sup>lt;sup>142</sup> Long EF, Brandeau ML and Owens DK. The cost-effectiveness and population outcomes of expanded HIV screening and antiretroviral treatment in the United States. *Annals of Internal Medicine*. 2010; 153(12): 778-89.
 <sup>143</sup> Long EF, Mandalia R, Mandalia S et al. Expanded HIV testing in low-prevalence, high-income countries: a

BC Centre for Disease Control. Personal communication, March, 2014.

<sup>&</sup>lt;sup>145</sup> Medical Services Commission. *Payment Schedule: Section 7 General Practice*. 2013. Available at http://www.health.gov.bc.ca/msp/infoprac/physbilling/payschedule/pdf/7-general-practice.pdf. Accessed December 2013.

<sup>&</sup>lt;sup>146</sup> Statistics Canada. Average Hourly Wages of Employees by Selected Characteristics and Occupation, Unadjusted Data, by Province (Monthly) (British Columbia). 2013. Available at http://www.statcan.gc.ca/tablestableaux/sum-som/l01/cst01/labr69k-eng.htm. Accessed December 2013.

<sup>&</sup>lt;sup>147</sup> Dr. Mel Krajden, Associate Medical Director, BCCDC Public Health Microbiology and Reference Laboratory, BC Centre for Disease Control. Personal communication, March, 2014.

<sup>&</sup>lt;sup>148</sup> Medical Services Commission. *Payment Schedule: Section 7 General Practice*. 2013. Available at http://www.health.gov.bc.ca/msp/infoprac/physbilling/payschedule/pdf/7-general-practice.pdf. Accessed December 2013.

<sup>&</sup>lt;sup>149</sup> Centre for Health Services and Policy Research. *The Canadian Rx Atlas: Third Edition*. 2013. Available at http://www.chspr.ubc.ca/sites/default/files/file\_upload/publications/2013/RxAtlas/canadianrxatlas2013.pdf. Accessed January 2014.

BC may be as high as \$47.00 per day.<sup>150</sup> We have used this higher estimate in our sensitivity analysis.

- **Direct medical costs avoided** The annual direct medical costs (excluding medications) associated with HIV/AIDS in Canada have been estimated by stage of infection at \$1,684 for asymptomatic HIV, \$2,534 for symptomatic HIV and \$9,715 for AIDS (in 2009 \$).<sup>151</sup> We used the annual direct medical costs associated with symptomatic HIV, updated to 2013 \$ (\$2,688 Table 3-4, row *w*) to estimate direct medical costs avoided associated with HIV infections avoided.
- **Discount rate** of 3%

Based on these assumptions, the estimated cost per QALY would be \$43,846 (see Table 3-4, row gg).

We also modified several major assumptions and recalculated the cost per QALY as follows:

- Assume the prevalence of individuals living with HIV infections in BC is decreased from 11,700 to 9,400 (Table 3-3, row *a*): CE = \$58,382
- Assume the prevalence of individuals living with HIV infections in BC is increased from 11,700 to 14,000 (Table 3-3, row *a*): CE = \$34,087
- Assume that the early initiation of antiretroviral therapy is associated with a 96% reduction (from 64%) in the transmission rate per person-year (Table 3-3, row *hh*): CE = \$6,343
- Assume that the early initiation of antiretroviral therapy is associated with a 25% reduction (from 64%) in the transmission rate per person-year (Table 3-3, row *hh*): CE = \$127,310
- Assume screening once every 10 years rather than once every 5 years in the low-risk population (Table 3-4, row *d*): CE = \$17,719
- Assume screening once per lifetime rather than once every 5 years in the low-risk population (Table 3-4, row *d*): CE = -\$2,897
- Assume the cost of screening is reduced from \$7 and \$400 to \$5 and \$300 (Table 3-4, rows *m* & *n*): CE = \$42,263
- Assume the cost of screening is increased from \$7 and \$400 to \$9 and \$500 (Table 3-4, rows *m* & *n*): CE = \$45,429
- Assume the proportion of an office visit required is reduced from 0.75 to 0.50 (Table 3-4, row *l*): CE = \$25,876
- Assume the proportion of an office visit required is increased from 0.75 to 1.00 (Table 3-4, row *l*): CE = \$61,816
- Assume the average annual cost of antiretrovirals for HIV is increased from \$26 to \$47 per day (Table 3-4, row *s*): CE = \$38,789

<sup>&</sup>lt;sup>150</sup> Johnston KM, Levy AR, Lima VD et al. Expanding access to HAART: a cost-effective approach for treating and preventing HIV. *AIDS*. 2010; 24(12): 1929-35.

<sup>&</sup>lt;sup>151</sup> Kingston-Riechers, J. *The Economic Cost of HIV/AIDS in Canada*. Canadian AIDS Society, 2011. Available online at <u>http://www.cdnaids.ca/files.nsf/pages/economiccostofhiv-</u>

aidsincanada/\$file/Economic%20Cost%20of%20HIV-AIDS%20in%20Canada.pdf. Accessed July, 2014.

As noted above, the model is quite sensitive to a number of assumptions. If, for example, we assume the prevalence of individuals living with HIV infections in BC is 14,000 (Table 3-3, row *a*), the early initiation of antiretroviral therapy is associated with a 96% reduction in the transmission rate per person-year (Table 3-3, row *hh*), screening once per lifetime in the low-risk population (Table 3-4, row *d*) and the proportion of an office visit required is 0.50 (Table 3-4, row *l*), then the cost per QALY is reduced to -\$28,786. If we exclude patient time costs (Table 3-4, row *k*), the cost per QALY is further reduced to -\$31,504.

On the other hand, if we assume the prevalence of individuals living with HIV infections in BC is 9,400 (Table 3-3, row a), the early initiation of antiretroviral therapy is associated with a 25% reduction in the transmission rate per person-year (Table 3-3, row hh), screening once every five years in the low-risk population (Table 3-4, row d) and the proportion of an office visit required is 1.00 (Table 3-4, row l), then the cost per QALY is increased to \$190,884.

This high level of sensitivity to model assumptions has been noted by other analysts. In their recent analysis in the UK, for example, Long and co-authors observed a range between  $\pm 17,500$  and  $\pm 106,000$  per QALY (equivalent to \$32,298 and \$195,634 in Canadian dollars<sup>152</sup>) associated with expanded HIV screening in that country.<sup>153</sup>

http://www.bankofcanada.ca/rates/exchange/daily-converter/. Accessed June 2014.

<sup>&</sup>lt;sup>152</sup> Based on a conversion rate of 1.8456 effective June 19, 2014. See

<sup>&</sup>lt;sup>153</sup> Long EF, Mandalia R, Mandalia S et al. Expanded HIV testing in low-prevalence, high-income countries: a cost-effectiveness analysis for the United Kingdom. *PLoS One*. 2014; 9(4): e95735.

Row Label	Variable	Base Case	Data Source
а	Proportion of population high risk	2.85%	√
b	Proportion of population low risk	97.15%	=1-a
c	Screening rate in high risk populations	Annual	v
d	Screening rate in low risk populations	Every 5 years	√
e	Lifetime screens in high risk populations	38,084	Calculated
f	Lifetime screens in low risk populations	265,655	Calculated
g	Total screens	303,738	=e+f
<u> </u>	# of true positive screens	24.82	Table 3-3, row x
i	Estimated # of false positive screens	24.82	=h
	Costs of screening and counseling	24.02	-11
i	Cost of 10-minute office visit	\$34.00	٧
k	Value of patient time and travel for office visit	\$57.56	V V
	Proportion of office visit required	0.75	Assumed
 m	Cost per screen	\$7	Assumed √
n	Cost per true/false positive screen	\$400	V
0	Cost per counselling session	\$83.28	V
		\$9,891,353	 =(g*j*l)+(g*m)+(h+i)*
p	Cost of screening Cost of counselling	\$4,135	=(h+i)*o
q	Patient time costs	\$13,112,382	=(1+1)*0 = g*k*l
r	Costs of antiretrovirals	\$15,112,582	= g · K · I
6		\$26	√
S	Cost per day of treatment	Ş20	=Table 3-3, row x * Tab
t	Cost of antiretrovirals	\$10,365,092	3-3, row cc *365 * s
	Costs avoided		
u	HIV infections avoided - treatment with ART	30.62	Table 3-3, row kk + Tab 3-3, row nn
v	Cost of antiretrovirals avoided	-\$12,787,610	= -u * Table 3-3, row cc*365*s
w	Annual direct medical costs (excluding medications)	\$2,688	V
vv	associated with symptomatic HIV	ŞZ,088	v
x	Direct medical costs avoided	-\$3,621,441	= -u * Table 3-3, row cc*
	CE calculation		
У	Cost of screening and counseling (undiscounted)	\$23,007,870	= p+q+r
Z	Cost of antiretrovirals (undiscounted)	\$10,365,092	= t
аа	Costs avoided (undiscounted)	-\$16,409,051	= v+x
bb	QALYs saved (undiscounted)	387	Table 3-3, row qq
СС	Cost of screening and counseling (3% discount rate)	\$13,063,190	Calculated
dd	Cost of antiretrovirals (3% discount rate)	\$5,884,994	Calculated
ee	Costs avoided (3% discount rate)	-\$9,316,575	Calculated
ff	QALYs saved (3% discount rate)	220	Calculated
gg	CE (\$/QALY saved)	\$43,846	=(cc+dd+ee)/ff

# Table 3-4: CE of Screening to Detect and Treat HIV in a Birth Cohort of 40,000

√ = Estimates from the literature

#### Summary

Table 10-5: Screening to D in a Birth (	iagnose and Cohort of 40		/ Infections
Su	ummary		
	Base		
	Case	Ra	nge
<b>CPB</b> (Potential QALYs Gained)			
3% Discount Rate	220	128	325
0% Discount Rate	387	225	573
Gap between B.C. Current (20%) an	nd 'Best in the Wo	orld' (70%)	
3% Discount Rate	157	91	232
0% Discount Rate	276	160	409
CE (\$/QALY) including patient time	costs		
3% Discount Rate	\$43,846	-\$2,897	\$127,310
0% Discount Rate	\$43,846	-\$2,897	\$127,310
CE (\$/QALY) excluding patient time costs			
3% Discount Rate	\$9,955	-\$10,121	\$68,923
0% Discount Rate	\$9,955	-\$10,121	\$68,923

#### Chlamydia / Gonorrhea

There is a strong overlap in the at-risk populations for chlamydia and gonorrhea with both STIs often seen in the same individual. Indeed, the USPSTF recommends "chlamydia and gonorrhea screening for all sexually active women younger than 25 years (including adolescents), even if they are not engaging in high-risk sexual behaviours."<sup>154</sup> They further note that younger women tend to be at higher risk as they tend to have more new sex partners, their immune system tends to be relatively immature and the presence of "columnar epithelium on the adolescent exocervix."

Following are the specific recommendations from the USPSTF and the CTFPHC with respect to screening for chlamydia and gonorrhea.

#### Chlamydia – USPSTF Recommendations (2007)

Chlamydial infection is the most common sexually transmitted bacterial infection in the United States. In women, genital chlamydial infection may result in urethritis, cervicitis, pelvic inflammatory disease (PID), infertility, ectopic pregnancy, and chronic pelvic pain. Chlamydial infection during pregnancy is related to adverse pregnancy outcomes, including miscarriage, premature rupture of membranes, preterm labor, low birth weight, and infant mortality.

Screen for chlamydial infection in all sexually active nonpregnant young women age 24 years or younger and for older nonpregnant women who are at increased risk. (A recommendation)

Screen for chlamydial infection in all pregnant women age 24 years or younger and in older pregnant women who are at increased risk. (B recommendation)

Do not routinely screen for chlamydial infection in women age 25 years or older, regardless of whether they are pregnant, if they are not at increased risk. (C recommendation)

*Current evidence is insufficient to assess the balance of benefits and harms of screening for chlamydial infection for men. (I statement)*<sup>155</sup>

The USPSTF has currently released an updated draft version of screening for chlamydia and gonorrhea.<sup>156</sup> The draft recommendation most relevant to the current project is to screen "for chlamydia and gonorrhea in sexually active women age 24 years and younger and in older women who are at increased risk for infection." This recommendation is now given a 'B' rating compared to the previous 'A' rating in 2007 (see above).

#### Chlamydia – CTFPHC Recommendations (1994)

Although there is sufficient evidence linking chlamydial infections to many complications, there is currently insufficient evidence in males and non-pregnant females to show that screening is effective in preventing these complications. Thus routine screening is not recommended in the general population (D Recommendation).

<sup>&</sup>lt;sup>154</sup> Meyers D, Wolff T, Gregory K et al. USPSTF recommendations for STI screening. *American Family Physician*. 2008; 77(6): 819-24.

<sup>&</sup>lt;sup>155</sup> U.S. Preventive Services Task Force. Screening for chlamydial infection: U.S. Preventive Services Task Force recommendation statement. *Annals of Internal Medicine*. 2007; 147(2): 128-34.

<sup>&</sup>lt;sup>156</sup> U.S. Preventive Services Task Force. Screening for Chlamydia and Gonorrhea: U.S. Preventive Services Task Force Recommendation Statement Draft

<sup>2014.</sup> Available at http://www.uspreventiveservicestaskforce.org/draftrec2.htm. Accessed May 2014.

However, the high burden of illness caused by chlamydia and favourable economic evaluation studies suggest that screening of certain populations at high risk for asymptomatic chlamydial infection may be useful to try and prevent symptoms and to reduce overall cost of infection (B Recommendation). These high risk groups are – sexually active females less than 25 years old, new partner or two partners in preceding year, cervical friability, use of non-barrier contraception and women symptomatic with mucopurulent discharge or intermenstrual bleeding.

*Although the benefits may be related to treatment with erythromycin, there is fair evidence (Level II-2) that screening of pregnant women leads to improvements in pregnancy outcome (B Recommendation).*<sup>157</sup>

#### Gonorrhea – USPSTF Recommendations (2005)

Infection because of Neisseria gonorrhoeae remains the second most common reportable disease in the United States, the first being Chlamydia trachomatis. In women, gonorrhea is a major cause of cervicitis and pelvic inflammatory disease. Pelvic inflammatory disease, in turn, can lead to ectopic pregnancy, infertility, and chronic pelvic pain. Gonorrhea in pregnancy is associated with adverse outcomes, including chorioamnionitis, premature rupture of membranes, and preterm labor. Perinatal transmission to infants can cause severe conjunctivitis resulting in blindness if untreated and, rarely, sepsis with associated meningitis, endocarditis, or arthritis. In men, gonorrhea can result in symptomatic urethritis, epididymitis, and prostatitis. Emerging evidence suggests gonococcal infection facilitates susceptibility to and transmission of HIV in both men and women.

The U.S. Preventive Services Task Force recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors). (B recommendation)

The USPSTF found insufficient evidence to recommend for or against routine screening for gonorrhea infection in men at increased risk for infection. (I recommendation)

The USPSTF recommends against routine screening for gonorrhea infection in men and women who are at low risk for infection. (D recommendation)

The USPSTF found insufficient evidence to recommend for or against routine screening for gonorrhea infection in pregnant women who are not at increased risk for infection. (I recommendation)

*The USPSTF strongly recommends prophylactic ocular topical medication for all newborns against gonococcal ophthalmia neonatorum. (A recommendation)*<sup>158</sup>

#### Gonorrhea - CTFPHC Recommendations (1994)

Despite the development of different diagnostic methods, Gram stain and culture of urethral or vaginal smears remain the methods of choice for diagnosing infection with Neisseria gonorrheae. The prevalence of this organism in asymptomatic individuals is so low that screening should be considered only in high-risk groups.

<sup>&</sup>lt;sup>157</sup> Canadian Task Force on Preventive Health Care. *Canadian Guide to Clinical Preventive Health Care: Chapter* 60: Screening for Chlamydial Infection. 1994. Available at http://canadiantaskforce.ca/wpcontent/uploads/2013/03/Chapter60 chlamydia94.pdf?0136ff. Accessed November 2013.

<sup>&</sup>lt;sup>158</sup> U.S. Preventive Services Task Force. Screening for gonorrhea: recommendation statement. *Annals of Family Medicine*. 2005; 3(3): 263-7.

These include individuals under age 30 years with at least 2 sexual partners in the previous year or age  $\leq 16$  years at first intercourse, prostitutes, and sexual contacts of individuals known to have a sexually transmitted disease (STD). Of greater note is the increase in penicillin-resistant organisms necessitating changes in antibiotic management. Previous studies have shown that treatment is efficacious.

Abstinence is the most effective way to prevent transmission of STDs. There is also fair evidence to support the use of condoms. Given the effectiveness of counselling, educational pamphlets and educational videotape in improving compliance with clinic follow-up, there is fair evidence to provide counselling or educational materials to prevent the spread of gonorrhea (B Recommendation).

The low prevalence rate of infection with N. gonorrheae would make mass screening of the general population an inefficient intervention (D Recommendation).

However, screening should be performed in certain populations: 1) individuals under 30 years, particularly adolescents, with at least 2 sexual partners in the previous year; 2) prostitutes; 3) sexual contacts of individuals known to have a sexually transmitted disease; and 4) age  $\leq 16$  years at first intercourse (A Recommendation).

*The frequency with which such screening should take place has not been examined, but subjects are presumably at risk when they continue behaviours that place them at increased risk, such as prostitution.*<sup>159</sup>

#### **Utilization of This Clinical Preventive Service**

#### Currently in British Columbia

In 2010, a total of 132,093 screening tests were completed for females between the ages of 15 and 29 in BC.<sup>160</sup> Based on the population of females between the ages of 15 and 29 (454,059), this suggests a screening rate of 29.1% in B.C. that year.

The number of new chlamydia infections has increased during the last decade in B.C., from 8,074 in 2003 to 12,364 in 2012 (see Figure 4-1).<sup>161</sup>

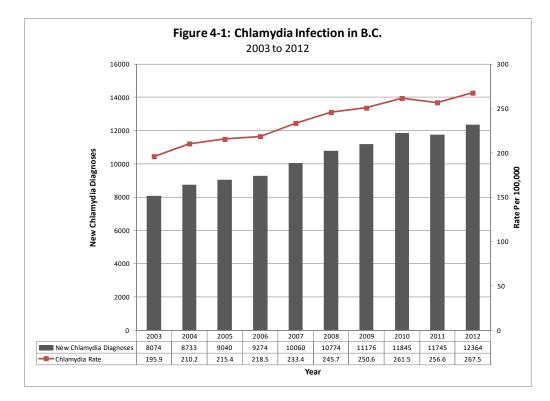
<sup>&</sup>lt;sup>159</sup> Beagan BL and Wang EEL. *Canadian Guide to Clinical Preventive Health Care: Chapter 59: Prevention of Gonorrhea*. 1994. Available at http://canadiantaskforce.ca/wp-

content/uploads/2013/03/Chapter59\_gonorrhea94.pdf?0136ff. Accessed November 2013.

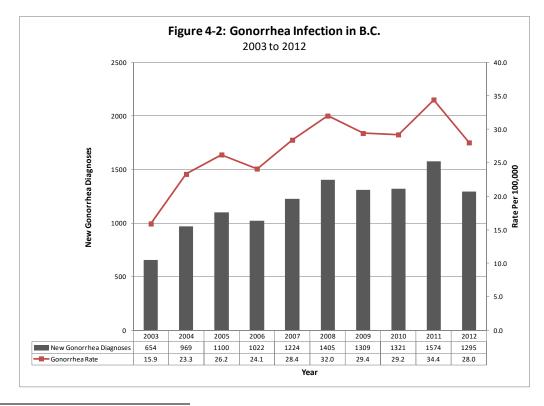
<sup>&</sup>lt;sup>160</sup> Dr. Mark Gilbert, Surveillance & Online Sexual Health Services, Clinical Prevention Services, BC Centre for Disease Control. Personal communication, May, 2014.

<sup>&</sup>lt;sup>161</sup> BC Centre for Disease Control. British Columbia Annual Summary of Reportable Diseases 2012. 2013.

Available at http://www.bccdc.ca/NR/rdonlyres/F30377E3-D33E-4755-B3F4-6844E01BD678/0/FinalAR2012.pdf. Accessed November 2013.



The number of new gonorrhea infections has also increased during the last decade in B.C., from 654 in 2003 to a high of 1,574 in 2011(see Figure 4-2).<sup>162</sup>



<sup>162</sup> BC Centre for Disease Control. British Columbia Annual Summary of Reportable Diseases 2012. 2013. Available at http://www.bccdc.ca/NR/rdonlyres/F30377E3-D33E-4755-B3F4-6844E01BD678/0/FinalAR2012.pdf. Accessed November 2013.

#### Best in the World

In the United States, the screening rate for chlamydia among females with Medicare health plans between the ages of 16-25 increased from 25.3% in 2000 to 43.6% in 2006, with a slight dip in 2007 down to 41.6%. In 2007, the highest state was Hawaii with a rate of 57.8%, but with a sample size of only 8,200, while California achieved the second highest rate of 48.6% with a sample size of 448,800.<sup>163</sup>

#### **Relevant British Columbia Population in 2013**

The USPSTF recommends that screening be performed in all sexually active females younger than 25. The CTFPHC also recommends screening in individuals under 30 years with at least 2 sexual partners in the previous year. This means that approximately 191,583 females would be eligible for screening in B.C. in 2013 (see Table 4-1).

#### Modelling CPB and CE

No models are available from the Partnership for Prevention and HealthPartners Research for screening for chlamydia or gonorrhea. In this section, we will calculate the CPB and CE associated with screening the estimated 191,583 females ages 12-29 at increased risk for infection with chlamydia and gonorrhea.

<sup>&</sup>lt;sup>163</sup> Centers for Disease Control and Prevention. Chlamydia screening among sexually active young female enrollees of health plans--United States, 2000-2007. *Morbidity and Mortality Weekly Report*. 2009; 58(14): 362-5.

In estimating CPB, we used the results based on a state transition simulation model developed by Hu and colleagues.<sup>164</sup> They found the most cost-effective approach to screening included annual screening in at-risk women ages 15 to 29 years of age followed by semi-annual screening for those with a history of infection. Our analysis is based on the assumption that this screening approach would be followed. Unless otherwise noted, the following assumptions are based on their analysis.

- In the absence of screening, the lifetime risk of chronic pelvic pain, infertility and ectopic pregnancy is 3.44%, 3.88% and 1.74%, respectively (Table 4-2, rows *d*, *e* & *f*).
- With the screening protocol noted above, the lifetime risk of chronic pelvic pain, infertility and ectopic pregnancy is reduced by 41% (Table 4-2, rows g).
- Chronic pelvic pain is associated with a 0.40 reduction in quality of life for a period of 5 years (Table 4-2, rows *n*).
- Infertility is associated with a 0.18 reduction in quality of life up until age 50. We assumed the average infection would occur at age  $21^{165}$  with 29 potential years of infertility (Table 4-2, rows *o*).
- Ectopic pregnancy is associated with a 0.42 reduction in quality of life for a period of 4 weeks (Table 4-2, rows *p*).
- Current best practices suggest that adherence with screening would be approximately 50%, as noted above (Table 4-2, rows *b*).<sup>166</sup>

Based on these assumptions, the calculation of CPB (Table 4-2, row *t*) is 1,115 QALYs. This represents the potential CPB moving from no screening to approximately 50% screening uptake. If we assume that 29% of the at-risk population ages 15-29 in BC has been screened, then the gap in CPB (between 29% and 50%) would be 468 QALYs (Table 4-2, row *v*).

As noted by Hu and colleagues, the effectiveness and cost-effectiveness associated with their modelling is highly sensitive to a number of key assumptions.<sup>167</sup> Furthermore, there is significant debate about these key assumptions. For example, Hu and colleagues assumed that 30% of infections with chlamydia would lead to acute pelvic inflammatory disease (PID), with a range from 10-40%. Subsequent research suggests that the rate might be much lower, resulting in a change in the lower end of the range from 10% to just 0.43%.<sup>168,169</sup> Others

<sup>&</sup>lt;sup>164</sup> Hu D, Hook EW and Goldie SJ. Screening for Chlamydia trachomatis in women 15 to 29 years of age: a costeffectiveness analysis. *Annals of Internal Medicine*. 2004; 141(7): 501-13.

<sup>&</sup>lt;sup>165</sup> Oakeshott P, Kerry S, Aghaizu A et al. Randomised controlled trial of screening for Chlamydia trachomatis to prevent pelvic inflammatory disease: the POPI (prevention of pelvic infection) trial. *British Medical Journal*. 2010; 340(340): c1642.

 <sup>&</sup>lt;sup>166</sup> Centers for Disease Control and Prevention. Chlamydia screening among sexually active young female enrollees of health plans--United States, 2000-2007. *Morbidity and Mortality Weekly Report*. 2009; 58(14): 362-5.
 <sup>167</sup> Hu D, Hook III EW and Goldie SJ. The impact of natural history parameters on the cost-effectiveness of Chlamydia trachomatis screening strategies. *Sexually Transmitted Diseases*. 2006; 33(7): 428-36.

<sup>&</sup>lt;sup>168</sup> van Valkengoed IG, Morré SA, van den Brule AJ et al. Overestimation of complication rates in evaluations of Chlamydia trachomatis screening programmes - implications for cost-effectiveness analyses. *International Journal of Epidemiology*. 2004; 33(2): 416-25.

<sup>&</sup>lt;sup>169</sup> Hu D, Hook III EW and Goldie SJ. The impact of natural history parameters on the cost-effectiveness of Chlamydia trachomatis screening strategies. *Sexually Transmitted Diseases*. 2006; 33(7): 428-36.

indicate that we simply do not know very much about the natural progression from infection with either chlamydia or gonorrhea to PID.<sup>170</sup>

There is also significant debate about whether screening is associated with any significant reduction in PID and its sequelae. In a seminal article published in the *New England Journal of Medicine* in 1996, Scholes et al. present the results of a randomized controlled clinical trial in which they observed a significant reduction in PID in women screened for chlamydia (relative risk of 0.44; 95% CI of 0.20 to 0.90).<sup>171</sup> Subsequent research, however, has not been able to replicate these results. The Prevention of Pelvic Infection (POPI) trial in the UK, also a randomized controlled trial, found a non-significant reduction in PID associated with screening (relative risk of 0.65; 95% CI of 0.34 to 1.22).<sup>172</sup>

Assumptions about the proportion of women with an infection that progresses to PID and the effectiveness of screening (and early treatment) in reducing the proportion of women with an infection who progress to PID are critical to any analysis about the effectiveness and cost-effectiveness of screening. In fact, Low notes that "under realistic assumptions, introducing a chlamydia screening programme is likely to be an expensive intervention".<sup>173</sup> She further notes that many chlamydia screening programs have been uncritically accepted as being effective.

With these caveats in mind, we modified several major assumptions and recalculated the CPB as follows:

- Assume the potential adherence rate with screening is reduced from 50% to 40% (Table 4-2, rows *b*): CPB = 892
- Assume the potential adherence rate with screening is increased from 50% to 60% (Table 4-2, rows *b*): CPB = 1,338
- Assume the effectiveness of screening in reducing chronic pelvic pain, infertility and ectopic pregnancies is reduced from 41% to 10% (Table 4-2, rows *b*): CPB = 272

<sup>&</sup>lt;sup>170</sup> Herzog SA, Heijne JC, Althaus CL et al. Describing the progression from Chlamydia trachomatis and Neisseria gonorrhoeae to pelvic inflammatory disease: systematic review of mathematical modeling studies. *Sexually Transmitted Diseases*. 2012; 39(8): 628-37.

<sup>&</sup>lt;sup>171</sup> Scholes D, Stergachis A, Heidrich FE et al. Prevention of pelvic inflammatory disease by screening for cervical chlamydial infection. *New England Journal of Medicine*. 1996; 334(21): 1362-6.

<sup>&</sup>lt;sup>172</sup> Oakeshott P, Kerry S, Aghaizu A et al. Randomised controlled trial of screening for Chlamydia trachomatis to prevent pelvic inflammatory disease: the POPI (prevention of pelvic infection) trial. *British Medical Journal*. 2010; 340(340): c1642.

<sup>&</sup>lt;sup>173</sup> Low N. Screening programmes for chlamydial infection: when will we ever learn? *British Medical Journal*. 2007; 334(7596): 725-8.

Table	Table 4-2. CPB of Screening to Detect and Treat Chiamyula/Gonormea in a					
	Birth Cohort of 40,000 (B.C.)					
Row						
Label	Variable	Base Case	Data Source			
а	At-risk population in B.C. birth cohort of 40,000	20,000	V			
b	Potential adherence with screening	50%	V			
С	At-risk population screened	10,000	= a*b			
d	Lifetime risk of chronic pelvic pain (CPP) without screening	3.44%	V			
е	Lifetime risk of infertility without screening	3.88%	V			
f	Lifetime risk of ectopic pregnancy (EP) without screening	1.74%	V			
g	Effectiveness of screening in reducing CPP, infertility and EP	41%	٧			
h	Lifetime risk of chronic pelvic pain with screening	2.03%	= (1-g)*d			
i	Lifetime risk of infertility with screening	2.29%	= (1-g)*e			
j	Lifetime risk of ectopic pregnancy with screening	1.03%	=(1-g)*f			
k	Cases of chronic pelvic pain avoided with screening	141	=(c*d)-(c*h)			
_	Cases of infertility avoided with screening	159	=(c*e)-(c*i)			
m	Cases of ectopic pregnancy avoided with screening	71	=(c*f)-(c*j)			
n	QALYs parameters - chronic pelvic pain (5 years)	0.40	٧			
0	QALYs parameters - infertility (to age 50)	0.18	V			
р	QALYs parameters - ectopic pregnancy (4 weeks)	0.42	V			
q	QALYs gained with screening - chronic pelvic pain	282	=k*n*5			
r	QALYs gained with screening - infertility	831	=l*o*29			
S	QALYs gained with screening - ectopic pregnancy	2.3	=m*p*0.077			
t	Total QALYs gained, 50% adherence with screening	1,115	=q+r+s			
u	Estimated current uptake in BC	29%	V			
v	Total QALYs gained, Utilization increasing from 29% to 50%	468	=t-(u/b)*t			

# Table 4-2: CPB of Screening to Detect and Treat Chlamydia/Gonorrhea in a

*√* = Estimates from the literature

In calculating CE, we made the following assumptions:

- Proportion of at-risk population with infection We assumed that 5.68% of the at-risk population would test positive for either chlamydia or gonorrhea (Table 4-3, row f).<sup>174</sup> This assumption was varied between 2% and 33% in the sensitivity analysis.175
- Screening protocol We assumed that screening included annual screening in at-• risk women ages 15 to 29 years of age followed by semi-annual screening for those with a history of infection (Table 4-3, rows g, h and i).<sup>176</sup>
- Cost of an office visit We estimated the average cost of a visit to a General • Practitioner to be \$34.00 based on information from the B.C. Medical Services Commission 2013 payment schedule<sup>177</sup> (Table 4-3, row *j*).

effectiveness analysis. Annals of Internal Medicine. 2004; 141(7): 501-13.

<sup>177</sup> Medical Services Commission. Payment Schedule: Section 7 General Practice. 2013. Available at http://www.health.gov.bc.ca/msp/infoprac/physbilling/payschedule/pdf/7-general-practice.pdf. Accessed December 2013.

<sup>&</sup>lt;sup>174</sup> Oakeshott P, Kerry S, Aghaizu A et al. Randomised controlled trial of screening for Chlamydia trachomatis to prevent pelvic inflammatory disease: the POPI (prevention of pelvic infection) trial. British Medical Journal. 2010; 340(340): c1642.

<sup>&</sup>lt;sup>175</sup> Hu D, Hook III EW and Goldie SJ. The impact of natural history parameters on the cost-effectiveness of Chlamydia trachomatis screening strategies. Sexually Transmitted Diseases. 2006; 33(7): 428-36. <sup>176</sup> Hu D, Hook EW and Goldie SJ. Screening for Chlamydia trachomatis in women 15 to 29 years of age: a cost-

- **Patient time costs** For patient time costs (Table 4-3, row *k*), we assumed an hourly wage of \$24.39 (the B.C. average in 2013)<sup>178</sup> plus 18% benefits applied to the estimated two hours of patient time required for a cost per screening visit of \$57.56.
- Costs of screening tests Hu et al. estimated the cost of a urine nucleic acid amplification test to be \$13 (2000 US dollars).<sup>179</sup> We have converted this to equivalent Canadian costs by using a reduction of 29% to reflect excess health care prices in the U.S.<sup>180,181</sup> and then adjusted these costs to 2013 Canadian dollars using the health and personal care component of the B.C. Consumer Price Index (CPI) (+17.1%) for a cost of \$10.81. Robinson et al. estimated the costs to be £7.35 (in 2005).<sup>182</sup> We used the exchange rate for July of 2005 (£1.58 per Canadian dollar) and then adjusted these costs to 2013 Canadian dollars using the health and personal care (represented the cost of \$12.70. We used an estimate of \$12 (with a range from \$10-\$14 in the sensitivity analysis) per screening test in the model (Table 4-3, row *m*).
- Average cost of antibiotic treatment The treatment of choice for gonorrhea infection is cefiximine 800 mg PO in a single dose (estimated cost of \$20.46 including dispensing fee<sup>183</sup>) and azithromycin 1 g PO in a single dose (estimated cost of \$17.22 including dispensing fee<sup>184</sup>) or ceftriaxone 250 mg IM in a single dose and azithromycin 1g PO in a single dose.<sup>185</sup> The treatment of choice for chlamydia infection is doxycycline 100 mg 2x daily for 7 days (estimated cost of \$21.91 including dispensing fee<sup>186</sup>) or a single dose of azithromycin 1g PO if poor compliance is expected.<sup>187</sup> We used an average cost of \$19.86 (Table 4-3, row *p*) with a range from \$17.22 to \$21.91.
- **Discount rate** of 3%

Based on these assumptions, the estimated cost per QALY would be \$9,900 (see Table 4-3, row v).

<sup>&</sup>lt;sup>178</sup> Statistics Canada. Average Hourly Wages of Employees by Selected Characteristics and Occupation, Unadjusted Data, by Province (Monthly) (British Columbia). 2013. Available at http://www.statcan.gc.ca/tablestableaux/sum-som/l01/cst01/labr69k-eng.htm. Accessed December 2013.

<sup>&</sup>lt;sup>179</sup> Hu D, Hook EW and Goldie SJ. Screening for Chlamydia trachomatis in women 15 to 29 years of age: a costeffectiveness analysis. *Annals of Internal Medicine*. 2004; 141(7): 501-13.

<sup>&</sup>lt;sup>180</sup> Anderson GF, Reinhardt UE, Hussey PS et al. It's the prices, stupid: why the United States is so different from other countries. *Health Affairs*. 2003; 22(3): 89-105.

<sup>&</sup>lt;sup>181</sup> Reinhardt U. Why Does US Health Care Cost So Much? (Part I). 2008. Available at

http://faculty.ses.wsu.edu/rayb/econ340/Articles/health/Health\_Costs.doc. Accessed December 2013.

<sup>&</sup>lt;sup>182</sup> Robinson S, Roberts T, Barton P et al. Healthcare and patient costs of a proactive chlamydia screening programme: the Chlamydia Screening Studies project. *Sexually Transmitted Infections*. 2007; 83(4): 276-81.
<sup>183</sup> Papific Plus Cross. *Pharmacu Company*. 2014. Available at http://pharmacu.company.acm.company.ac

<sup>&</sup>lt;sup>183</sup> Pacific Blue Cross. *Pharmacy Compass*. 2014. Available at http://pharmacycompass.ca/BestPrice. Accessed March 2014.

<sup>&</sup>lt;sup>184</sup> Pacific Blue Cross. *Pharmacy Compass*. 2014. Available at http://pharmacycompass.ca/BestPrice. Accessed March 2014.

<sup>&</sup>lt;sup>185</sup> College of Registered Nurses of British Columbia. CRNBC Certified Practice Decision Support Tool for Gonorrhea. 2014. Available at

https://crnbc.ca/Standards/CertifiedPractice/Documents/ReproductiveHealth/721GonorrheaReportableSTIDST.pdf . Accessed March 2014.

<sup>&</sup>lt;sup>186</sup> Pacific Blue Cross. *Pharmacy Compass*. 2014. Available at http://pharmacycompass.ca/BestPrice. Accessed March 2014.

<sup>&</sup>lt;sup>187</sup> BC Centre for Disease Control. *British Columbia Treatment Guidelines: Sexually Transmitted Infections in Adolescents and Adults*. 2007. Available at http://www.bccdc.ca/NR/rdonlyres/46AC4AC5-96CA-4063-A563-0BA9F4A0A6E9/0/STI\_Quick\_Reference\_Guidelines\_20090821.pdf. Accessed March 2014.

We also modified several major assumptions and recalculated the cost per QALY as follows:

- Assume the effectiveness of screening in reducing chronic pelvic pain, infertility and ectopic pregnancies is reduced from 41% to 10% (Table 4-2, rows *b*): CE = \$40,591
- Assume that the proportion of the at-risk population who would test positive for either chlamydia or gonorrhea is reduced from 5.68% to 2.0% (Table 4-3, row *f*): CE = \$9,476
- Assume that the proportion of the at-risk population who would test positive for either chlamydia or gonorrhea is increased from 5.68% to 33.0% (Table 4-3, row *f*): CE = \$13,048
- Assume the portion of an office visit required is decreased from 75% to 50% (Table 4-3, row *l*): CE = \$7,128
- Assume the portion of an office visit required is increased from 75% to 100% (Table 4-3, row *l*): CE = \$12,673
- Assume the cost of a screening test is reduced from \$12 to \$10 (Table 4-3, row *m*): CE = \$9,658
- Assume the cost of a screening test is increased from \$12 to \$14 (Table 4-3, row *m*): CE = \$10,143
- Assume the cost for antibiotic treatment is decreased from \$19.86 to \$17.22 (Table 4-3, row *p*): CE = \$9,883
- Assume the cost for antibiotic treatment is increased from \$19.86 to \$21.91 (Table 4-3, row *p*): CE = \$9,914

Cohort of 40,000 (B.C.)							
Label	Variable	Base Case	Data Source				
а	At-risk population screened	10,000	Table 4-2, row c				
b	# of annual screens between age 15 and 24	10	V				
С	Total # of screens, 15 - 24	100,000	=a*b				
d	% Population at-risk between 25-29	6%	٧				
е	Total # of screens, 25 - 29	3,000	=d*a*5				
f	% with chlamydia/gonorrhea infection	5.68%	٧				
g	Total screens - positive	5,850	= (c+e)*d				
h	Total screens - negative	97,150	= c+e-g				
i	Additional follow-up screens in positive women	5,850	= g				
	Costs of screening						
j	Cost of 10-minute office visit	\$34.00	٧				
k	Cost of patient time and travel for office visit	\$57.56	√				
Ι	Portion of office visit needed	75%	Assumed				
m	Cost per screening test	\$12	√				
n	Costs of screening	\$8,780,962	= (g+h+i)*(((j+k)*l)*m				
0	Costs of antibiotics						
р	Cost per treatment	\$19.86	√				
q	Cost of antibiotics	\$116,189	=g*p				
	CE calculation						
r	Costs (undiscounted)	\$8,897,151	= n+q				
S	QALYs saved (undiscounted)	1,115	Table 4-2, row t				
t	Costs (3% discount rate)	\$7,293,334	Calculated				
u	QALYs saved (3% discount rate)	737	Calculated				
v	CE (\$/QALY saved)	\$9,900	= t/u				

# Table 4-3: CE of Screening to Detect and Treat Chlamydia/Gonorrhea in a Birth

*√* = Estimates from the literature

#### Summary

Table 4-4: Screening to Diagnose and Treat									
Chlamydia/Gonorrhea Infections in a Birth Cohort of 40,000									
Su	ummary								
	Base								
	Case	Ra	nge						
CPB (Potential QALYs Gained)									
Assume No Current Service									
3% Discount Rate	737	180	884						
0% Discount Rate	1,115	272	1,388						
Gap between B.C. Current (29%	6) and 'Best in th	e World' (50%)	)						
3% Discount Rate	309	75	457						
0% Discount Rate	468	114	691						
CE (\$/QALY) including patient time	costs								
3% Discount Rate	\$9,900	\$7,128	\$40,591						
0% Discount Rate	\$7,980	\$5,745	\$32,717						
<b>CE</b> (\$/QALY) <b>excluding</b> patient time costs									
3% Discount Rate	\$4,671	\$3,642	\$19,153						
0% Discount Rate	\$3,765	\$2,935	\$15,437						

#### **Behavioural Counseling Interventions**

### Definition

In 2002, the USPSTF published an article outlining its vision for a broader appreciation of the importance of behavioural counselling interventions in clinical care.<sup>188</sup> The paper includes important definitional and context information for this area and we have thus quoted liberally from the paper below.

Behavioral counseling interventions address complex behaviors that are integral to daily living; they vary in intensity and scope from patient to patient; they require repeated action by both patient and clinician, modified over time, to achieve health improvement; and they are strongly influenced by multiple contexts (family, peers, worksite, school, and community). Further, "counseling" is a broadly used but imprecise term that covers a wide array of preventive and therapeutic activities, from mental health or marital therapy to the provision of health education and behavior change support. Thus, we have chosen to use the term "behavioral counseling interventions" to describe the range of personal counseling and related behaviorchange interventions that are effectively employed in primary care to help patients change health-related behaviors. (p.270)

Behavioral counseling interventions in clinical care are those activities delivered by primary care clinicians and related healthcare staff to assist patients in adopting, changing, or maintaining behaviors proven to affect health outcomes and health status. Common health promoting behaviors include smoking cessation, healthy diet, regular physical activity, appropriate alcohol use, and responsible use of contraceptives. (p. 269-70)

The strongest evidence for the efficacy of primary care behavior-change interventions comes from tobacco-cessation research and, to a lesser extent, problem drinking. Accumulating evidence also shows the effectiveness of similar interventions for other behaviors. These interventions often provide more than brief clinician advice. Effective interventions typically involve behavioral counseling techniques and use of other resources to assist patients in undertaking advised behavior changes. For example, intervention adjuncts to brief clinician advice may involve a broader set of healthcare team members (e.g., nurses, other office staff, health educators, and pharmacists), a number of complementary communication channels (e.g., telephone counseling, video or computer assisted interventions, self-help guides, and tailored mailings), and multiple contacts with the patient. (p. 268)

In 2014, the USPSTF published an article discussing challenges it encounters in aggregating the behavioural counselling intervention literature, including clear descriptions of the study population, intervention protocols, assessment of outcomes, and linking behaviour changes to health outcomes.<sup>189</sup> Researchers are encouraged to pay closer attention to these issues in designing and writing up their behavioural intervention research.

<sup>&</sup>lt;sup>188</sup> Whitlock EP, Orleans CT, Pender N et al. Evaluating primary care behavioral counseling interventions: an evidence-based approach. *American Journal of Preventive Medicine*. 2002; 22(4): 267-84.

<sup>&</sup>lt;sup>189</sup> Curry S, Grossman D, Whitlock E et al. Behavioral counseling research and evidence-based practice recommendations: U.S. Preventive Services Task Force Perspectives. *Annals of Internal Medicine*. 2014; 160: 407-13.

### **Preventing Tobacco Use**

United States Preventive Services Task Force Recommendations (2013)

Tobacco use is the leading cause of preventable death in the United States. Each year, approximately 443 000 deaths are attributable to smoking, including nearly 161 000 deaths from cancer, 128 000 from cardiovascular diseases, and 103 000 from respiratory diseases. Smoking costs the United States approximately \$96 billion each year in direct medical costs and \$97 billion in productivity losses due to premature death.

*The USPSTF recommends that primary care clinicians provide interventions, including education or brief counseling, to prevent initiation of tobacco use in school-aged children and adolescents. (B Recommendation)*<sup>190</sup>

In their review of the evidence,<sup>191</sup> the USPSTF noted that the 2012 Surgeon General's Report concluded that there is a "large, robust, and consistent" evidence base that documents known effective strategies for reducing tobacco use among youths and young adults.<sup>192</sup> These strategies include coordinated, multi-component campaigns that combine media campaigns, price increases, school-based policies and programs and community-wide changes in policies and norms. The purpose of the USPSTF review was not to reconsider the evidence covered by the Surgeon General's Report, but rather "to review the evidence for the efficacy and harms of primary-care relevant interventions that aim to reduce tobacco use among children and adolescents."<sup>193</sup>

The USPSTF review concluded that "behaviour-based interventions were effective only in reducing smoking initiation among non-smoking young persons." Furthermore, "neither behaviour-based nor bupropion cessation interventions improved cessation rates."<sup>194</sup>

Utilization of This Clinical Preventive Service

#### **Currently in British Columbia**

We were unable to find any information about the utilization of primary care based interventions aimed at reducing smoking initiation among non-smoking young persons in British Columbia.

The Canadian Community Health Survey does provide information on physician counselling (for smoking), as well as the use of smoking cessation aids by people who smoke.

<sup>&</sup>lt;sup>190</sup> Moyer VA. Primary care interventions to prevent tobacco use in children and adolescents: U.S. Preventive Services Task Force recommendation statement. *Annals of Internal Medicine*. 2013; 159(8): 552-7.

<sup>&</sup>lt;sup>191</sup> Patnode CD, O'Connor E, Whitlock EP et al. Primary care-relevant interventions for tobacco use prevention and cessation in children and adolescents: a systematic evidence review for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*. 2013; 158(4): 253-60.

<sup>&</sup>lt;sup>192</sup> U.S. Department of Health and Human Services. *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General.* 2012. Available at

http://www.cdc.gov/tobacco/data\_statistics/sgr/2012/consumer\_booklet/pdfs/consumer.pdf. Accessed January 2014.

<sup>&</sup>lt;sup>193</sup> Patnode CD, O'Connor E, Whitlock EP et al. Primary care-relevant interventions for tobacco use prevention and cessation in children and adolescents: a systematic evidence review for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*. 2013; 158(4): 253-60.

<sup>&</sup>lt;sup>194</sup> Patnode CD, O'Connor E, Whitlock EP et al. Primary care-relevant interventions for tobacco use prevention and cessation in children and adolescents: a systematic evidence review for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*. 2013; 158(4): 253-60.

Unfortunately, this is an optional section, therefore not completed by most provinces. The only provinces to complete this section in the last two cycles were Manitoba in 2010 and Alberta in 2007/08. In order to separate this service from preventing tobacco use in adults, we used ages 12 to 19. Based on patients surveyed in these two provinces, the CCHS found that 65.7% of patient's physicians were aware that their patients smoked. Of those patients, 72.3% were advised by their health care provider to quit smoking at least once during the previous 12 month period. Just under half (44.9%) of patients were offered specific help or information. When asked about the specific help or information offered (allowing all options that applied) the most common recommendation was the provision of self-help information (54.7%), the nicotine patch or gum (32.1%) or to use Zyban or another medication (6.5%). In addition, 10.7% said that their physicians offered to counsel them.

It is relevant to recall that the USPSTF review found no evidence that neither behaviourbased nor bupropion cessation interventions provided in primary care improved cessation rates in children and adolescents.

#### Best in the World

We found one older U.S. study which found that 35% of paediatricians, family physicians and general dentists reported "always" providing smoking prevention counselling to 16-18 year-olds. A further 30% reported "frequently" providing this intervention. In 13 to 15 year-olds, the respective percentages were 26% and 28%.<sup>195</sup>

#### Relevant British Columbia Population in 2010

The 2010 Canadian Community Health Survey groups respondents into the following 'type of smoker' categories:<sup>196</sup>

- 1. Daily smoker
- 2. Occasional smoker (former daily smoker)
- 3. Always an occasional smoker
- 4. Former daily smoker
- 5. Former occasional smoker
- 6. Never smoked

Based on this information, we present the number of daily and occasional (categories 2 & 3 above) smokers in B.C. in 2010 in Table 5-1 below. In 2010, for persons aged 12 to 19, there were an estimated 23,271 (5.7% of population) daily and occasional smokers in B.C. Of these, 14,415 were males and 8,856 were females.

	Table 5-1: Smokers in British Columbia in 2010Based on 2010 CCHS DataAges 12 to 19											
	Tot	tal Popula	tion	Da	aily Smok	ers	Occasi	ional Sm	okers	Current S	mokers as	% of Pop.
Age Group	Males	Females	Total	Males	Females	Total	Males	Females	Total	Males	Females	Total
12-14	73,171	68,779	141,950	459	-	459	97	-	97	0.76%	0.00%	0.39%
15-17	81,088	74,831	155,919	4,383	2,994	7,377	1,274	208	1,482	6.98%	4.28%	5.68%
18-19	57,055	55,256	112,311	4,661	4,479	9,140	3,541	1,175	4,716	14.38%	10.23%	12.34%
Total	211,314	198,866	410,180	9,503	7,473	16,976	4,912	1,383	6,295	6.82%	4.45%	5.67%

<sup>&</sup>lt;sup>195</sup> Gregorio DI. Counseling adolescents for smoking prevention: a survey of primary care physicians and dentists. *American Journal of Public Health.* 1994; 84(7): 1151-3.

<sup>&</sup>lt;sup>196</sup> This analysis is based on the Statistics Canada's Canadian Community Health 2010 Public Use Microdata File. All computations, use and interpretation of these data are entirely that of H. Krueger & Associates Inc.

## Modelling CPB and CE

No model is available from the Partnership for Prevention and HealthPartners Research Foundation to calculate the CPB and CE of primary care based interventions aimed at reducing smoking initiation among non-smoking young persons. In this section, we will calculate the CPB and CE associated with interventions aimed at reducing smoking initiation among non-smoking children and adolescents based on the following assumptions for CPB and CE:

- An average of 11.5 life years lost per smoker (Table 5-3, row *c*). An average of 10.5 of these life-years can be regained by stopping smoking at age 30 (Table 5-3, row *g*), 9.5 by stopping smoking at age 40 (Table 5-3, row *j*) and 6.5 by stopping smoking at age 50 (Table 5-3, row *l*).<sup>197</sup>
- On average, 57.3% of smokers would quit (become former smokers) by the age of 25-34 (Table 5-3, row *e*), 60.4% by age 35-44 (Table 5-3, row *h*) and 68.9% by age 45-54 (Table 5-3, row *k*) (see Table 5-2).<sup>198</sup>

Table 5-2: Smoking Occurrence         British Columbia, 2010									
AGE GROUP									
SMOKING CATEGORY	18-24	25-34	35-44	45-54	55-64	65+			
DAILY SMOKER	50,238	91,696	94,232	114,679	70,612	47,346			
OCCASIONAL SMOKER (FORMER DAILY SMOKER)	17,203	27,935	21,481	18,486	9,914	12,950			
ALWAYS AN OCCASIONAL SMOKER	31,786	18,272	15,056	7,787	6,320	296			
FORMER DAILY SMOKER	27,365	77,671	110,446	203,967	183,720	256,094			
FORMER OCCASIONAL SMOKER	53,224	107,195	89,353	108,870	83,717	92,489			
NEVER SMOKED	225,389	267,255	288,143	265,911	209,738	223,185			
SMOKERS	179,816	322,769	330,568	453,789	354,283	409,175			
% of FORMER SMOKERS	44.8%	57.3%	60.4%	68.9%	75.5%	85.2%			

• Interventions aimed at reducing smoking initiation among non-smoking children and adolescents have an effectiveness of 19% (RR 0.81, 95% CI of 0.70 to 0.93).<sup>199</sup>

Based on these assumptions, the CPB associated with interventions aimed at reducing smoking initiation among non-smoking children and adolescents is 1,299 (Table 5-3, row gg).

We also modified a major assumption and recalculated the CPB as follows:

- Assume the effectiveness of interventions aimed at reducing smoking initiation among non-smoking children and adolescents is reduced from 19% to 7% (Table 5-3, row *p*): CPB = 478
- Assume the effectiveness of interventions aimed at reducing smoking initiation among non-smoking children and adolescents is increased from 19% to 30% (Table 5-3, row *p*): CPB = 2,051.

<sup>&</sup>lt;sup>197</sup> Jha P, Ramasundarahettige C, Landsman V et al. 21st-century hazards of smoking and benefits of cessation in the United States. *New England Journal of Medicine*. 2013; 368(4): 341-50.

<sup>&</sup>lt;sup>198</sup> This analysis is based on the Statistics Canada's Canadian Community Health 2010 Public Use Microdata File. All computations, use and interpretation of these data are entirely that of H. Krueger & Associates Inc.

<sup>&</sup>lt;sup>199</sup> Patnode CD, O'Connor E, Whitlock EP et al. Primary care-relevant interventions for tobacco use prevention and cessation in children and adolescents: a systematic evidence review for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*. 2013; 158(4): 253-60.

		Base Case	Data Source
Fstim	ate of Life Years Lost without Intervention	Dase Case	Data Source
a	% of 12-19 year-olds initiating smoking in B.C.	5.67%	Table 5-1
b	Estimated # in birth cohort initiating smoking between ages 12-19	2,268	= a* 40,000
<u>с</u>	Life-years lost per smoker	11.5	√
d	Potential life-years lost	26,082	= c * b
u e	Proportion former smokers at age 30	57.3%	Table 5-2
f	Former smokers at age 30	1,300	= e * b
-	Life-years gained by stopping smoking at age 30	1,300	 √
g h	Proportion former smokers at age 40	60.4%	Table 5-2
i	Former smokers at age 40	1,370	= h * b
:	Life-years gained by stopping smoking at age 40	9.5	D
J k	Proportion former smokers at age 50	68.9%	Table 5-2
K I	Life-years gained by stopping smoking at age 50	6.5	v Table 3-2
	Former smokers at age 50		= k * b
m	Former smokers at age 50	1,563	
n	Life-years gained by stopping smoking	15,566	= (f*g)+(i- f)*j+(m-i)*l
-	Estimated Life Vears Lest without Intervention	10,516	= d - n
0 Ectim	Estimated Life Years Lost without Intervention ate of Life Years Lost with Intervention	10,516	= u - n
	Effectiveness of intervention	19.0%	V
р			= a * (p - 1)
q	Estimated # in birth cohort initiating smoking between ages 12-19	1,837	*40,000
r	Life-years lost per smoker	11.5	V
S	Potential life-years lost	21,126	= r * q
t	Proportion former smokers at age 30	57.3%	Table 19-2
u	Former smokers at age 30	1,053	= t * q
v	Life-years gained by stopping smoking at age 30	10.5	V
w	Proportion former smokers at age 40	60.4%	Table 19-2
х	Former smokers at age 40	1,110	= w * q
у	Life-years gained by stopping smoking at age 40	9.5	V
z	Proportion former smokers at age 50	68.9%	Table 19-2
аа	Life-years gained by stopping smoking at age 50	6.5	V
bb	Former smokers at age 50	1,266	= z * q
сс	Life-years gained by stopping smoking	12,609	= (u*v)+(x-
	, , , , , , , , , , , , , , , , , , , ,		u)*y+(bb-x)*aa
	Estimated Life Years Lost with Intervention	8,518	= S - CC
	lation of CPB		
	CPB Attributable to Mortality	1,998	= o - dd
ff	Potential coverage of this service	65%	V
gg	Potential CPB in BC	1,299	=ee * ff

# Table 5-3: Clinically Preventable Burden of Interventions for Tobacco Use Prevention in Children and Youth for Birth Cohort of 40,000 Individuals (B.C.)

*√* = Estimates from the literature

In estimating CE, we made the following assumptions:

• **Cost of an office visit** - We estimated the average cost of a visit to a General Practitioner to be \$34.00 based on information from the B.C. Medical Services Commission 2013 payment schedule<sup>200</sup> (Table 5-4, row *a*).

<sup>&</sup>lt;sup>200</sup> Medical Services Commission. *Payment Schedule: Section 7 General Practice*. 2013. Available at http://www.health.gov.bc.ca/msp/infoprac/physbilling/payschedule/pdf/7-general-practice.pdf. Accessed December 2013.

- **Patient time costs** For patient time costs (Table 5-4, row *b*), we assumed an hourly wage of \$24.39 (the B.C. average in 2013)<sup>201</sup> plus 18% benefits applied to the estimated two hours of patient time required for a cost per physician visit of \$57.56.
- We assumed that 50% of an office visit (Table 5-4, row *c*) would be required for the intervention. This assumption was modified from 25% to 75% in the sensitivity analysis.
- The USPSTF evidence review suggests that the effectiveness of the intervention lasts for at least two years.<sup>202</sup> We have assumed that an intervention would be required three times between the ages of 12 and 19 for maximum effect (Table 5-4, row d).
- The annual medical costs avoided per additional year as never smoker (Table 5-4, row g) is taken from our work on the economic burden associated with the risk factors of smoking, excess weight and physical inactivity.<sup>203,204,205</sup>
- Discount rate of 3%.

Based on these assumptions, the CE associated with interventions aimed at reducing smoking initiation among non-smoking children and adolescents is -\$7,267 per QALY (Table 5-4, row *n*).

We also modified several major assumptions and recalculated the cost per QALY as follows:

- Assume the effectiveness of interventions aimed at reducing smoking initiation among non-smoking children and adolescents is reduced from 19% to 7% (Table 5-3, row *p*): \$/QALY = \$16,254
- Assume the effectiveness of interventions aimed at reducing smoking initiation among non-smoking children and adolescents is increased from 19% to 30% (Table 5-3, row *p*): \$/QALY = -\$12,292
- Assume the portion of an office visit needed for counseling is reduced from 50% to 25% (Table 5-4, row *c*): \$/QALY = -\$14,121
- Assume the portion of an office visit needed for counseling is increased from 50% to 75% (Table 5-4, row *c*): \$/QALY = -\$403
- Assume the annual medical costs avoided per additional year as never smoker is decreased from \$958 to \$901 (Table 5-4, row g): \$/QALY = -\$6,014
- Assume the annual medical costs avoided per additional year as never smoker is increased from \$958 to \$1,015 (Table 5-4, row g): \$/QALY = -\$8,511

<sup>&</sup>lt;sup>201</sup> Statistics Canada. Average Hourly Wages of Employees by Selected Characteristics and Occupation, Unadjusted Data, by Province (Monthly) (British Columbia). 2013. Available at http://www.statcan.gc.ca/tablestableaux/sum-som/l01/cst01/labr69k-eng.htm. Accessed December 2013.

<sup>&</sup>lt;sup>202</sup> Patnode CD, O'Connor E, Whitlock EP et al. Primary care-relevant interventions for tobacco use prevention and cessation in children and adolescents: a systematic evidence review for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*. 2013; 158(4): 253-60.

<sup>&</sup>lt;sup>203</sup> H Krueger & Associates Inc. *The Economic Benefits of Risk Factor Reduction in British Columbia: Tobacco Smoking, Excess Weight and Physical Inactivity.* 2013. Available at

http://krueger.ca/index.asp?Page=Projects#RFReduction. Accessed January 2014.

<sup>&</sup>lt;sup>204</sup> Krueger H, Williams D, Ready AE et al. Improved estimation of the health and economic burden of chronic disease risk factors in Manitoba. *Chronic Diseases and Injuries in Canada*. 2013; 33(4): 236-46.

<sup>&</sup>lt;sup>205</sup> Krueger H, Turner D, Krueger J et al. The economic benefits of risk factor reduction in Canada: tobacco smoking, excess weight and physical inactivity. *Canadian Journal of Public Health*. 2014; 105(1): e69-78.

		Base Case	Data Source
Cost of cou	unseling		
а	Cost of 10-minute office visit	\$34.00	V
b	Cost of patient time and travel for office visit	\$57.56	V
С	Portion of office visit needed for counseling	50%	assumed
d	# of interventions	3.0	V
е	Total cost of counseling per individual	\$137.34	= (a+b)*c*d
f	Estimated Cost of Counselling	\$5,493,600	= e * 40,000
stimated	Cost Avoidance		
g	Annual medical costs avoided per additional year as never smoker	\$958	V
h	Individuals in birth cohort not initiating smoking due to intervention	431	= Table 19-3 row b - Table 19-3 row q
i	Average life expectancy of a 15-19 year-old	66	V
j	Costs avoided	\$27,246,210	=g * h * i
E calculat	tion		
k	Estimated Cost of Counselling	\$5,493,600	= f
I	Costs avoided	\$27,246,210	= j
m	Potential QALYs saved	1,299	= Table 5-3 row gg
n	Estimated Cost of Counselling (3% discount rate)	\$5,036,212	
0	Costs avoided (3% discount rate)	\$7,702,450	
р	Potential QALYs saved (3% discount rate)	367	
q	Cost per QALY (CE)	-\$7,262	= (k - l) / m

# Table 5-4: Cost Effectiveness of Interventions for Tobacco Use Prevention inChildren and Youth for Birth Cohort of 40,000 Individuals (B.C.)

Notes:

✓ = Estimates from the literature

#### Summary

Table 5-5: Interventions for Tobacco Use Prevention in									
Children and Youth for Birth Cohort of 40,000									
S	ummary								
	Base								
	Case	Ran	ige						
<b>CPB</b> (Potential QALYs Gained)									
Assume No Current Service									
3% Discount Rate	367	135	580						
0% Discount Rate	1,299	478	2,051						
Gap between B.C. Current (Unk	known, assume (	0%) and Best in	the World (65%)						
3% Discount Rate	367	135	580						
0% Discount Rate	1,299	478	2,051						
CE (\$/QALY) including patient time	costs								
3% Discount Rate	-\$7,262	-\$14,121	\$16,254						
0% Discount Rate	-\$16,750	-\$18,865	-\$9,498						
<b>CE</b> (\$/QALY) <b>excluding</b> patient time	e costs								
3% Discount Rate	-\$15,886	-\$18,433	-\$7,154						
0% Discount Rate	-\$19,409	-\$20,195	-\$16,716						

### **Alcohol Screening and Brief Intervention**

Note that while this maneuver is specific to adults rather than children and youth, it is closely associated with the following maneuver (the use of long acting reversible contraception methods together with screening and counseling to reduce alcohol-exposed births) and thus is included in this report.

### United States Preventive Services Task Force Recommendations (2013)

The USPSTF uses the term "alcohol misuse" to define a spectrum of behaviors, including risky or hazardous alcohol use (for example, harmful alcohol use and alcohol abuse or dependence). Risky or hazardous alcohol use means drinking more than the recommended daily, weekly, or per-occasion amounts resulting in increased risk for health consequences. For example, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the U.S. Department of Agriculture define "risky use" as consuming more than 4 drinks on any day or 14 drinks per week for men, or more than 3 drinks on any day or 7 drinks per week for women (as well as any level of consumption under certain circumstances). "Harmful alcohol use" (defined by the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision) is a pattern of drinking that causes damage to physical or mental health.

"Alcohol abuse" (defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition) is drinking that leads an individual to recurrently fail in major home, work, or school responsibilities; use alcohol in physically hazardous situations (such as while operating heavy machinery); or have alcohol-related legal or social problems. "Alcohol dependence" (or alcoholism) (defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition) includes physical cravings and withdrawal symptoms, frequent consumption of alcohol in larger amounts than intended over longer periods, and a need for markedly increased amounts of alcohol to achieve intoxication.

An estimated 30% of the U.S. population is affected by alcohol misuse, and most of these persons engage in risky use. More than 85 000 deaths per year are attributable to alcohol misuse; it is the estimated third leading cause of preventable deaths in the United States.

The U.S. Preventive Services Task Force recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings (B Recommendation).

*The USPSTF concludes that the evidence is insufficient to recommend for or against screening and behavioral counseling interventions to prevent or reduce alcohol misuse by adolescents in primary care settings (I Statement).*<sup>206</sup>

#### Canadian Task Force on Preventive Health Care Recommendations (1994)

In 1989 the Canadian Task Force on the Periodic Health Examination concluded that there was fair evidence that routine case-finding for problem drinking, and that brief counselling intervention in patients identified thereby was effective in reducing alcohol consumption and related consequences. The studies which yielded this evidence have since been confirmed by seven new randomized controlled trials in

<sup>&</sup>lt;sup>206</sup> Moyer VA. Screening and behavioral counseling interventions in primary care to reduce alcohol misuse: U.S. preventive services task force recommendation statement. *Annals of Internal Medicine*. 2013; 159(3): 210-8.

study populations that included both men and women aged 18-60 years. Standardized interviewing strategies and questionnaires are more sensitive than clinical judgement and can be used routinely with all adults to raise the index of clinical suspicion of problem drinking. When problem drinkers are identified, either simple advice or brief counselling is effective in reducing alcohol consumption and diminishing the negative consequences of drinking. The intervention of simple advice or brief counselling is appropriate for the patient with mild to moderate as opposed to severe alcohol dependency. Problem drinking or mild to moderate, rather than severe dependency is the focus of this report.

Routine active case-finding of problem drinking by physicians is highly recommended on the basis of the high prevalence of this problem in medical practices, its association with adverse consequences before the stage of dependency is reached, and its amenability to a counselling intervention by physicians. Detection by biomarkers is not recommended, although these may be used to confirm clinical suspicions raised by use of the CAGE query, MAST or AUDIT questionnaires, and may be useful for monitoring the patient's progress. Either simple advice or the brief counselling intervention may be used with equal effectiveness in reducing alcohol consumption in problem drinkers. The counselling intervention is probably most effective in the context of an established and effective doctor-patient relationship.<sup>207</sup>

Utilization of This Clinical Preventive Service

#### **Currently in British Columbia**

We are not aware of any data in B.C. which indicates the overall proportion of problem drinkers who are asked by their clinician about alcohol consumption and who receive advice beyond simply to stop drinking. We did find the following quote in an article by Ogborne and DeWit: "The 1989 Canadian survey (Rush and Tyas, 1994) showed that only 9% of those who reported alcohol as having a negative effect in at least one life area also reported seeking help for drinking."<sup>208</sup> In a 2008/09 survey of non-pregnant B.C. women, less than 2% of women reported that their provider specifically talked to them about alcohol and its effects on conception and/or pregnancy.<sup>209</sup>

For comparison, a survey out of the Centre for Addictions and Substance Abuse found that in the U.S., 94% of primary care physicians failed to include substance abuse in their possible diagnosis when presented with a hypothetical case of early symptoms of alcohol abuse. Furthermore, of patients who did eventually seek out treatment (all substance abuse not only alcohol), 74.1% said that their primary physician was not a significant factor and 16.7% said they were involved only 'a little.'<sup>210</sup> This would leave 9.2% of patients to say their primary physician was 'involved a lot.'

<sup>&</sup>lt;sup>207</sup> Haggerty JL. Canadian Guide to Clinical Preventive Health Care: Chapter 42: Early Detection and Counselling of Problem Drinking. 1994. Health Canada. Available at http://www.phac-aspc.gc.ca/publicat/clinic-clinique/pdf/s6c42e.pdf. Accessed July 2008.

<sup>&</sup>lt;sup>208</sup> Ogborne AC, DeWit DJ. Lifetime use of professional and community services for help with drinking: results from a Canadian population survey. *Journal of Studies on Alcohol.* 1999; 60(6): 867-72.

<sup>&</sup>lt;sup>209</sup> BC Stats, Ministry of Citizens' Services, and the Women's Healthy Living Secretariat, Ministry of Healthy Living and Sport. *Healthy Choices in Pregnancy: Results from the Community Health Education and Social Services Omnibus Survey in British Columbia, April 2008 to March 2009*. Available at

http://www.health.gov.bc.ca/library/publications/year/2010/bcstats-hcip-report.pdf. Accessed February, 2014. <sup>210</sup> The National Center on Addiction and Substance Abuse. *Missed Opportunity: National Survey of Primary Care Physicians and Patients on Substance Abuse.* 2000. Available at http://www.casacolumbia.org/addiction-research/reports/national-survey-primary-care-physicians-patients-substance-abuse. Accessed October 2013.

#### Best in the World

A study of guidance for problem drinking was done using data drawn from the 1998 Healthcare for Communities Survey in the U.S.<sup>211</sup> Those who had visited a general medical provider (GMP) in the previous 12 months (n=7,371 or 74% of the study population) were interviewed to determine whether the GMP had inquired about alcohol or drug use; 29% indicated they had been asked. The 18-29 age group was most likely to be asked about alcohol and drug use (35.8%), whereas of those 60 and older, only 19.3% were asked. Of all the patients who were asked about alcohol or drug use, 21% received counselling or advice. Based on this survey, just over 6% (21% of 29%) of patients visiting a GMP received counseling or advice for alcohol misuse.

A 1997 survey of 10 states through the Behavioural Risk Factor Surveillance System found that 23% of binge drinkers (5 or more drinks on at least one occasion in the past month) who had a routine check-up in the previous year were talked to about their alcohol use.<sup>212</sup>

In a randomized controlled trial in Denmark, 143 GPs were encouraged to initiate screening and brief intervention (SBI) for problem drinking through direct mail, telephone or academic detailing. Eighty-one GPs requested an SBI package, but 43 of those doctors reported they had never initiated screening and brief intervention, leaving 38 of the original 143 GPs to initiate at least one iteration of SBI. Assuming problem drinkers are equally spread out between GPs, and that all problem drinkers were reached by those physicians who did initiate screening and brief interventions, it is possible that up to 26.6% of problem drinkers were reached.<sup>213</sup>

#### Relevant British Columbia Population in 2010

Based on the 2010 CCHS data, 44.1% of the B.C. population between the ages of 18 and 54 reported having 5 or more drinks on at least one occasion in the past 12 months. For those 55 years of age and older, this proportion decreases to 17.5%. The total population of 'problem drinkers' in B.C. in 2010 was 1,233,101, as indicated in Table 6-1.<sup>214</sup>

It is important to note that the use of self-reported CCHS data likely under-represents the prevalence of 'problem drinkers' in British Columbia. There are a number of reasons for this. First, when responding to surveys, individuals tend to underestimate their actual alcohol consumption,<sup>215</sup> particularly those who consume a higher volume of drinks.<sup>216</sup> Second, the CCHS excludes individuals who live in group shelters or on the streets and who are at a higher risk of consuming alcohol during pregnancy than the general population. And third, while the CCHS uses 5 or more drinks on one occasion to define binge drinking in males and

<sup>&</sup>lt;sup>211</sup> D'Amico EJ, Paddock SM, Burnam A et al. Identification of and guidance for problem drinking by general medical providers: results from a national survey. *Medical Care*. 2005; 43(3): 229-36.

<sup>&</sup>lt;sup>212</sup> Denny CH, Serdula MK, Holtzman D et al. Physician advice about smoking and drinking: are U.S. adults being informed? *American Journal of Preventive Medicine*. 2003; 24(1): 71-4.

<sup>&</sup>lt;sup>213</sup> Hansen LJ, Olivarius N, Beich A et al. Encouraging GPs to undertake screening and a brief intervention in order to reduce problem drinking: a randomized controlled trial. *Family Practice*. 1999; 16(6): 551-7.

<sup>&</sup>lt;sup>214</sup> This analysis is based on the Statistics Canada's Canadian Community Health Survey 2010 Public Use Microdata File. All computations, use and interpretation of these data are entirely that of H. Krueger & Associates Inc.

<sup>&</sup>lt;sup>215</sup> Stockwell T, Donath S, Cooper-Stanbury M et al. Under-reporting of alcohol consumption in household surveys: a comparison of quantity-frequency, graduated-frequency and recent recall. *Addiction*. 2004; 99(8): 1024-33.

<sup>&</sup>lt;sup>216</sup> Taylor B, Rehm J, Patra J et al. Alcohol-attributable morbidity and resulting health care costs in Canada in 2002: recommendations for policy and prevention. *Journal of Studies on Alcohol and Drugs*. 2007; 68(1): 36-47.

	Table 6-1: Alcohol ConsumptionBritish Columbia, 2010Canadian Community Health Survey (CCHS), Annual Component 2010										
	CCHS Surve the past 12		#1: During ve you had a			% of Population having 5 or more drinks on at least one occasion in the past 12 months					
Age Group	Total	No	Yes	Total	Never	At Least Once					
18-19	92,271	13,622	78,649	78,374	23,283	55,091	59.71%				
20-24	311,645	49,841	261,804	260,317	54,454	205,863	66.06%				
25-29	312,711	55,834	256,877	255,273	87,027	168,246	53.80%				
30-34	275,735	51,388	224,347	221,949	90,728	131,221	47.59%				
35-39	291,201	67,555	223,646	220,239	112,274	107,965	37.08%				
40-44	324,696	68,851	255,845	253,933	140,907	113,026	34.81%				
45-49	354,777	37,279	317,498	317,245	182,744	134,501	37.91%				
50-54	362,309	79,979	282,330	281,798	173,467	108,331	29.90%				
Total	2,325,345	424,349	1,900,996	1,889,128	864,884	1,024,244	44.05%				
55-59	297,995	67,304	230,691	228,061	152,965	75,096	25.20%				
60-64	264,869	57,925	206,944	205,897	141,702	64,195	24.24%				
65-69	206,626	50,263	156,363	154,644	122,943	31,701	15.34%				
70-74	157,443	36,625	120,818	119,963	99,521	20,442	12.98%				
75-79	114,657	33,820	80,837	80,476	69,432	11,044	9.63%				
80+	154,458	58,620	95,838	93,846	87,467	6,379	4.13%				
Total	1,196,048	304,557	891,491	882,887	674,030	208,857	17.46%				

females, evidence suggests that 4 or more drinks on one occasion would be a more appropriate definition for females.<sup>217</sup>

#### HealthPartners Research Foundation and Partnership for Prevention

As background data for the Clinical Prevention Policy Review Committee's *A Lifetime of Prevention* report,<sup>218</sup> H. Krueger & Associates Inc. was asked to duplicate the U.S. work of the Partnership for Prevention and HealthPartners Research Foundation using B.C.-specific data whenever possible to determine whether the U.S. rankings would hold in this province. We were able to access technical reports for 10 services, one of which was for screening and counseling to reduce alcohol misuse.<sup>219</sup>

The results of updating the original U.S. model with B.C.-specific data are included in Tables 6-2 to 6-5.

The first step in calculating original CPB was to calculate the alcohol attributable deaths (*mortality*) and years of life lost due to both chronic and acute conditions. As indicated in Table 6-2, an estimated 981 deaths and 22,829 years of life lost are attributable to alcohol

<sup>&</sup>lt;sup>217</sup> Wechsler H, Dowdall GW, Davenport A et al. A gender-specific measure of binge drinking among college students. *American Journal of Public Health*. 1995; 85(7): 982-5.

<sup>&</sup>lt;sup>218</sup> Clinical Prevention Policy Review Committee. A Lifetime of Prevention: A Report of the Clinical Prevention Policy Review Committee. 2009. Available at

http://www.health.gov.bc.ca/library/publications/year/2009/CPPR\_Lifetime\_of\_Prevention\_Report.pdf. Accessed August 2013.

<sup>&</sup>lt;sup>219</sup> H. Krueger & Associates Inc. *Establishing Priorities among Effective Clinical Prevention Services in British Columbia: Summary and Technical Report.* 2008. H. Krueger & Associates Inc.

misuse in a B.C. birth cohort of 40,000. Years of life lost due to chronic conditions are estimated at 8,361 while years of life lost due to acute conditions are estimated at 14,468. These values were used to populate rows a1 and a2 in Table 6-4.

The next step was to calculate the alcohol-attributable *morbidity*-related QALYs lost from both chronic and acute conditions. As indicated in Table 6-3, an estimated 5,485 QALYs are lost in a B.C. birth cohort of 40,000 due to alcohol-attributable morbidity. QALYs lost due to chronic conditions are estimated at 4,335 while QALYs lost due to acute conditions are estimated at 1,150. These values were used to populate rows *a3* and *a4* in Table 6-4.

40,000 (B.C.)									
	Alcohol		Alcohol	Average	Alcohol				
	Attributable		Attributable	Life	Attrib. Life				
Conditions	Fraction	Total Deaths	Deaths	Expectancy	Years Lost				
Chronic	r								
Acute pancreatitis	0.2400	41	10	13.8	135				
Alcohol abuse	1.0000	10	10	27.8	279				
Alcoholic cardiomyopathy	1.0000	10	10	20.8	214				
Alcohol dependence syndrome	1.0000	-	-		-				
Alcoholic polyneuropathy	1.0000	0	0	15.0	1				
Alcoholic gastritis	1.0000	1	1	22.4	14				
Alcoholic liver disease	1.0000	150	150	22.0	3,302				
Alcoholic psychosis	1.0000	7	7	13.4	96				
Breast cancer	0.0155	601	9	19.6	182				
Chronic hepatitis	0.0237	3	0	15.0	1				
Chronic pancreatitis	0.8400	4	3	17.1	57				
Epilepsy	0.1500	16	2	23.3	55				
Esophageal cancer	0.0589	186	11	15.2	167				
Esophageal varices	0.4000	3	1	15.8	19				
Fetal alcohol syndrome	1.0000	-	-		-				
Gastroesophageal hemorrhage	0.4700	1	0	11.9	6				
Hypertension	0.0454	772	35	9.9	347				
Ischemic heart disease	0.0018	8,196	15	9.1	134				
Laryngeal cancer	0.0896	60	5	16.3	88				
Liver cancer	0.0807	194	16	13.2	206				
Liver cirrhosis unspecified	0.6207	193	120	15.7	1,883				
Low birth weight/prematurity	0.0330	41	1	77.9	106				
Oropharyngeal cancer	0.0983	101	10	18.1	180				
Portal hypertension	0.4000	2	1	15.5	10				
Prostate cancer	0.0145	645	9	9.3	87				
Stroke, hemorrhagic	0.0856	527	45	12.5	564				
Stroke, ischemic	0.0565	464	26	7.7	202				
Supraventricular cardiac dysrhythmia	0.0282	140	4	6.6	26				
Chronic Total		12,369	503		8,361				
Acute	0.18	0	1	20.0	41				
Air space transport		8	1	28.8	41				
Alcohol poisoning	1.00	3	3	33.3	100				
Aspiration	0.18	16	3	13.6	40				
Child maltreatment	0.16	12	2	72.1	136				
Drowning	0.34	33	11	34.1	384				
Excessive blood alcohol level	1.00	0	0	21.9	1				
Fall injuries	0.32	291	93	9.4	876				
Fire injuries	0.42	36	15	20.2	308				
Firearm injuries	0.18	8	1	38.8	57				
Homicide	0.47	174	82	41.5	3,386				
Hypothermia	0.42	6	3	15.9	41				
Motor vehicle non-traffic crashes	0.18	13	2	28.8	68				
Motor vehicle traffic crashes (men)	0.33	330	109	37.0	4,028				
Motor vehicle traffic crashes (women)	0.20	162	32	41.3	1,342				
Occupational and machine injuries	0.18	19	3	25.2	85				
Other road vehicle crashes	0.18	8	1	34.0	47				
Poisoning (not alcohol)	0.29	111	32	34.1	1,093				
Suicide	0.23	353	81	29.5	2,393				
Water transport	0.18	7	1	33.5	45				
Acute Total		1,590	478		14,468				

			(B.C.)					
	Alcohol		Number of Life	AA		Duration of		AA
	Attributable	Incidence	Years Lived in	Disease		Condition	QALY	QALYs
Conditions	Fraction	Rate	<b>Relevant Cohort</b>	Cases	Туре	(in yrs)	Weight	Lost
Chronic			1		I			
Acute pancreatitis	0.2400	0.0010948	2,422,871	637	inpatient stays	0.058	0.3	11
Alcohol abuse	1.0000	0.0003334	2,422,871	808	inpatient stays	1.600	0.3	388
Alcohol dependence								
syndrome	1.0000	0.0005872	2,422,871		inpatient stays	1.600	0.3	683
Alcoholic gastritis	1.0000	0.0000299	2,422,871	72	inpatient stays	0.058	0.3	1
Alcoholic liver disease	1.0000	0.0002787	2,422,871	675	inpatient stays	7.800	0.2	1,053
Alcoholic psychosis	1.0000	0.0006021	2,422,871	1,459	inpatient stays	1.600	0.3	700
Breast cancer	0.0155	0.0009440	1,260,668	18	new cases	4.300	0.2	16
Chronic pancreatitis	0.8400	0.0000995	2,422,871	203	inpatient stays	0.058	0.3	4
Epilepsy	0.1500	0.0002687	2,422,871	98	inpatient stays	9.200	0.2	180
Esophageal cancer	0.0589	0.0000630	2,422,871	9	new cases	1.813	0.3	5
Gastroesophageal								
hemorrhage	0.4700	0.0000647	2,422,871	74	inpatient stays	0.057	0.3	1
Hypertension	0.0454	See stroke	s below					-
Ischemic heart disease	0.0020	0.0093660	2,422,871	45	inpatient stays	0.058	0.3	1
Laryngeal cancer	0.0896	0.0000490	2,422,871	11	new cases	4.302	0.2	9
Liver cancer	0.0807	0.0000770	2,422,871	15	new cases	1.770	0.3	8
Liver cirrhosis								
unspecified	0.6207	0.0001692	2,422,871	254	inpatient stays	7.800	0.2	397
Low birth weight/								
prematurity	0.0330	0.0001543	2,422,871	12	inpatient stays	0.249	0.3	1
Oropharyngeal cancer	0.0983	0.0001513	2,422,871	36	new cases	4.299	0.2	31
Prostate cancer	0.0145	0.0022970	1,162,203	39	new cases	4.500	0.2	35
Stroke	0.0430	0.0024882	2,422,871	259	1st strokes	7.800	0.4	809
Supraventricular								
cardiac dysrhythmia	0.0282	0.0022343	2,422,871	153	inpatient stays	0.058	0.3	3
Chronic Total				6,299				4,335
					•			
Acute								
Air space transport	0.18	0.0022103	2,621,410	1,043	injuries	0.077	0.3	24
Alcohol poisoning	1	See poisor	ing below					
Aspiration	0.18	0.0001269	2,621,410	60	injuries	0.077	0.3	1
Child maltreatment	0.16	0.0045169	594,297	430	injuries	0.115	0.3	15
Drowning	0.34	0.0000045	2,621,410	4	injuries	0.079	0.3	0
Fall injuries	0.32	0.0265129	2,621,410	22,240	injuries	0.077	0.3	513
Fire injuries	0.42	0.0015342	2,621,410	1,689	injuries	0.077	0.3	39
Firearm injuries	0.18	0.0000539	2,621,410	25	injuries	0.115	0.3	1
Homicide and assault	0.47	0.0061893	2,621,410	7,626	injuries	0.115	0.3	264
Motor vehicle traffic								
crashes	0.29	0.0104235	3,215,707	9,720	injuries	0.077	0.3	224
Occupational and								
machine injuries	0.18	0.0012189	2,621,410	575	injuries	0.077	0.3	13
Poisoning		0.0016947	2,621,410	1,288	injuries	0.077	0.3	30
Suicide and self harm		0.0012192	2,621,410	735	injuries	0.115		25
Water transport			air space transport				0.3	
Acute Total				45,436				1,15
			·					
Grand Total				51,735				5,48

# Table 6-3: Quality of Life Reduction Attributable to Alcohol Use in a Birth Cohort of 40,000

Table 6-4 provides an overview of calculating the clinically preventable burden associated with screening and counselling to reduce alcohol misuse. Based on the assumptions used in the modelling, an estimated 1,822 QALYs could be saved in a birth cohort of 40,000.

a Birth Cohort of 40,000 (B.C.)								
Row Label	Variable	Base Case	Data Source					
	Burden of disease attributable to non-dependent hazardo	ous drinking						
a1	Alcohol-attributable life years lost to chronic conditions	8,361	Table 6-2					
a2	Alcohol-attributable life years lost to acute conditions	14,468	Table 6-2					
a3	Alcohol-attributable morbidity-related QALYs lost from chronic conditions	4,335	Table 6-3					
a4	Alcohol-attributable morbidity-related QALYs lost from acute conditions	1,150	Table 12-3					
a5	Total alcohol-attributable QALYs lost	28,314	= a1 + a2 + a3 + a4					
a6	Delivery of screening and counseling	9%	V					
a7	Predicted alcohol-attributable QALYs lost	28,587	= a5 / (1 - a6 · a10 · a13)					
	Adherence, effectiveness, and efficacy							
a8	Adherence with screening	86.0%	V					
a9	Average sensitivity of CAGE & AUDIT questionnaires	70%	V					
a10	Effectiveness of counseling at changing behavior	17.4%	V					
a11	Efficacy of behavior change at reducing acute conditions	90%	Assumed					
a12	Efficacy of behavior change at reducing chronic conditions	25%	Assumed					
	Weighted efficacy of behavior change at reducing total		= [a11 · (a2 + a4)					
a13	alcohol-attributable QALYs lost	60.9%	+ a12 · (a1 + a3)] / a5					
a14	QALYs gained, CPB	1,822	$= a7 \cdot a8 \cdot a9 \cdot a10 \cdot a13$					

Table 6-4: CPB of Screening and Counseling to Reduce Alcohol Misuse for

Table 6-5 provides an overview of calculating the cost effectiveness associated with screening and counseling to reduce alcohol misuse. Based on the assumptions used in the modelling, the cost per QALY saved is -\$24,391 (Table 6-5, row a57).

Table 6	-5: CE of Screening and Counseling to Redu 40,000 (B.C.		suse for a Birth Cohort of
Row	Variable		Data Sourco
Label a15	Years of life in birth cohort between ages 18-55	Base Case 1,443,493	Data Source √
a15 a16	Years of life in birth cohort ages 55+	1,058,727	v V
a10 a17	Portion of person-years with alcohol misuse, ages 18-54	48.00%	v v
a18	Portion of person-years with alcohol misuse, ages 55+	15.30%	V
	Costs of screening and counseling		
a19	Cost of 10-minute office visit	\$26.71	V
a20	Value of patient time and travel for office visit	\$41.51	√
a21	Portion of 10-minute office visit for screen	10%	Assumed
a22	Portion of 10-minute office visit for history for false positives	20%	Assumed
a23	Portion of 10-minute office visit for history and counseling for true positives	50%	Assumed
a24	Screens per year ages 18-55	1.0	Assumed
a25	Screens per year ages 55+	0.5	Assumed
a26	Average specificity of CAGE & AUDIT questionnaires	85%	v
a27	Cost of screening over lifetime of birth cohort	\$11,574,997	= (a15 · a24 + a16 · a25) · a8 · (a19 + a20) · a21
a28	Cost of thorough history and counseling, including false positives, over lifetime of birth cohort	\$18,000,053	$= (a15 \cdot a24 \cdot a17 + a16 \cdot a25 \cdot a18)$ $\cdot a8 \cdot a9 \cdot (a19 + a20) \cdot a23 +$ $(a15 \cdot a24 \cdot (1 - a17) + a16 \cdot a25 \cdot (1 - a18)) \cdot a8 \cdot (1 - a18)) \cdot a8 \cdot (1 - a26) \cdot (a19 + a20) \cdot a22$
	Financial savings		
a29	Alcohol-attributable medical costs	\$229,115,590	√
a30	Other alcohol-attributable costs, including alcohol- related crimes, motor vehicle crashes, fire destruction and social welfare administration	\$406,926,623	V
a31	Predicted alcohol-attributable medical costs in the absence of current screening	\$231,343,878	= a29 / (1 - a6 · a10 · a13)
a32	Predicted other alcohol-attributable costs in the absence of current screening	\$412,547,249	= a30 / (1 - a6 · a10 · a11)
a33	Prevented alcohol-attributable medical costs	\$15,418,730	= a31 · a8 · a9 ·a10 · a13
a34	Portion of other (non-medical) alcohol-attributable costs preventable through behavior change	90%	Assumed
a35	Prevented other (non-medical) alcohol attributable costs	\$38,892,149	= a32 · a8 · a9 · a10 · a34
	Discounting and CE calculation		
a36	Median year for screen from age 18	24	V
a37	Corresponding discount factor for 3% annual rate	0.49	Present value tables
	Median year for follow-up history and counseling		
a38	from age 18	24	V
a39	Corresponding discount factor for 3% rate	0.49	Present value tables
a40	Median year for LYs saved	47	V Drocont value tables
a41	Corresponding discount factor for 3% rate	0.25	Present value tables
a42	Median year for acute QALYs saved	23	· · · · · · · · · · · · · · · · · · ·
a43	Corresponding discount factor for 3% rate	0.51	Present value tables
a44	Median year for chronic QALYs saved Corresponding discount factor for 3% rate	33	= a48 + 10 (i.e., acute + 10) Present value tables
a45 a46	Median year for medical costs prevented	0.38	= a48 + 5 (i.e., acute + 5)
a46 a47	Corresponding discount factor for 3% rate	0.44	= a48 + 5 (I.e., acute + 5) Present value tables
a47 a48	Median year for non-medical costs prevented	23	= acute
a48 a49	Corresponding discount factor for 3% rate	0.51	Present value tables
a49 a50	Portion of QALYs saved from LYs saved (acute and chronic)	0.88	= (a1·a12 + a2·a11) / (a5 · a13)
a51	Portion of QALYs saved from acute morbidity prevented	0.06	= (a4 · a11) / (a5 · a13)
a52	Portion of QALYs saved from chronic morbidity prevented	0.06	= (a3 · a12) / (a5 · a13)
a53	Discounted cost of initial screen	\$5,671,748	= a27 · a37
a54	Discounted costs of follow-up history and counseling	\$8,820,026	= a28 · a39
a55	Discounted costs saved	\$26,619,237	= a33 · a47 + a35 · a49
a56	Discounted QALYs saved	497	= a14 · (a50 · a41 + a51 · a43 + a52 · a45)
a57	CE (\$/QALY saved)	-\$24,391	= (a53 + a54 - a55) / a56
	Net cost per person ever screened	-\$305	= (a53 + a54 - a55) / Cell C58

√ = Estimates from the literature

# Updating CPB and CE

For the current process, the Lifetime Prevention Schedule Expert Advisory Committee recommended that the previous modelling results be updated based on the following:<sup>220</sup>

- Incorporate the best available updated data on the clinical effectiveness of the maneuver, if appropriate
- Incorporate the best available updated evidence on the age to start or stop the maneuver, if appropriate
- Incorporate updated B.C. population numbers for the applicable cohort
- Incorporate updated data on the utilization of the maneuver in B.C. by this cohort
- Incorporate updated costs (from 2000 to 2013 Canadian dollars)
- Run a sensitivity analysis for both CPB and CE based on major assumptions included in the models

The number of years lived used in Table 6-3 was updated by sex and 5-year age group based on life tables for 2009 to 2011 for B.C. (from the previous 2000 to 2002 life tables).<sup>221</sup> The updated calculation of QALYs lost to alcohol-attributable morbidity of 5,650 (see Table 6-6) compares to the previous estimate of 5,485 (see Table 6-3). QALYs lost due to chronic conditions are estimated at 4,468 while QALYs lost due to acute conditions are estimated at 1,182. These values were used to populate rows *a3* and *a4* in Table 6-7.

 <sup>&</sup>lt;sup>220</sup> H. Krueger & Associates Inc. Evidence Review and Economic Modelling of Preventive Health Maneuvers to Update the BC Lifetime Prevention Schedule: Methodology Report. October 21, 2013.
 <sup>221</sup> See http://www.statcan.gc.ca/pub/84-537-x/2013005/tbl-eng.htm. Accessed December 2013.

			(B.C.)					
	Alcohol		Number of Life	AA		Duration of		AA
	Attributable	Incidence	Years Lived in	Disease		Condition	QALY	QALYs
Conditions	Fraction	Rate	Relevant Cohort	Cases	Туре	(in yrs)	Weight	Lost
Chronic								
Acute pancreatitis	0.2400	0.0010948	2,497,396	656	inpatient stays	0.058	0.3	11
Alcohol abuse	1.0000	0.0003334	2,497,396	833	inpatient stays	1.600	0.3	400
Alcohol dependence								
syndrome	1.0000	0.0005872	2,497,396	1,467	inpatient stays	1.600	0.3	704
Alcoholic gastritis	1.0000	0.0000299	2,497,396	75	inpatient stays	0.058	0.3	1
Alcoholic liver disease	1.0000	0.0002787	2,497,396	696	inpatient stays	7.800	0.2	1,086
Alcoholic psychosis	1.0000	0.0006021	2,497,396	1,504	inpatient stays	1.600	0.3	722
Breast cancer	0.0155	0.0009440	1,300,953	19	new cases	4.300	0.2	16
Chronic pancreatitis	0.8400	0.0000995	2,497,396	209	inpatient stays	0.058	0.3	4
Epilepsy	0.1500	0.0002687	2,497,396	101	inpatient stays	9.200	0.2	185
Esophageal cancer	0.0589	0.0000630	2,497,396	9	new cases	1.813	0.3	5
Gastroesophageal								
hemorrhage	0.4700	0.0000647	2,497,396	76	inpatient stays	0.057	0.3	1
Hypertension	0.0454	See stroke	s below					-
Ischemic heart disease	0.0020	0.0093660	2,497,396	47	inpatient stays	0.058	0.3	1
Laryngeal cancer	0.0896	0.0000490	2,497,396	11	new cases	4.302	0.2	9
Liver cancer	0.0807	0.0000770	2,497,396	16	new cases	1.770	0.3	8
Liver cirrhosis								
unspecified	0.6207	0.0001692	2,497,396	262	inpatient stays	7.800	0.2	409
Low birth weight/								
prematurity	0.0330	0.0001543	2,497,396	13	inpatient stays	0.249	0.3	1
Oropharyngeal cancer	0.0983	0.0001513	2,497,396	37	new cases	4.299	0.2	32
Prostate cancer	0.0145	0.0022970	1,196,443	40	new cases	4.500	0.2	36
Stroke	0.0430	0.0024882	2,497,396	267	1st strokes	7.800	0.4	834
Supraventricular								
cardiac dysrhythmia	0.0282	0.0022343	2,497,396	157	inpatient stays	0.058	0.3	3
Chronic Total				6,493				4,468
Acute				4 070		0.077		
Air space transport	0.18	0.0022103	2,696,260	1,073	injuries	0.077	0.3	25
Alcohol poisoning	1	See poisor				0.077		
Aspiration		0.0001269	2,696,260	62	injuries	0.077	0.3	1
Child maltreatment		0.0045169	597,390	432	injuries	0.115	0.3	15
Drowning	0.34	0.0000045	2,696,260	4	injuries	0.079	0.3	0
Fall injuries	0.32	0.0265129	2,696,260	22,875	injuries	0.077	0.3	528
Fire injuries		0.0015342	2,696,260	1,737	injuries	0.077	0.3	40
Firearm injuries	0.18	0.0000539	2,696,260	26	injuries	0.115	0.3	1
Homicide and assault	0.47	0.0061893	2,696,260	7,843	injuries	0.115	0.3	271
Motor vehicle traffic	0.00	0.0404005	2 202 650	0.050		0.077		220
crashes	0.29	0.0104235	3,293,650	9,956	injuries	0.077	0.3	230
Occupational and	0.40	0.0012102	2,000,200	502	in lucit	0.077	0.0	
machine injuries		0.0012189	2,696,260	592	injuries	0.077	0.3	14
Poisoning		0.0016947	2,696,260	1,325	injuries	0.077	0.3	31
Suicide and self harm		0.0012192	2,696,260	756	injuries	0.115	0.3	26
Water transport	0.18	included in	air space transport				0.3	4 4 4 4
Acute Total				46,681				1,182
Adde Total								

The previous model estimated the effectiveness of counseling at changing behavior to be 17.4% (see Table 6-4, row a10). A more recent meta-analysis for the USPSTF found an improvement of 10.9% (95% CI of 8.3% to 13.4%) in the proportion of adults achieving

recommended drinking limits associated with brief counselling interventions.<sup>222</sup> The same meta-analysis also found an 11.8% (95% CI of 8.3% to 13.4%) improvement in the proportion of adults with no heavy drinking episodes after 12 months. We used the 10.9% to populate row all of Table 6-7 (effectiveness of counseling at changing behavior re: chronic conditions) and the 11.8% to populate row a12 of Table 6-7 (effectiveness of counseling at changing behavior re: acute conditions).

Based on the above assumptions, the updated calculation of CPB is 1,136 QALYs (see Table 6-7, row a15). The CPB of 1,136 represents the gap between no coverage and the 'best in the world' coverage estimated at 35%.

Table	6-7: CPB of Screening and Counseling to R	educe Al	cohol Misuse for
	a Birth Cohort of 40,000 (B	s.C.)	
Row	Veriekle	Dava Casa	Dete Course
Label	Variable Burden of disease attributable to non-dependent hazardo	Base Case	Data Source
a1	Alcohol-attributable life years lost to chronic conditions	8,361	Table 12-2
a2	Alcohol-attributable life years lost to acute conditions	14,468	Table 12-2
a3	Alcohol-attributable morbidity-related QALYs lost from chronic conditions	4,468	Table 12-6
a4	Alcohol-attributable morbidity-related QALYs lost from acute conditions	1,182	Table 12-6
a5	Alcohol-attributable QALYs lost to chronic conditions	12,829	=a1 + a3
a6	Alcohol-attributable QALYs lost to acute conditions	15,650	=a2 + a4
a7	Current delivery of screening and counseling	0%	V
a8	Predicted alcohol-attributable QALYs lost to chronic conditions	12,829	= a6 / (1 - a7 * a11)
a9	Predicted alcohol-attributable QALYs lost to acute conditions	15,650	= a6 / (1 - a7 * a11)
	Adherence, effectiveness, and efficacy		
a10	Adherence with screening	35.0%	V
a11	Effectiveness of counseling at changing behavior re: chronic conditions	10.9%	V
a12	Effectiveness of counseling at changing behavior re: acute conditions	11.8%	V
a13	Potential QALYs gained chronic conditions	489	= a8 * a18 * a19
a14	Potential QALYs gained acute conditions	646	= a9 * a18 * a20
a15	QALYs gained, CPB	1,136	= a13 + a14

We also modified several major assumptions and recalculated the CPB as follows:

Assume the effectiveness of counselling at changing behaviour is at the lower end of • the 95% CI for both chronic and acute conditions (Table 6-7, rows *all* and *al2*): CPB = 778

<sup>&</sup>lt;sup>222</sup> Jonas DE, Garbutt JC, Amick HR et al. Behavioral counseling after screening for alcohol misuse in primary care: a systematic review and meta-analysis for the U.S. Preventive Services Task Force. Annals of Internal Medicine. 2012; 157(9): 645-54.

- Assume the effectiveness of counselling at changing behaviour is at the higher end of the 95% CI for both chronic and acute conditions (Table 6-7, rows *al1* and *al2*): CPB = 1,489
- Assume the 'best in the world' delivery of screening and counselling is reduced from 35% to 25% (Table 6-7, row *a10*): CPB = 811
- Assume the 'best in the world' delivery of screening and counselling is increased from 35% to 45% (Table 6-7, row *a10*): CPB = 1,460

In updating the estimated CE for screening and counseling to reduce alcohol misuse, we made the following updates/assumptions:

- Years of life in birth cohort between ages 18-55 and 55+ The number of years lived used in Table 6-5 (rows *a15* and *a16*) was updated by sex and 5-year age group based on life tables for 2009 to 2011 for B.C. (from the previous 2000 to 2002 life tables) (rows *a* and *b* in Table 6-9).<sup>223</sup>
- **Portion of person-years with alcohol misuse, ages 18-54 and 55+** Updated based on number of years lived and proportion of persons by age group with alcohol misuse updated with 2010 CCHS data (see Table 6-8). The respective values for portion of person-years with alcohol misuse were used to populate rows *c* and *d* in Table 6-9.

		le 6-8: Al				
	B % of Population	ritish Colu	imbia, 20	13	# of	% of
	Having 5 or More				person-	person-
	Drinks on at Least	# of Life Ye	ars Lived fro	m Age x to	years with	years with
	One Occasion in Past	x+5 in Bi	rth Cohort o	f 40,000	alcohol	alcohol
Age Group	12 Months	Males	Females	Total	misuse	misuse
18-19	59.71%	39,405	40,141	79,546	47,493	
20-24	66.06%	98,208	100,211	198,419	131,070	
25-29	53.80%	97,819	100,045	197,864	106,455	
30-34	47.59%	97,405	99,855	197,260	93,875	
35-39	37.08%	96,890	99,582	196,472	72,843	
40-44	34.81%	96,205	99,181	195,386	68,014	
45-49	37.91%	95,252	98,588	193,840	73,488	
50-54	29.90%	93,864	97,705	191,570	57,280	
SubTotal	44.05%	715,048	735,309	1,450,357	650,518	44.9%
55-59	25.20%	91,787	96,375	188,162	47,418	
60-64	24.24%	88,655	94,335	182,990	44,350	
65-69	15.34%	83,935	91,159	175,094	26,863	
70-74	12.98%	76,895	86,173	163,068	21,172	
75-79	9.63%	66,677	78,375	145,052	13,972	
80+	4.13%	112,851	159,367	272,218	11,242	
SubTotal	17.46%	520,800	605,785	1,126,585	165,018	14.6%

• **Cost of an office visit** - We estimated the average cost of a visit to a General Practitioner to be \$34.00 based on information from the B.C. Medical Services Commission 2013 payment schedule<sup>224</sup> (Table 6-9, row *h*).

 <sup>&</sup>lt;sup>223</sup> See <u>http://www.statcan.gc.ca/pub/84-537-x/2013005/tbl-eng.htm</u>. Accessed December 2013.
 <sup>224</sup> Medical Services Commission. *Payment Schedule: Section 7 General Practice*. 2013. Available at http://www.health.gov.bc.ca/msp/infoprac/physbilling/payschedule/pdf/7-general-practice.pdf. Accessed December 2013.

- **Patient time costs** For patient time costs (Table 6-9, row *i*), we assumed an hourly wage of \$24.39 (the B.C. average in 2013)<sup>225</sup> plus 18% benefits applied to the estimated two hours of patient time required for a cost per physician visit of \$57.56.
- Alcohol-attributable medical and other costs A report by Rehm et al. estimated the annual "direct health care costs" of alcohol consumption in Canada in 2002 to be \$3.3 billion, with a further \$4.2 billion for law enforcement, prevention and research, fire and traffic accident damage costs.<sup>226</sup> We used these costs to estimate an annual per capita cost per individuals with alcohol misuse in Canada (i.e., \$431 and \$537 for health care and other costs, respectively). These costs were then updated to 2013 dollars using the health and personal care component of the B.C. Consumer Price Index (CPI) (+13.4%).<sup>227</sup> The result is an estimated \$488 in alcohol-attributable medical costs (Table 6-9, row *t*) and \$609 in alcohol-attributable other costs (Table 6-9, row *u*) per person with alcohol misuse per year.
- We assumed that the average behavioural counselling intervention would take 80% of an office visit (Table 6-9, row *n*) and be required an average of 2.5 times (Table 6-9, row *o*).
- We assumed that the behavioural counselling interventions would be required once every five years (Table 6-9, row *p*).
- Discount rate of 3%

Based on these assumptions, the estimated cost per QALY would be \$1,175 (see Table 6-9, row gg).

We also modified a major assumption and recalculated the cost per QALY as follows:

- Assume the effectiveness of counselling at changing behaviour is at the lower end of the 95% CI for both chronic and acute conditions (Table 6-7, rows *al1* and *al2*):
   \$/QALY = \$15,804
- Assume the effectiveness of counselling at changing behaviour is at the higher end of the 95% CI for both chronic and acute conditions (Table 6-7, rows *al1* and *al2*): \$/QALY = -\$6,360

<sup>&</sup>lt;sup>225</sup> Statistics Canada. Average Hourly Wages of Employees by Selected Characteristics and Occupation, Unadjusted Data, by Province (Monthly) (British Columbia). 2013. Available at http://www.statcan.gc.ca/tablestableaux/sum-som/l01/cst01/labr69k-eng.htm. Accessed December 2013.

<sup>&</sup>lt;sup>226</sup> Rehm J, Gnam W, Popova S et al. The social costs of alcohol, illegal drugs, and tobacco in Canada, 2002. *Journal of Studies on Alcohol and Drugs*. 2007; 68(6): 886-95.

<sup>&</sup>lt;sup>227</sup> Statistics Canada. *Table326-0021* - *Consumer Price Index (CPI), 2009 Basket, Annual (2002=100 unless otherwise noted).* 2013. Available at

http://www5.statcan.gc.ca/cansim/a26?lang=eng&retrLang=eng&id=3260021&paSer=&pattern=&stByVal=1&p1=1&p2=37&tabMode=dataTable&csid=. Accessed December 2013.

Statistics Canada. *Consumer Price Index, Health and Personal Care, by Province (Monthly) (British Columbia).* 2013. Available at http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/cpis13f-eng.htm. Accessed December 2013.

Row			
Label	Variable	Base Case	Data Source
а	Years of life in birth cohort between ages 18-55	1,450,357	<b>v</b>
b	Years of life in birth cohort ages 55+	1,126,585	√
с	Portion of person-years with alcohol misuse, ages 18-54	44.85%	Table 6-8
d	Portion of person-years with alcohol misuse, ages 55+	14.65%	Table 6-8
е	Person-years with alcohol misuse, ages 18-54	650,518	= a * c
f	Person-years with alcohol misuse, ages 55+	165,018	= b * d
g	Total person-years with alcohol misuse	815,535	= e + f
	Costs of screening and counseling		
h	Cost of 10-minute office visit	\$34.00	٧
i	Value of patient time and travel for office visit	\$57.56	٧
j	Portion of 10-minute office visit for screen	20%	Assumed
k	Screens per year ages 18-55	1.0	Assumed
I	Screens per year ages 55+	0.2	Assumed
m	Cost of screening over lifetime of birth cohort	\$10,739,727	=q*((a*k)*(h+i)*j)+q*((b*l)*(h+i)*j
n	Portion of 10-minute office visit for behavioural counseling	80%	Assumed
	intervention	8078	Assumed
0	Number of behavioural counseling interventions	2.5	٧
р	Intervention required every 5 years	0.2	Assumed
q	Adherence with screening	35%	Table 6-7 row a10 - Table 6-7 row a
r	Total behavioural counseliing interventions over lifetime of	142,719	= (g*o)*q*p
1	birth cohort	142,719	- (g 0) q p
s	Cost of behavioural counseliing interventions over lifetime of	\$10,453,860	= ((h + i) * n) * r
5	birth cohort	<i>910,433,000</i>	- ((11 + 1) + 1) + 1
	Costs avoided		
t	Annual per capita alcohol-attributable medical costs	-\$488	٧
	Annual per capita other alcohol-attributable costs, including		
u	alcohol-related crimes, motor vehicle crashes, fire destruction	-\$609	√
	and social welfare administration		
v	Life-years free of alcohol misuse with behavioural counselling	32,397	=(Table 6-7 row a11 + Table 6-7 row
	interventions	•	a12)/2*g*q
w	Prevented alcohol-attributable costs	-\$35,545,777	= v * (t + u)
х	CE calculation		
У	Cost of initial screen (undiscounted)	\$10,739,727	= m
Z	Costs of behavioural counseliing interventions (undiscounted)	\$10,453,860	= s
aa	Costs avoided (undiscounted)	-\$35,545,777	= w
bb	QALYs saved (Undiscounted)	1,136	Table 6-7 row a15
CC	Cost of initial screen (3% discount rate)	\$5,788,828	
dd	Costs of behavioural counseliing interventions (3% discount rate)	\$5,634,743	
ee	Costs avoided (3% discount rate)	-\$11,010,129	
ff	QALYs saved (3% discount rate)	352	
gg	CE (\$/QALY saved)	\$1,175	= (cc+dd-ee) / ff

#### √ = Estimates from the literature

# Summary

Table 6-10: Screening and	d Counseling	to Reduc	e Alcohol
Misuse for a Bi	irth Cohort o	of 40,000	
Su	ummary		
	Base		
	Case	Rai	nge
<b>CPB</b> (Potential QALYs Gained)			
Assume No Current Service			
3% Discount Rate	352	241	461
0% Discount Rate	1,136	778	1,489
Gap between B.C. Current (Unk	nown, assume 0%	6) and 'Best in	the World' (35%)
3% Discount Rate	352	241	461
0% Discount Rate	1,136	778	1,489
CE (\$/QALY) including patient time	costs		
3% Discount Rate	\$1,175	-\$6,360	\$15,804
0% Discount Rate	-\$12,636	-\$16,895	-\$4,358
<b>CE</b> (\$/QALY) <b>excluding</b> patient time	costs		
3% Discount Rate	-\$19,238	-\$21,930	-\$13,996
0% Discount Rate	-\$24,367	-\$25,842	-\$21,463

## The Prevention of Fetal Alcohol Spectrum Disorder

Prevalence of Alcohol Consumption During Pregnancy

Maternal alcohol consumption during pregnancy is an established cause of Fetal Alcohol Spectrum Disorder (FASD). While heavy consumption and binge drinking are clearly associated with FASD, the available research is less consistent with respect to modest levels of consumption.<sup>228</sup> As noted by Walker and colleagues, "the inconclusive nature of the body of research does not allow for the establishment of a non-harmful threshold for maternal alcohol consumption, and therefore, the public health promotion of no alcohol use during pregnancy is the safest measure to reduce fetal harm."<sup>229</sup>

Alcohol's teratogenic effects exist along a continuum from subtle to the most serious outcome, namely Fetal Alcohol Syndrome (FAS). FASD is a non-diagnostic term used as an umbrella term for the following four diagnoses:

- Fetal Alcohol Syndrome (FAS)
- Partial FAS (pFAS)
- Alcohol-Related Neuro-developmental Disorder (ARND)
- Alcohol-Related Birth Defects (ARBD).

The majority of Canadian women of child-bearing age consume alcohol. Based on Canadian Community Health Survey (CCHS) data for 2005, 81.9% of females between the ages of 20-49 consumed some alcohol within the year prior to being surveyed (see Table 7-1).<sup>230</sup>

	Table 7-1: Alcohol ConsumptionCanada, 2005All Females Aged 20-49												
Have you drank alcohol in the last 12 months?	20-24	25-29	30-34	35-39	40-44	45-49	Total						
Yes	920,639	861,554	839,404	908,551	1,104,714	1,043,152	5,678,014						
No	142,844	199,930	210,379	220,078	244,134	235,032	1,252,397						
% Yes	86.6%	81.2%	80.0%	80.5%	81.9%	81.6%	81.9%						
How often did you drink?	20-24	25-29	30-34	35-39	40-44	45-49	Tota	I					
Less than once a month	213,203	244,367	261,878	255,218	275,087	267,592	1,517,345	26.7%					
Once a month	140,708	125,286	119,556	135,042	128,953	102,667	752,212	13.2%					
2 to 3 times a month	196,732	146,438	144,390	143,097	175,324	147,970	953,951	16.8%					
Once a week	194,871	185,290	140,760	165,595	214,516	201,836	1,102,868	19.4%					
2 to 3 times a week	144,189	124,081	133,051	153,375	214,243	201,412	970,351	17.1%					
4 to 6 times a week	21,911	23,596	27,541	27,574	49,120	46,341	196,083	3.5%					
Every day	8,556	10,855	10,994	27,388	46,677	73,840	178,310	3.1%					

<sup>&</sup>lt;sup>228</sup> Bakker R, Pluimgraaff LE, Steegers EA et al. Associations of light and moderate maternal alcohol consumption with fetal growth characteristics in different periods of pregnancy: the Generation R Study. *International Journal of Epidemiology*. 2010; 39(3): 777-89.

 <sup>&</sup>lt;sup>229</sup> Walker MJ, Al-Sahab B, Islam F et al. The epidemiology of alcohol utilization during pregnancy: an analysis of the Canadian Maternity Experiences Survey (MES). *BioMed Central Pregnancy and Childbirth*. 2011; 11(1): 52.

<sup>&</sup>lt;sup>230</sup> This analysis is based on the Statistics Canada's Canadian Community Health Survey 2005 Public Use Microdata File. All computations, use and interpretation is entirely that of H. Krueger & Associates Inc.

The levels of alcohol consumption vary across Canada, although consumption in British Columbia in women of child-bearing age is similar to the Canadian average (see Table 7-2).<sup>231</sup>

	Table 7-2: Alcohol ConsumptionBritish Columbia, 2005All Females Aged 20-49													
Have you drank alcohol in the last 12 months?	20-24	25-29	30-34	35-39	40-44	45-49	Total	<u>.</u>						
Yes	121,852	110,520	118,520	114,475	134,833	146,040	746,240							
No	19,176	25,788	31,736	28,292	41,672	28,316	174,980							
% Yes	86.4%	81.1%	78.9%	80.2%	76.4%	83.8%	81.0%							
How often did you drink?	20-24	25-29	30-34	35-39	40-44	45-49	Tota	al						
Less than once a month	29,480	27,636	28,518	24,436	27,601	35,143	172,814	23.2%						
Once a month	17,787	14,910	16,941	15,182	17,691	15,794	98,305	13.2%						
2 to 3 times a month	25,007	18,256	20,399	19,918	21,478	20,885	125,943	16.9%						
Once a week	24,999	24,153	24,364	18,436	25,576	24,814	142,342	19.1%						
2 to 3 times a week	18,507	17,669	22,024	24,373	29,061	30,888	142,522	19.1%						
4 to 6 times a week	3,982	5,278	4,738	4,709	6,584	5,723	31,014	4.2%						
Every day	2,091	2,010	1,344	7,133	6,628	12,482	31,688	4.2%						

While the majority of women of child-bearing age consume some level of alcohol, most appear to refrain from using alcohol while pregnant. In 2007/08 for example, just 7.2% of pregnant women in B.C. reported consuming alcohol while pregnant (see Table 7-3).<sup>232</sup> This compares to a range of between 4.0% and 13.8% in the various geographic regions of Canada.<sup>233</sup> This rate also appears to have decreased over time in B.C., from 11.9% in 2000/01. This decrease in the self-reported rate of alcohol consumption during pregnancy has been observed throughout Canada.<sup>234</sup>

 <sup>&</sup>lt;sup>231</sup> This analysis is based on the Statistics Canada's Canadian Community Health Survey 2005 Public Use Microdata File. All computations, use and interpretation is entirely that of H. Krueger & Associates Inc.
 <sup>232</sup> This analysis is based on the Statistics Canada's Canadian Community Health Survey 2007/08 Public Use Microdata File. All computations, use and interpretation is entirely that of H. Krueger & Associates Inc.
 <sup>233</sup> Walker MJ, Al-Sahab B, Islam F et al. The epidemiology of alcohol utilization during pregnancy: an analysis of the Canadian Maternity Experiences Survey (MES). *BioMed Central Pregnancy and Childbirth*. 2011; 11(1): 52.

<sup>&</sup>lt;sup>234</sup> Thanh NX and Jonsson E. Drinking alcohol during pregnancy: evidence from Canadian Community Health Survey 2007/2008. *Canadian Journal of Clinical Pharmacology*. 2010; 17(2): e302-7.

	Table 7-3: Pregnancy and Alcohol ConsumptionBritish Columbia, 2007 & 2008 CombinedPregnant Females Aged 20-49													
Did you drink any alcohol during your last pregnancy?	20-24	25-29	30-34	35-39	40-44	45-49	Total							
Yes	1,446	1,830	2,150	3,690	428	821	10,365							
No	15,037	31,990	39,020	33,114	11,907	2,542	133,610							
% Yes	8.8%	5.4%	5.2%	10.0%	3.5%	24.4%	7.2%							
How often did you drink?	20-24	25-29	30-34	35-39	40-44	45-49	Tota	al						
Less than once a month	636	1,830	1,913	3,476	428	821	9,104	87.8%						
Once a month	-	-	141	136	-	-	277	2.7%						
2 to 3 times a month	-	-	-	78	-	-	78	0.8%						
Once a week	-	-	-	-	-	-	-	0.0%						
2 to 3 times a week	-	-	97	-	-	-	97	0.9%						
4 to 6 times a week	-	-	-	-	-	-	-	0.0%						
Every day	810	-	-	-	-	-	810	7.8%						

The self-reported rate of alcohol consumption during pregnancy in Canada of between 5 and 15% is considerably lower than the rate noted in other countries including France, Spain, Denmark, Australia, Chile, Mexico and Russia.<sup>235</sup> In an international study including 5,628 pregnant women surveyed at 15 weeks gestation from New Zealand, Australia, Ireland and the United Kingdom, for example, only 40% reported no alcohol consumption.<sup>236</sup> One-fifth reported 1-2 drinks per week; one-quarter reported 3-7 drinks per week; 11% reported 8-14 drinks per week and 5% reported >14 drinks per week. In addition, 1,905 (34%) reported binge drinking (6 or more drinks per drinking session) in the 3 months prior to their pregnancy. Of these 1,905, the majority (1,288 or 68%) reported binge drinking during the first 15 weeks of gestation and 840 reported at least two episodes of binge drinking. In the US, 30.3% of women reported drinking alcohol at some time during pregnancy, of which 8.3% reported binge drinking (4+ drinks on one occasion).<sup>237</sup> Binge drinking prior to pregnancy was the strongest predictor of both drinking during pregnancy (OR=8.52, 95% CI 6.67-10.88) and binge drinking during pregnancy (OR=36.02, 95% CI 24.63-52.69).

Using self-report data such as the CCHS likely represents an underestimate of a 'negative' behaviour, such as alcohol consumption during pregnancy. When responding to surveys, individuals tend to underestimate their actual alcohol consumption,<sup>238</sup> particularly those who consume a higher volume of drinks.<sup>239</sup> Furthermore, the CCHS excludes women who live in group shelters or on the streets, are currently in treatment programs or those in hospital or chronic care for mental health/addictions problems and who are at a higher risk of consuming

<sup>&</sup>lt;sup>235</sup> Zelner I and Koren G. Alcohol consumption among women. *Journal of Population Therapeutics and Clinical Pharmacology*. 2013; 20(2): e201-6.

<sup>&</sup>lt;sup>236</sup> McCarthy FP, O'Keeffe LM, Khashan AS et al. Association between maternal alcohol consumption in early pregnancy and pregnancy outcomes. *Obstetrics & Gynecology*. 2013; 122(4): 830-7.

<sup>&</sup>lt;sup>237</sup> Ethen MK, Ramadhani TA, Scheuerle AE et al. Alcohol consumption by women before and during pregnancy. *Maternal and Child Health Journal*. 2009; 13(2): 274-85.

<sup>&</sup>lt;sup>238</sup> Stockwell T, Donath S, Cooper-Stanbury M et al. Under-reporting of alcohol consumption in household surveys: a comparison of quantity-frequency, graduated-frequency and recent recall. *Addiction*. 2004; 99(8): 1024-33.

<sup>&</sup>lt;sup>239</sup> Taylor B, Rehm J, Patra J et al. Alcohol-attributable morbidity and resulting health care costs in Canada in 2002: recommendations for policy and prevention. *Journal of Studies on Alcohol and Drugs*. 2007; 68(1): 36-47.

alcohol during pregnancy than the general population, thus underestimating overall prevalence.<sup>240,241</sup>

This underestimate of self-reported alcohol consumption in pregnant women is supported by the research of Ethan and colleagues, who found that actual consumption is about three times that reported in surveys enquiring about alcohol consumption during the past month.<sup>242</sup> Alvik et al. used a longitudinal approach to ask about alcohol consumption at 17 and 30 weeks of pregnancy and 6 months after term.<sup>243</sup> They found that concurrently reported alcohol consumption during pregnancy is just under half that retrospectively reported 6 months after term. That is, once the baby was six months old, women admitted to consuming almost twice as much alcohol during their pregnancy than they admitted to while pregnant.

#### **Unplanned Pregnancies**

Half of all pregnancies in the United States are unplanned.<sup>244</sup> In adolescents (15-19 year olds) this increases to 82% and remains high at 64% in young adults (20-24 years old). These high rates of unplanned pregnancies did not decrease between 2001 and 2006.

The situation is similar in Britain.<sup>245</sup> In that country, only 12% of pregnancies in adolescents (16-19 year olds) are planned. This increases to 40% in young adults (20-24 years old) and to between 60-70% thereafter (see Table 7-4).

Unplanned Ambivalent Planned												
Age at Interview (years)	%	95% CI	%	95% CI	%	95% C						
16-19	45.2%	30.8-60.5	43.2%	28.7-59.0	11.6%	5.2-23						
20-24	17.4%	11.9-24.7	42.7%	34.2-51.5	40.0%	31.1-49						
25-29	11.0%	7.3-16.3	26.8%	21.1-33.5	62.2%	54.9-68						
30-34	14.2%	8.4-23.1	18.1%	12.6-25.3	67.7%	58.7-75						
35-44	12.9%	6.2-25.0	25.6%	15.1-40.1	61.4%	47.4-73						
Outcome of Pregnancy												
Full Term Pregnancy	5.7%	3.7-8.9	28.0%	23.6-32.9	66.3%	61.1-71						
Miscarriage	33.6%	23.2-45.8	31.1%	20.8-43.6	35.3%	25.5-46						
Abortion	57.1%	44.0-69.3	32.5%	22.1-45.0	10.4%	4.4-22						

<sup>&</sup>lt;sup>240</sup> Thanh NX and Jonsson E. Drinking alcohol during pregnancy: evidence from Canadian Community Health Survey 2007/2008. *Canadian Journal of Clinical Pharmacology*. 2010; 17(2): e302-7

<sup>&</sup>lt;sup>241</sup> Public Health Agency of Canada. *Alcohol Use and Pregnancy: An Important Canadian Public Health and Social Issue*. 2005. Available at http://www.addictionresearchchair.ca/wp-content/uploads/Alcohol-Use-and-Pregnancy-An-Important-Canadian-Health-and-Social-Issue.pdf. Accessed December 2013.

<sup>&</sup>lt;sup>242</sup> Ethen MK, Ramadhani TA, Scheuerle AE et al. Alcohol consumption by women before and during pregnancy. *Maternal and Child Health Journal*. 2009; 13(2): 274-85.

 <sup>&</sup>lt;sup>243</sup> Alvik A, Haldorsen T, Groholt B et al. Alcohol consumption before and during pregnancy comparing concurrent and retrospective reports. *Alcoholism: Clinical and Experimental Research*. 2006; 30(3): 510-5.
 <sup>244</sup> Finer LB and Zolna MR. Unintended pregnancy in the United States: incidence and disparities, 2006. *Contraception*. 2011; 84(5): 478-85.

<sup>&</sup>lt;sup>245</sup> Wellings K, Jones K, Mercer C et al. The prevalence of unplanned pregnancy and associated factors in Britian: findings from the third National Survey of Sexual Attitudes and Lifestyles (Natsal-3). *The Lancet*. 2013; 382(9907): 1807-16.

Alcohol consumption may have a role in unplanned conceptions. Young people are more likely to engage in sex without the use of contraception when they are drinking.<sup>246</sup> One-third of pregnant 14- to 21-year-olds in the U.S. reported they were drinking when they became pregnant.<sup>247</sup> Preconception binge drinking is associated with an increased risk of an unintended pregnancy.<sup>248</sup> Alcohol use in the preconception period predicts alcohol use during the prenatal period.<sup>249,250</sup> The 2005 PHAC report, *Alcohol Use and Pregnancy: An Important Canadian Public Health and Social Issue,* notes that "given the prevalence of binge drinking and sexual activity among teens and young adults, and the tendency for these activities to be combined, this population is increasingly seen as an important target for universal prevention."<sup>251</sup>

Unplanned pregnancies, especially in younger women, also tend to be identified later in their term.<sup>252</sup> Floyd and colleagues found that almost half of women consumed alcohol during the 3 months prior to pregnancy recognition. The majority of these women did not know that they were pregnant until after the fourth week of their pregnancy.<sup>253</sup> Early exposure in the first 2-6 weeks of pregnancy may be sufficient for permanent changes in fetal brain development.<sup>254</sup>

#### The Role of Contraception in Unplanned Pregnancies

An estimated half of unintended pregnancies in the U.S. result from contraceptive failure. Long-acting reversible contraception (specifically the contraceptive implant and intrauterine devices [IUD])<sup>255</sup> is much more effective than the more commonly used oral contraceptive pill, transdermal patch, contraceptive vaginal ring or condoms (pill, patch or ring - PPR). This is especially the case with adolescents.<sup>256,257</sup> On average, long-acting reversible contraception

<sup>&</sup>lt;sup>246</sup> Boyce W, Doherty M, Fortin C et al. *Canadian Youth, Sexual Health and HIV/AIDS Study: Factors Influencing Knowledge, Attitudes and Behaviours.* 2003. Available at

http://www.cmec.ca/Publications/Lists/Publications/Attachments/180/CYSHHAS\_2002\_EN.pdf. Accessed December 2013.

<sup>&</sup>lt;sup>247</sup> Flanigan B, McLean A, Hall C et al. Alcohol use as a situational influence on young women's pregnancy risk-taking behaviors. *Adolescence*. 1990; 25(97): 205-14.

<sup>&</sup>lt;sup>248</sup> Naimi TS, Lipscomb LE, Brewer RD et al. Binge drinking in the preconception period and the risk of unintended pregnancy: implications for women and their children. *Pediatrics*. 2003; 111(1): 1136-41.

<sup>&</sup>lt;sup>249</sup> Ethen MK, Ramadhani TA, Scheuerle AE et al. Alcohol consumption by women before and during pregnancy. *Maternal and Child Health Journal*. 2009; 13(2): 274-85.

<sup>&</sup>lt;sup>250</sup> Floyd RL, Jack BW, Cefalo R et al. The clinical content of preconception care: alcohol, tobacco, and illicit drug exposures. *American Journal of Obstetrics & Gynecology*. 2008; 199(6): S333-9.

<sup>&</sup>lt;sup>251</sup> Public Health Agency of Canada. *Alcohol Use and Pregnancy: An Important Canadian Public Health and Social Issue*. 2005. Available at http://www.addictionresearchchair.ca/wp-content/uploads/Alcohol-Use-and-Pregnancy-An-Important-Canadian-Health-and-Social-Issue.pdf. Accessed December 2013.

<sup>&</sup>lt;sup>252</sup> Cornelius MD, Lebow HA and Day NL. Attitudes and knowledge about drinking: relationships with drinking behavior among pregnant teenagers. *Journal of Drug Education*. 1997; 27(3): 231-43.

<sup>&</sup>lt;sup>253</sup> Floyd RL, Decoufle P and Hungerford DW. Alcohol use prior to pregnancy recognition. *American Journal of Preventive Medicine*. 1999; 17(2): 101-7.

<sup>&</sup>lt;sup>254</sup> Clarren SK and Salmon A. Prevention of fetal alcohol spectrum disorder: proposal for a comprehensive approach. *Expert Review of Obstetrics & Gynecology*. 2010; 5(1): 23-30.

<sup>&</sup>lt;sup>255</sup> American College of Obstetricians and Gynecologists Committee on Gynecologic Practice - Long-Acting Reversible Contraception Working Group. *ACOG Committee Opinion No. 450: Increasing Use of Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy.* 2009. Available at

http://www.acog.org/~/media/Committee%20Opinions/Committee%20on%20Gynecologic%20Practice/co450.pdf ?dmc=1&ts=20130529T0357139633. Accessed July 2014.

<sup>&</sup>lt;sup>256</sup> Grimes DA, Lopez LM, Schulz KF et al. Immediate post-partum insertion of intrauterine devices. *Cochrane Database of Systematic Reviews*. 2010; 5: CD003036

has a contraceptive failure rate of 0.27 per 100 participant-years, compared to 4.55 for PPR.<sup>258</sup> In women less than 21 years of age, the failure rate of PPR is almost double that of women over the age of 21.<sup>259</sup> Failure is most often associated with incorrect or inconsistent use of contraception or its non-use during sexual intercourse.

The success associated with long-acting reversible contraception (LARC) means that they are now considered by many experts as a first-line contraceptive for women.<sup>260,261,262</sup> For example, in December of 2009 the American College of Obstetricians and Gynecologists noted that "LARC methods have few contraindications, and almost all women are eligible for implants and intrauterine devices. Because of these advantages and the potential to reduce unintended pregnancy rates, LARC methods should be offered as first-line contraceptive methods and encouraged as options for most women. To increase use of LARC methods, barriers such as lack of health care provider knowledge or skills, low patient awareness, and high upfront costs must be addressed."<sup>263</sup>

The B.C. Provincial Health Officer's 2008 Annual report titled *The Health and Well-Being of Women in British Columbia* cites results from the most recent Canadian Contraceptive Survey which found "that even with new methods becoming available, women favour a small number of contraceptive options—oral contraceptives, condoms and withdrawal—and are often unaware of new advances in birth control. Less than 4 per cent of women surveyed had used more recently approved contraceptive options, such as LARC methods" (p.33).<sup>264</sup> The report notes that this may be due to lack of awareness but could also reflect prohibitive costs "as most Canadian women must pay the total cost of these methods unless they have private insurance coverage" (p.33). One of the reports' recommendations is to "improve access to contraception, especially long-acting reversible contraception" (p.242).

In an effort to address this cost issue, the Affordable Care Act in the U.S. mandates that most private insurance plans written after August 1, 2012 are required to include all FDA-approved contraceptive methods and contraception counselling without deductibles or co-pay.<sup>265,266</sup>

<sup>&</sup>lt;sup>257</sup> Committee on Adolescent Health Care Long-Acting Reversible Contraception Working Group. Adolescents and long-acting reversible contraception: implants and intrauterine devices. *Obstetrics & Gynecology*. 2012; 120(4): 983-8.

<sup>&</sup>lt;sup>258</sup> Winner B, Peipert JF, Zhao Q et al. Effectiveness of long-acting reversible contraception. *New England Journal of Medicine*. 2012; 366(21): 1998-2007.

<sup>&</sup>lt;sup>259</sup> Winner B, Peipert JF, Zhao Q et al. Effectiveness of long-acting reversible contraception. *New England Journal of Medicine*. 2012; 366(21): 1998-2007.

<sup>&</sup>lt;sup>260</sup> Davis AJ. Intrauterine devices in adolescents. Current Opinion in Pediatrics. 2011; 23(5): 557-65.

<sup>&</sup>lt;sup>261</sup> Tang J, Lopez L, Mody S et al. Hormonal and intrauterine methods for contraception for women aged 25 years and younger *Cochrane Database of Systematic Reviews*. 2012; 11.

<sup>&</sup>lt;sup>262</sup> World Health Organization. *Medical Eligibility Criteria for Contraceptive Use* 2009. Available at http://whqlibdoc.who.int/publications/2010/9789241563888 eng.pdf. Accessed July 2014.

<sup>&</sup>lt;sup>263</sup> Committee on Gynecologic Practice. *Increasing Use of Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy.* 2009. Available at

http://www.acog.org/~/media/Committee%20Opinions/Committee%20on%20Gynecologic%20Practice/co450.pdf ?dmc=1&ts=20131129T1756504944. Accessed November 2013.

<sup>&</sup>lt;sup>264</sup> Ministry of Health. *Provincial Health Officer's 2008 Annual Report: The Health and Well-being of Women in British Columbia.* 2011. Available at http://www.health.gov.bc.ca/pho/pdf/phoannual2008.pdf. Accessed December 2013.

<sup>&</sup>lt;sup>265</sup> Finer LB and Sonfield A. The evidence mounts on the benefits of preventing unintended pregnancy. *Contraception*. 2013; 87(2): 126-7.

<sup>&</sup>lt;sup>266</sup> Health Resources and Services Administration. *Women's Preventive Services Guidelines: Affordable Care Act Expands Prevention Coverage for Women's Health and Well-Being* U.S. Department of Health and Human Services. Available at http://www.hrsa.gov/womensguidelines/. Accessed July 2014.

#### Prevalence of FASD

Although women who drink during pregnancy are at risk of having a child with FASD, prevalence and incidence rates of the former cannot be equated with prevalence and incidence rates of the latter. Also, women who drink during pregnancy are not a homogeneous group, and include women who are alcohol dependent, women who abuse alcohol on an episodic basis, and women who drink infrequently or regularly at low amounts. Amount, timing and frequency of alcohol intake, alongside other factors such as mother's health and genetic susceptibility of the fetus, are critical factors in determining risk for FASD.<sup>267</sup> (p.19)

Estimates of the incidence and prevalence of FASD vary widely. The most commonly used current estimate in the general Canadian population is 1 per 100 live births.<sup>268</sup> In estimating the economic burden associated with FASD in Canada, Thanh and Jonsson used a range of 3-9 / 1,000 live births.<sup>269</sup> This estimate of 1 / 100 appears to be based on population level estimates from the U.S. of 9.1 / 1,000 live births.<sup>270</sup> A review of the literature by May and co-authors, focusing on recent in-school studies, led the authors to conclude that "the current prevalence of FASD in populations of younger school children may be as high as 2-5% in the US and some Western European countries."<sup>271</sup> Research in aboriginal populations in Northern B.C. estimate the rate of FASD in some communities to be as high as 190 / 1,000 live births<sup>272</sup> and FAS at 25 / 1,000 live births.<sup>273</sup> Lange et al. assessed the prevalence of FASD in a child-care settings (e.g., orphanage, foster care, child welfare system), resulting in an estimated rate of 169 / 1,000 (95% CI of 109 – 238).<sup>274</sup> Estimates from other countries can also be quite high, including a range from 23-63 / 1,000 in Italy<sup>275</sup> and 135-208 / 1,000 in South Africa.<sup>276</sup>

#### Prevention of FASD

The Public Health Agency of Canada (PHAC) 2008 report *Fetal Alcohol Spectrum Disorder* (*FASD*) *Prevention: Canadian Perspectives* notes that "FASD prevention work is complex; it

<sup>&</sup>lt;sup>267</sup> Public Health Agency of Canada. *Alcohol Use and Pregnancy: An Important Canadian Public Health and Social Issue*. 2005. Available at http://www.addictionresearchchair.ca/wp-content/uploads/Alcohol-Use-and-Pregnancy-An-Important-Canadian-Health-and-Social-Issue.pdf. Accessed December 2013.

<sup>&</sup>lt;sup>268</sup> Stade B, Ali A, Bennett D et al. The burden of prenatal exposure to alcohol: revised measurement of cost. *Canadian Journal of Clinical Pharmacology*. 2009; 16(1): e91-102.

<sup>&</sup>lt;sup>269</sup> Thanh NX and Jonsson E. Drinking alcohol during pregnancy: evidence from Canadian Community Health Survey 2007/2008. *Canadian Journal of Clinical Pharmacology*. 2010; 17(2): e302-7.

<sup>&</sup>lt;sup>270</sup> Chudley AE, Conry J, Cook JL et al. Fetal alcohol spectrum disorder: Canadian guidelines for diagnosis. *Canadian Medical Association Journal*. 2005; 172(5 Suppl): S1-S21.

<sup>&</sup>lt;sup>271</sup> May PA, Gossage JP, Kalberg WO et al. Prevalence and epidemiologic characteristics of FASD from various research methods with an emphasis on recent in-school studies. *Developmental Disabilities Research Reviews*. 2009; 15(3): 176-92.

<sup>&</sup>lt;sup>272</sup> Robinson GC, Conry JL and Conry RF. Clinical profile and prevalence of fetal alcohol syndrome in an isolated community in British Columbia. *Canadian Medical Association Journal*. 1987; 137(3): 203-7.

<sup>&</sup>lt;sup>273</sup> Asante K and Nelms-Maztke J. *Report on the Survey of Children with Chronic Handicaps and Fetal Alcohol Syndrome in the Yukon and Northwest British Columbia.* Whitehorse: Council for Yukon Indians; 1985.

<sup>&</sup>lt;sup>274</sup> Lange S, Shield K, Rehm J et al. Prevalence of fetal alcohol spectrum disorders in child care settings: a metaanalysis. *Pediatrics*. 2013; 132(4): e980-95.

<sup>&</sup>lt;sup>275</sup> May PA, Fiorentino D, Coriale G et al. Prevalence of children with severe fetal alcohol spectrum disorders in communities near Rome, Italy: new estimated rates are higher than previous estimates. *International Journal of Environmental Research and Public Health*. 2011; 8(6): 2331-51.

<sup>&</sup>lt;sup>276</sup> May PA, Blankenship J, Marais AS et al. Approaching the prevalence of the full spectrum of fetal alcohol spectrum disorders in a South African population-based study. *Alcoholism: Clinical and Experimental Research*. 2013; 37(5): 818-30.

involves much more than providing information about the risks of alcohol use in pregnancy."<sup>277</sup> The report suggests a four-part model of prevention.

- 1. The first level of prevention is about raising public awareness through campaigns and other broad strategies. Closely linked to public awareness/social marketing, campaigns can be public policy and health promotion activities that are supportive of girls' and women's health. The engagement and involvement of a broad range of people at the community level is key to advancing social support and social change.
- 2. The second level of prevention is about girls and women of childbearing years having the opportunity for safe discussion of pregnancy, alcohol use, and related issues, with their support networks and healthcare providers.
- 3. The **third level of prevention** is even more specific. It is about the provision of recovery and support services that are specialized, culturally specific and accessible for women with alcohol problems and related mental health concerns. These services are needed not only for pregnant women, but also before pregnancy and throughout the childbearing years.
- 4. Finally, the **fourth level of FASD prevention** is about supporting new mothers to maintain healthy changes they have been able to make during pregnancy. Postpartum support for mothers who were not able to make significant changes in their substance use during pregnancy is also vital. This will assist them to continue to improve their health and social support, as well as the health of their children. Early interventions for children who potentially have FASD are also important at this stage.

The focus of the current review is on the potential for a brief intervention in a clinical environment to assist in preventing FASD. A brief intervention has been defined by the U.S. Substance Abuse and Mental Health Services Administration as "a single session or multiple sessions of motivational discussion focussed on increasing insight and awareness regarding substance use and motivation toward behavioural change."<sup>278</sup> This would largely fit within the PHAC second level of prevention and consist primarily of reducing fetal exposure to alcohol and/or reducing unplanned conception in a situation where alcohol is likely to be consumed during pregnancy.

There are essentially two options for achieving positive outcomes with respect to preventing FASD. One option is the use of effective contraception as a principal step in reducing the risk for an alcohol-exposed pregnancy. The second option is the elimination of alcohol consumption during pregnancy. A key question is whether a brief intervention in a clinical setting is effective at enhancing the use of effective contraception and/or reducing/eliminating alcohol consumption during pregnancy. Changes in these intermediate behaviours at the population level should result in a reduction of alcohol exposed births and thus FASD.

#### Is Long-acting Reversible Contraception Effective In Preventing Alcohol-Exposed Pregnancies?

We noted earlier that half of all pregnancies in the United States are unplanned, that alcohol consumption may have a role in unplanned conceptions and that unplanned pregnancies,

<sup>&</sup>lt;sup>277</sup> Public Health Agency of Canada. *Fetal Alcohol Spectrum Disorder (FASD) Prevention: Canadian Perspectives.* 2008. Available at http://www.phac-aspc.gc.ca/hp-ps/dca-dea/prog-ini/fasd-etcaf/publications/cp-pc/index-eng.php. Accessed December 2013.

<sup>&</sup>lt;sup>278</sup> Quoted in Agency for Healthcare Research and Quality. Screening, Behavioral Counseling, and Referral in Primary Care to Reduce Alcohol Misuse. 2011. Available at

http://effectivehealthcare.ahrq.gov/ehc/products/269/729/Alcohol-Misuse\_Protocol\_20110721.pdf. Accessed December 2013.

especially in younger women, also tend to be identified later in their term. One could argue that unplanned pregnancies are at a significantly higher risk of being alcohol-exposed than planned pregnancies.

To estimate the number of unplanned or ambivalent births that would occur within a B.C. birth cohort of 40,000, we first calculated the current B.C. birth rate for females between the ages of 15 and 49 based on actual births between 2008 and 2011 (see Table 7-5).

	Table 7-5: Number of Births and Birth Rates of Women Aged 15-49           British Columbia, 2008 to 2011																					
# of Women <sup>1</sup>								E	Birth Rate per 1,000 <sup>2</sup>						# of Births					Total		
Year	15-19	20-24	25-29	30-34	35-39	40-44	45-49	15-19	20-24	25-29	30-34	35-39	40-44	45-49	15-19	20-24	25-29	30-34	35-39	40-44	45-49	Births
2009	138,430	150,944	155,712	145,057	152,919	164,931	185,345	10.4	43.0	82.1	98.8	54.0	10.3	0.7	1,440	6,491	12,784	14,332	8,258	1,699	130	45,132
2010	137,510	156,438	160,111	149,041	151,176	163,886	184,921	9.9	38.8	80.1	97.3	54.6	11.1	0.7	1,361	6,070	12,825	14,502	8,254	1,819	129	44,961
2011	136,280	158,294	161,333	152,489	148,672	163,638	182,323	9.3	35.4	76.2	97.3	54.2	10.9	0.6	1,267	5,604	12,294	14,837	8,058	1,784	109	43,953
Mean	137,407	155,225	159,052	148,862	150,922	164,152	184,196	9.9	39.0	79.4	97.8	54.3	10.8	0.7	1,356	6,055	12,634	14,557	8,190	1,767	123	44,682
		imates 2013.		-,				ography/D					ovember 3		,	-,	,	,	-,	,		.,

The calculated birth rates were then used to estimate the number of live births by a B.C. birth cohort of 40,000 (see Table 7-6).

Table 7-6	Table 7-6: Expected Live Births in the BirthCohort of 40,0002013 B.C. Population											
	# of Life Years											
	Lived from Age x											
	to x+5 in Birth	Birth										
	Cohort of 40,000	Rate	Expected									
Age Group	Females	/1000	Births									
15-19	100,353	9.87	990									
20-24	100,211	39.01	3,909									
25-29	100,045	79.43	7,947									
30-34	99,855	97.79	9,765									
35-39	99,582	54.27	5,404									
40-44	99,181	10.77	1,068									
45-49	98,588	0.67	66									
Total	697,815		29,148									

This information in Table 7-6 was combined with the information in Table 7-4 above to create Table 7-7. Of the 29,148 estimated births in a B.C. birth cohort of 40,000, approximately 59.2% would be planned (17,246), 26.3% would be ambivalent (7,668) and 14.5% (4,234) would be unplanned.

Table 7	7-7: Estimated	Planneo	Cohor	lanned/ t of 40,0 C. Popula	000	lent Liv	e Birth	s in the I	Birth
	# of Life Years Lived from Age x to x+5 in Birth Cohort of 40,000	Birth Rate	Expected	Plar	ned	Ambiy	/alent	Unpla	inned
Age Group	Females	/1000	Births	%	#	%	#	%	#
15-19	100,353	9.87	990	11.6%	115	43.2%	428	45.2%	448
20-24	100,211	39.01	3,909	40.0%	1,564	42.7%	1,669	17.3%	676
25-29	100,045	79.43	7,947	62.2%	4,943	26.8%	2,130	11.0%	874
30-34	99,855	97.79	9,765	67.7%	6,611	18.1%	1,767	14.2%	1,387
35-39	99,582	54.27	5,404	61.4%	3,318	25.6%	1,383	13.0%	703
40-44	99,181	10.77	1,068	61.4%	656	25.6%	273	13.0%	139
45-49	98,588	0.67	66	61.4%	40	25.6%	17	13.0%	9
Total	697,815		29,148	<b>59.2%</b>	17,246	26.3%	7,668	14.5%	4,234

LARC methods have been shown to reduce unintended pregnancies. Adolescents and women at risk of unintended pregnancies were offered free LARC in the US CHOICE study. The rate of teenage birth within the CHOICE cohort was 6.3 per 1,000 compared to the national average of 34.3 per 1,000.<sup>279</sup>

Adolescents who do not initiate a LARC method have up to a 35 times increased risk of a rapid repeat pregnancy compared with their peers using LARC.<sup>280</sup>

The use of LARC methods inserted immediately after an abortion are highly effective, safe and desirable as post abortion contraception.<sup>281</sup>

A Canadian cross-section survey conducted in November of 2006 found that less that 4% of sexually active women who were not trying to conceive used LARC methods. Over half used condoms (54.3%), 43.7% used oral contraceptives and 11.6% used withdrawal while 14.9% never used contraception.<sup>282</sup>

#### Are Brief Interventions Effective In Preventing Alcohol-Exposed Pregnancies?

Manwell and coauthors randomly assigned 205 females ages 18-40 with problem drinking behaviours to an intervention or control group.<sup>283</sup> The intervention group received two 15-minute physician delivered counselling visits that included advice, education and contracting by using a scripted workbook. The trial found a significant treatment effect in reducing both 7 day alcohol use and binge drinking episodes over the 48 month follow-up period. Women in the intervention group who became pregnant had the most dramatic decreases in alcohol use.

<sup>&</sup>lt;sup>279</sup> Peipert JF, Madden T, Allsworth JE et al. Preventing unintended pregnancies by providing no-cost contraception. *Obstetrics & Gynecology*. 2012; 120(6): 1291-7.

<sup>&</sup>lt;sup>280</sup> Baldwin MK and Edelman AB. The effect of long-acting reversible contraception on rapid repeat pregnancy in adolescents: a review. *Journal of Adolescent Health*. 2013; 52(4): S47-S53.

<sup>&</sup>lt;sup>281</sup> Ames CM and Norman WV. Preventing repeat abortion in Canada: is the immediate insertion of intrauterine devices postabortion a cost-effective option associated with fewer repeat abortions? *Contraception*. 2012; 85(1): 51-5.

<sup>&</sup>lt;sup>282</sup> Black A, Yang Q, Wen SW et al. Contraceptive use among Canadian women of reproductive age: results of a national survey. *Journal of Obstetrics and Gynaecology Canada*. 2009; 31(7): 627-40.

<sup>&</sup>lt;sup>283</sup> Manwell LB, Fleming MF, Mundt MP et al. Treatment of problem alcohol use in women of childbearing age: results of a brief intervention trial. *Alcoholism: Clinical and Experimental Research.* 2000; 24(10): 1517-24.

Chang et al. report the results from a randomized controlled trial involving 304 pregnant women and their partners at risk of alcohol consumption.<sup>284</sup> The brief intervention involved one session lasting an average of 25 minutes. They found that prenatal alcohol use was significantly reduced in both the treatment and control groups. However, the brief intervention reduced subsequent consumption most significantly in women with the highest initial levels of consumption, and the effects of the intervention were significantly enhanced when a partner participated.

An estimated 13% of college women in the U.S. are risky drinkers and use contraception ineffectively.<sup>285</sup> Ingersoll and colleagues randomly assigned 228 college female students at risk of an alcohol-exposed pregnancy (AEP) with the intervention group receiving a one-session motivational interviewing–based intervention.<sup>286</sup> At four months post intervention, the rate of AEP risk was significantly lower in the intervention group (20.2%) than in the control group (34.9%).<sup>287</sup>

In another randomized controlled trial, Floyd and colleagues assessed the effectiveness of receiving information plus four brief motivational intervention sessions combined with one contraception consultation visit versus just receiving information in preventing AEPs.<sup>288</sup> A total of 830 sexually active but non-pregnant women with behaviours of risky drinking and ineffective contraception use were included. Across the 90 day follow-up period, women in the intervention group significantly reduced their risk of an AEP. At 3 months the OR was 2.31 (95% CI, 1.69-3.20), remaining at 2.15 (95% CI, 1.52-3.06) at six months and 2.11 (95% CI, 1.47-3.03) at 9 months.

Evidence such as this led the Clinical Working Group of the Select Panel on Preconception Care, Centers for Disease Control and Prevention (CDC), to make the following recommendation in 2008 for women in the preconception period:

All childbearing-aged women should be screened for alcohol use and brief interventions should be provided in primary care settings including advice regarding the potential for adverse health outcomes. Brief interventions should include accurate information about the consequences of alcohol consumption including the effects of drinking during pregnancy, that effects begin early during the first trimester and that no safe level of consumption has been established. Contraception consultation and services should be offered and pregnancy delayed until it can be an alcohol-free pregnancy.<sup>289</sup>

<sup>&</sup>lt;sup>284</sup> Chang G, McNamara TK, Orav EJ et al. Brief intervention for prenatal alcohol use: a randomized trial. *Obstetrics & Gynecology*. 2005; 105(5): 991-8.

<sup>&</sup>lt;sup>285</sup> Ingersoll KS, Ceperich SD, Nettleman MD et al. Risk drinking and contraception effectiveness among college women. *Psychology and Health.* 2008; 23(8): 965-81.

<sup>&</sup>lt;sup>286</sup> Ingersoll KS, Ceperich SD, Nettleman MD et al. Reducing alcohol-exposed pregnancy risk in college women: initial outcomes of a clinical trial of a motivational intervention. *Journal of Substance Abuse Treatment*. 2005; 29(3): 173-80.

<sup>&</sup>lt;sup>287</sup> Ceperich SD and Ingersoll KS. Motivational interviewing + feedback intervention to reduce alcohol-exposed pregnancy risk among college binge drinkers: determinants and patterns of response. *Journal of Behavioral Medicine*. 2011; 34(5): 381-95.

<sup>&</sup>lt;sup>288</sup> Floyd RL, Sobell M, Velasquez MM et al. Preventing alcohol-exposed pregnancies: a randomized controlled trial. *American Journal of Preventive Medicine*. 2007; 32(1): 1-10.

<sup>&</sup>lt;sup>289</sup> Quoted in Floyd RL, Weber MK, Denny C et al. Prevention of fetal alcohol spectrum disorders. *Developmental Disabilities Research Reviews*. 2009; 15(3): 193-9.

In 2004, the United States Preventive Services Task Force (USPSTF) reviewed the available literature regarding the effectiveness of behavioural counselling interventions in primary care to reduce risky/harmful alcohol use by adults. They found that "six to 12 months after good-quality, brief, multicontact behavioral counseling interventions (those with up to 15 minutes of initial contact and at least 1 follow-up), participants reduced the average number of drinks per week by 13% to 34% more than controls did, and the proportion of participants drinking at moderate or safe levels was 10% to 19% greater compared with controls. One study reported maintenance of improved drinking patterns for 48 months."<sup>290</sup>

The USPSTF has since updated its evidence review, arriving at the following conclusion:

A total of 23 trials and six systematic reviews were included. The trials generally enrolled subjects with risky/hazardous drinking, usually excluding those with alcohol dependence. Among adults receiving interventions, consumption decreased by 3.6 drinks per week [...], 12 percent fewer subjects reported heavy drinking episodes[...], and 11 percent more subjects reported drinking beneath recommended limits [...] compared with controls[...]. The best evidence of effectiveness is for brief (generally, 10 to 15 minutes) multicontact interventions.<sup>291</sup>

This most recent evidence update resulted in the recommendation (for adults aged 18 years or older) to "screen for alcohol misuse and provide brief interventional counselling interventions to persons engaged in risky or hazardous drinking,"<sup>292</sup> which is similar to the recommendation resulting from the 2004 evidence review. Both the 2004 and the current recommendations received a 'B' grade, meaning that "the USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial."<sup>293</sup>

In Canada, less than 50% of Canadian health care providers frequently discuss alcohol use with women of childbearing age. Lack of time is considered to be the primary barrier to discussing adverse effects of alcohol prior to conception. Once women are pregnant, however, 94% inquire about alcohol use.<sup>294</sup>

#### Consequences of FASD

#### Quality of Life Associated with FASD

FASD can have a significant impact on the day to day activities and quality of life of those living with the diagnosis.<sup>295</sup> Slade et al. attempted to quantify this impact by analysing input

<sup>&</sup>lt;sup>290</sup> Whitlock EP, Polen MR, Green CA et al. Behavioral counseling interventions in primary care to reduce risky/harmful alcohol use by adults: a summary of the evidence for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*. 2004; 140(7): 557-68.

<sup>&</sup>lt;sup>291</sup> Jonas DE, Garbutt JC, Brown JM et al. *Screening, Behavioral Counseling, and Referral in Primary Care to Reduce Alcohol Misuse.* 2012. Available at

http://www.effectivehealthcare.ahrq.gov/ehc/products/269/1134/CER64\_AlcoholMisuse\_FinalReport\_20120608.p df. Accessed December 2013.

<sup>&</sup>lt;sup>292</sup> Moyer VA. Screening and behavioral counseling interventions in primary care to reduce alcohol misuse: U.S. Preventive Services Task Force recommendation statement. *Annals of Internal Medicine*. 2013: online advance edition.

<sup>&</sup>lt;sup>293</sup> Moyer VA. Screening and behavioral counseling interventions in primary care to reduce alcohol misuse: U.S. Preventive Services Task Force recommendation statement. *Annals of Internal Medicine*. 2013: online advance edition.

 <sup>&</sup>lt;sup>294</sup> Tough SC, Clarke M, Hicks M et al. Attitudes and approaches of Canadian providers to preconception counselling and the prevention of fetal alcohol spectrum disorders. *Journal of FAS International*. 2005; 3: e3.
 <sup>295</sup> Stade B, Beyene J, Buller K et al. Feeling different: the experience of living with fetal alcohol spectrum disorder. *Canadian Journal of Clinical Pharmacology*. 2011; 18(3): e475-85.

from 126 Canadian children and adolescents with FASD. The mean health related quality of life for this group was 0.47 (95% CI of 0.42 - 0.52), compared to 0.93 (95% CI of 0.92 - 0.94) for the general Canadian population of children and adolescents.<sup>296</sup> A value of 1.00 is considered to represent perfect health while a value of 0 usually represents death.

#### **Costs Associated with FASD**

Slade and colleagues asked 250 caregivers of children, youth and adults with FASD from throughout Canada to complete a comprehensive Health Services Utilization Inventory to estimate the annual costs associated with a diagnosis of FASD. Costs were assessed from a societal perspective as well as that of the government and the patient (see Table 7-8).<sup>297</sup> This is the most comprehensive assessment of costs currently available in Canada, although the Centre for Alcohol and Mental Health is in the process of expanding this comprehensive cost estimate.<sup>298,299</sup>

<sup>&</sup>lt;sup>296</sup> Stade BC, Stevens B, Ungar WJ et al. Health-related quality of life of Canadian children and youth prenatally exposed to alcohol. *Health and Quality of Life Outcomes*. 2006; 4: 81.

<sup>&</sup>lt;sup>297</sup> Stade B, Ali A, Bennett D et al. The burden of prenatal exposure to alcohol: revised measurement of cost. *Canadian Journal of Clinical Pharmacology*. 2009; 16(1): e91-102.

<sup>&</sup>lt;sup>298</sup> Popova S, Stade B, Lange S et al. *Methodology for Estimating the Economic Impact of Fetal Alcohol Spectrum Disorder: Summary Report.* 2012. Available at

http://knowledgex.camh.net/reports/Documents/Popova\_etalMethodologySummary\_March30\_12Final\_E.pdf. Accessed December 2013.

<sup>&</sup>lt;sup>299</sup> Popova S, Stade B, Lange S et al. *Economic Impact of Fetal Alcohol (FAS) and Fetal Alcohol Spectrum Disorders (FASD): A Systematic Literature Review*. 2012. Available at

http://knowledgex.camh.net/reports/Documents/economic\_impact\_fas\_litreview12.pdf. Accessed December 2013.

	Canada, 2	007	
		Ministry of Health/Social	
Component	Societal Cost (\$)	Services Cost (\$)	Patient Cost (
Direct Costs: Medical			
Hospitalization	\$1,445.45	\$1,445.45	N/A
Emergency Room/Clinic Visits	\$660.82	\$660.82	N/A
	\$2,106.27	\$2,106.27	
Visits to Health Professionals			
Family Doctor	\$301.15	\$301.15	N/A
, Orthopedic Surgery	\$67.68	\$67.68	N/A
Urologist	\$46.10	\$46.10	N/A
Allergist	\$6.08	\$6.08	N/A
Pediatrician	\$241.65	\$241.65	N/A
Psychiatrist	\$892.00	\$892.02	N/A
Occupational Therapist	\$444.12	\$352.00	\$92.12
Physiotherapist	\$91.00	\$91.00	\$0.00
Speech Therapist	\$58.54	\$28.31	\$30.23
Psychologist	\$737.39	\$122.00	\$615.39
	\$2,885.71	\$2,147.99	\$737.74
Medical Devices	\$416.02	\$282.00	\$134.02
Medication Dispensing Fees	\$56.00	\$47.50	\$8.50
Prescription Medications	\$800.00	\$592.00	\$208.00
Non-Prescription Medication	\$218.08	N/A	\$218.08
Diagnostic Tests	\$148.00	\$148.00	N/A
	\$1,638.10	\$1,069.50	\$568.60
Total	\$6,630.08	\$5,323.76	\$1,306.34
	+ + + + + + + + + + + + + + + + + + + +	<i>++++</i>	
Direct Costs: Education	¢100 F0	¢108 F0	NI / A
Home Schooling	\$198.50	\$198.50	N/A
Special Schooling	\$3,237.60	\$3,237.60	N/A
Residential Program	\$1,600.00	\$1,000.00	\$600.00
Post-Secondary Education - Tutor	\$64.00	N/A	\$64.00
Job Education	\$160.00 <b>\$5,260.10</b>	\$160.00	N/A
Total	\$5,260.10	\$4,596.10	\$664.00
Direct Costs: Social Services	4151.01	4454.04	
Respite Care	\$151.84	\$151.84	N/A
Foster Care	\$2,000.40	\$2,000.40	N/A
Institutionalization	\$1,654.95	\$1,654.95	N/A
ODSP	\$143.34	\$143.34	N/A
Legal Aid	\$125.00 \$4,075.53	\$125.00	N/A
Total	<del>، ۲۰</del> , ۳, ۵, ۵۵	\$4,075.53	
Out-of-Pocket	6452.46	N/ / A	6450.40
Transportation Per Visit	\$152.16	N/A	\$152.16
Parking	\$162.00	N/A	\$162.00
Externalizing Behaviours	\$2,500.12	N/A	\$2,500.12
Total Total Direct Costs	\$2,814.28 \$18,779.99	<u> </u>	\$2,814.28 \$4,784.62
		22,222,22	÷+,704.02
Indirect Costs: Productivity Losses	\$1,430.65		
Total Costs	\$20,210.64		

# Table 7-8: Estimated Average Annual Cost of FASD per Case Canada 2007

Source: Stade B, Ali A, Bennett D et al. The burden of prenatal exposure to alcohol: revised measurement of cost. Canadian Journal of Clinical Pharmacology . 2009; 16(1): e91-102

## Modelling CPB and CE

In the previous section, we updated the original U.S. model for screening and counseling to reduce alcohol misuse of the Partnership for Prevention and HealthPartners Research Foundation using updated B.C.-specific data. The model does not include the prevention of FASD. In this section, we will calculate the clinically preventable burden and cost-effectiveness associated with behavioural counseling interventions and LARC methods intended to reduce alcohol-exposed pregnancies.

We first calculated the current B.C. birth rate for females between the ages of 15 and 49 based on actual births between 2008 and 2011 (see Table 7-5). The calculated birth rates were then used to estimate the number of live births by a B.C. birth cohort of 40,000 (see Table 7-6). The estimate of 29,148 was used to populate row *a* in Table 7-9.

Additional assumptions made in calculating CPB (Table 7-9) include:

- 1% of births are currently diagnosed with FASD (see above).
- An individual with FASD would lose 20 years of life expectancy, roughly equivalent to the excess mortality associated with schizophrenia.<sup>300,301,302</sup> The average life expectancy of an individual with FASD would therefore be 62.3 years, 20 years less than the current average life expectancy at birth for a newborn in B.C. of 82.3 years.
- A 0.46 reduction in quality of life associated with FASD (see above).<sup>303</sup>
- Behavioural counselling interventions are associated with 10.9% (95% CI of 8.3% to 13.4%) more subjects reporting drinking below recommended limits (see above).<sup>304</sup>
- 59.2% of births in B.C. are planned, 26.3% are ambivalent and 14.5% are unplanned (see Table 7-7).
- The use of LARC methods would reduce the number of unplanned births in B.C. by  $80\%^{305}$  and the number of 'ambivalent' births by an estimated 40%.
- Adherence with LARC is estimated at 85%.<sup>306,307</sup>

Based on these assumptions, the use of LARC methods together with screening and counseling to reduce alcohol-exposed births would result in 3,752 QALYs gained in a B.C. birth cohort of 40,000 (Table 7-9, row t).

<sup>&</sup>lt;sup>300</sup> Brown S. Excess mortality of schizophrenia. A meta-analysis. *British Journal of Psychiatry*. 1997; 171(6): 502-8.

<sup>&</sup>lt;sup>301</sup> Tiihonen J, Lönnqvist J, Wahlbeck K et al. 11-year follow-up of mortality in patients with schizophrenia: a population-based cohort study (FIN11 study). *The Lancet*. 2009; 374(9690): 620-7.

<sup>&</sup>lt;sup>302</sup> Laursen TM. Life expectancy among persons with schizophrenia or bipolar affective disorder. *Schizophrenia Research*. 2011; 131: 101-4.

<sup>&</sup>lt;sup>303</sup> Stade BC, Stevens B, Ungar WJ et al. Health-related quality of life of Canadian children and youth prenatally exposed to alcohol. *Health and Quality of Life Outcomes*. 2006; 4: 81.

<sup>&</sup>lt;sup>304</sup> Jonas DE, Garbutt JC, Amick HR et al. Behavioral counseling after screening for alcohol misuse in primary care: a systematic review and meta-analysis for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*. 2012; 157(9): 645-54.

<sup>&</sup>lt;sup>305</sup> Peipert JF, Madden T, Allsworth JE et al. Preventing unintended pregnancies by providing no-cost contraception. *Obstetrics & Gynecology*. 2012; 120(6): 1291-7.

<sup>&</sup>lt;sup>306</sup> Cleland K, Peipert JF, Westhoff C et al. Family planning as a cost-saving preventive health service. *New England Journal of Medicine*. 2011; 364(18):

<sup>&</sup>lt;sup>307</sup> Trussell J, Henry N, Hassan F et al. Burden of unintended pregnancy in the United States: potential savings with increased use of long-acting reversible contraception. *Contraception*. 2013; 87(2): 154-61.

	Cohort of 40,000 (B.C.)		
Row Label	Variable	Base Case	Data Source
а	Expected live births	29,148	Table 17-6
b	Planned live births	17,246	Table 17-7
С	Ambivalent live births	7,668	Table 17-7
d	Unplanned live births	4,234	Table 17-7
е	Effectiveness of LARC at reducing ambivalent live births	0.40	٧
f	Effectiveness of LARC at reducing unplanned live births	0.80	V
g	FASD Births in B.C. without LARC	291	= a * 0.01
h	FASD Births in B.C. with LARC	227	= (a-(c*e)- (d*f))*.01
i	FASD births potentially avoided by using LARC	65	= g - h
j	Adherence with LARC	85.0%	V
k	FASD births avoided by using LARC	55	= I * j
I	Effectiveness of counseling at changing behavior	10.9%	V
m	Adherence with screening	70.0%	Assumed
n	FASD births avoided by counselling	22	=g*l*m
0	Life Years Lost per FASD	20.0	٧
р	Life years lived per FASD	62.3	V
q	Reduction in QoL associated with FASD	0.46	V
r	Life years gained	1,542	=(k+n)*o
S	QALYs gained	2,210	=((k+n)*p)*q
t	Total QALYs gained, CPB	3,752	= r+s

## Table 7-9: CPB of Screening and Counseling to Reduce FASD in a Birth Cohort of 40.000 (B.C.)

√ = Estimates from the literature

We also modified several major assumptions and recalculated the CPB as follows:

- The base case assumption for FASD prevalence is 1% of live births. As noted earlier, however, the current prevalence of FASD in populations of younger school children may be as high as 2-5% in the U.S. and some Western European countries.<sup>308</sup> A prevalence of 2% would increase the CPB from 3,752 to 7,504.
- Assume the effectiveness of counselling at changing behaviour is reduced from 10.9% to 8.3% (Table 7-9, row *l*): CPB = 3,494
- Assume the effectiveness of counselling at changing behaviour is increased from 10.9% to 13.4% (Table 7-9, row *l*): CPB = 4,000
- Assume that the reduction in QoL associated with FASD is modified from 0.46 to 0.41 (Table 7-9, row q): CPB = 3,512
- Assume that the reduction in QoL associated with FASD is modified from 0.46 to 0.52 (Table 7-9, row q): CPB = 4,040

<sup>&</sup>lt;sup>308</sup> May PA, Gossage JP, Kalberg WO et al. Prevalence and epidemiologic characteristics of FASD from various research methods with an emphasis on recent in-school studies. *Developmental Disabilities Research Reviews*. 2009; 15(3): 176-92.

In estimating the CE associated with the use of LARC methods together with screening and counseling to reduce alcohol-exposed births, we began with the general alcohol model and then made the following changes/additions:

• Calculate the years of life lived in the birth cohort by females ages 15-49 as well as the number and percent of years with alcohol misuse for this group (see Table 7-10). The years of life lived (697,815) was used to populate row *a* in Table 7-11. The percent of person years with alcohol misuse (34.5%) was used to populate row *b* in Table 7-12.

	Table 7-10: Alcohol Misuse British Columbia, 2013 Ages 15 to 49										
	% of Populat	ion Having 5 or		Ages 1:	51049						
	•	on at Least One	# of Life Y	ears Lived	from Age x	# of P	erson-year	s with	% of	Person-y	ears
	Occasion in F	Past 12 Months	to x+5 in	Birth Coho	rt of 40,000	Al	cohol Misu	ise	with	Alcohol M	isuse
Age Group	Males	Females	Males	Females	Total	Males	Females	Total	Males	Females	Total
15-19	42.2%	33.5%	98,512	100,353	198,865	41,536	33,646	75,182	42.2%	33.5%	37.8%
20-24	76.9%	52.6%	98,208	100,211	198,419	75,498	52,664	128,162	76.9%	52.6%	64.6%
25-29	58.4%	49.2%	97,819	100,045	197,864	57,128	49,207	106,336	58.4%	49.2%	53.7%
30-34	56.8%	36.0%	97,405	99,855	197,260	55,291	35,993	91,284	56.8%	36.0%	46.3%
35-39	58.7%	18.6%	96,890	99,582	196,472	56,919	18,556	75,475	58.7%	18.6%	38.4%
40-44	47.8%	22.0%	96,205	99,181	195,386	46,014	21,801	67,815	47.8%	22.0%	34.7%
45-49	48.1%	29.3%	95,252	98,588	193,840	45,811	28,865	74,676	48.1%	29.3%	38.5%
Total			680,291	697,815	1,378,106	378,197	240,733	618,929	55.6%	34.5%	44.9%

• Calculate the years of life lived in the birth cohort by females ages 15-49 who engage in sexual intercourse (see Table 7-11).<sup>309</sup> The percent of person years with sexual intercourse (77.8%) was used to populate row d in Table 7-12.

Table 7-11: Sexual Intercourse British Columbia, 2013 Females Ages 15 to 49					
# of Life Years Lived # of Person-years % Sexual from Age x to x+5 in with Sexual Age Group Intercourse Birth Cohort of 40,000 Intercourse					
15-17	17.5%	60,212	10,537		
18-19	58.5%	40,141	23,483		
20-24	82.3%	100,211	82,474		
25-29	85.2%	100,045	85,238		
30-34	87.9%	99,855	87,772		
35-39	86.1%	99,582	85,740		
40-44	84.9%	99,181	84,205		
45-49	84.9%	98,588	83,701		
Total	77.8%	697,815	543,150		

<sup>&</sup>lt;sup>309</sup> "This analysis is based on the Statistics Canada's Canadian Community Health Survey 1.1 Public Use Microdata File and the Canadian Community Health Survey 2010 Public Use Microdata File. All computations, use and interpretation of these data are entirely that of H. Krueger & Associates Inc."

- Trussell et al. calculated the costs of contraceptive use per year, taking into account product costs as well as initial, follow-up and removal (if applicable) consultation costs.<sup>310</sup> The pill cost \$654 per year (Table 7-12, row *f*) while the LARC implant costs \$337 per year (Table 7-12, row *h*). We have estimated the cost of condoms to be \$46 per year (Table 7-12, row *g*), based on an annual average of 66 vaginal intercourse events per sexually active female ages 18-49<sup>311</sup> and a unit cost of \$0.68/condom.<sup>312</sup> In calculating overall coasts of contraception, we assumed that 50% of women would be using the pill and 50% condoms.<sup>313</sup>
- We assumed that females who tested positive (for alcohol misuse) would require an average of 1.5 follow-up visits for a total of 2.5 visits (Table 7-12, row *q*).
- The annual cost attributable to an individual living with FASD is based on the annual estimate of \$20,211 in 2007 (see Table 7-8) adjusted to 2013 using the health and personal care component of the B.C. Consumer Price Index (CPI) (+6.6).<sup>314</sup> The adjusted cost of \$21,541 was used to populate row p in Table 7-12.
- Potential costs avoided with a reduction in abortions following an unintended pregnancy have not been included in the model.<sup>315,316,317</sup>
- Discount rate of 3%

Based on these assumptions, the estimated cost per QALY is -\$2,829 (see Table 7-12, row *aa*).

The model is sensitive to a number of assumptions. For example:

- Assume the effectiveness of counseling at changing behavior is *increased* from 10.9% to 13.4% (Table 7-9, row *l*): \$/QALY = -\$3,203
- Assume the effectiveness of counseling at changing behavior is *decreased* from 10.9% to 8.3% (Table 7-9, row *l*): \$/QALY = -\$2,384
- Assume the prevalence of FASD is increased from 1% to 2%: ALY = -\$5,842

<sup>&</sup>lt;sup>310</sup> Trussell J, Henry N, Hassan F et al. Burden of unintended pregnancy in the United States: potential savings with increased use of long-acting reversible contraception. *Contraception*. 2013; 87(2): 154-61.

<sup>&</sup>lt;sup>311</sup> Herbenick D, Reece M, Schick V et al. Sexual behaviors, relationships, and perceived health status among adult women in the United States: results from a national probability sample. *Journal of Sexual Medicine*. 2010; 7 (Suppl 5): 277-90.

 $<sup>^{312}</sup>$  This unit cost is based on posted costs at London Drugs and Costco which resulted in a range of \$0.43 to \$0.92 per unit. We used the midpoint of \$0.68 / unit..

<sup>&</sup>lt;sup>313</sup> Black A, Yang Q, Wen SW et al. Contraceptive use among Canadian women of reproductive age: results of a national survey. *Journal of Obstetrics and Gynaecology Canada*. 2009; 31(7): 627-40.

<sup>&</sup>lt;sup>314</sup> Statistics Canada. *Table326-0021* - *Consumer Price Index (CPI), 2009 Basket, Annual (2002=100 unless otherwise noted).* 2013. Available at

http://www5.statcan.gc.ca/cansim/a26?lang=eng&retrLang=eng&id=3260021&paSer=&pattern=&stByVal=1&p1=1&p2=37&tabMode=dataTable&csid=. Accessed December 2013.

Statistics Canada. *Consumer Price Index, Health and Personal Care, by Province (Monthly) (British Columbia)*. 2013. Available at http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/cpis13f-eng.htm. Accessed December 2013.

<sup>&</sup>lt;sup>315</sup> Ames CM and Norman WV. Preventing repeat abortion in Canada: is the immediate insertion of intrauterine devices postabortion a cost-effective option associated with fewer repeat abortions? *Contraception*. 2012; 85(1): 51-5.

<sup>&</sup>lt;sup>316</sup> Baldwin MK and Edelman AB. The effect of long-acting reversible contraception on rapid repeat pregnancy in adolescents: a review. *Journal of Adolescent Health*. 2013; 52(4): S47-S53.

<sup>&</sup>lt;sup>317</sup> Trussell J, Henry N, Hassan F et al. Burden of unintended pregnancy in the United States: potential savings with increased use of long-acting reversible contraception. *Contraception*. 2013; 87(2): 154-61.

Table 7-12: CE of Screening and Counseling to Reduce FASD in a Birth Cohort of 40,000			
	(B.C.)		
Row Label	Variable	Base Case	Data Source
а	Years of life in birth cohort between ages 15-49 (females)	697,815	Table 17-10
b	Portion of person-years with alcohol misuse, ages 15-49 (females)	34.50%	Table 17-10
с	Person-years with alcohol misuse, ages 15-49 (females)	240,733	=b*a
d	Portion of person-years with sexual intercourse, ages 15- 49 (females)	77.84%	Table 17-11
е	Person-years with sexual intercourse, ages 15-49 (females)	543,150	=d*a
	Costs of Contraception		
f	Oral contraceptive (the pill) - per year	\$654	V
g	Male condoms - per year	\$46	V
h	LARC Implant - per year	\$337	V
i	Cost of contraception - current utilization	\$190,102,506	=(f+g)/2*e
j	Cost of contraception - LARC implant	\$183,041,556	=h*e
-	Costs of screening and counseling		
k	Cost of 10-minute office visit	\$34.00	V
1	Value of patient time and travel for office visit	\$57.56	V
m	Portion of 10-minute office visit for screen	20%	Assumed
n	Screens per year ages 15-49	1.0	Assumed
0	Cost of screening over lifetime of birth cohort	\$12,778,384	= a*(k+l)*m
р	Portion of 10-minute office visit for behavioural counseling interventions	80%	Assumed
q	Number of behavioural counseling interventions	2.5	Assumed
r	Intervention required every 5 years	0.2	Assumed
S	Total behavioural counselling interventions over lifetime of birth cohort	120,366	= c*q*r
t	Cost of behavioural counselling interventions over lifetime of birth cohort	\$8,816,591	= s*(k+l)*p
	Financial savings		
р	Annual costs attributable to an individual with FASD	-\$21,541	V
q	Years of life with FASD avoided	1,542	Table 17-9 row r
r	Costs attributable to FASD	-\$33,218,073	v
S	LARC contraceptive	-\$7,060,950	=j-i
	CE calculation		
t	Cost of initial screen, follow-up history and counseling (undiscounted)	\$21,594,975	=o+t
v	Costs avoided (undiscounted)	-\$40,279,024	=r+s
w	QALYs saved (undiscounted)	3,752	Table 17-9 row t
x	Cost of initial screen, follow-up history and counseling (3% discount rate)	\$13,655,327	
у	Costs avoided (3% discount rate)	-\$18,541,357	
z	QALYs saved (3% discount rate)	1,727	
аа	CE (\$/QALY saved)	-\$2,829	=(x+y)/z

v = Estimates from the literature

## Summary

Table 7-13: LARC and Screeni		•	uce FASD in
	hort of 40,0 mmary		
	Base		
	Case	Rar	nge
<b>CPB</b> (Potential QALYs Gained)			
Assume No Current Service			
3% Discount Rate	1,727	1,608	3,454
0% Discount Rate	3,752	3,494	7,504
Gap between B.C. Current (Unkno	wn, assume 0%	) and 'Best in t	he World' (70%)
3% Discount Rate	1,727	1,608	3,454
0% Discount Rate	3,752	3,494	7,504
CE (\$/QALY) including patient time co	sts		
3% Discount Rate	-\$2,829	-\$5,842	-\$2,384
0% Discount Rate	-\$4,980	-\$6,917	-\$4,694
<b>CE</b> (\$/QALY) <b>excluding</b> patient time co	osts		
3% Discount Rate	-\$7,800	-\$8,327	-\$7,722
0% Discount Rate	-\$8,599	-\$8,726	-\$8,580

Combining Alcohol and FASD Models

Table 7-14: Combining Alcohol and FASD Models				
Summary				
	Base			
	Case	Rar	nge	
CPB (Potential QALYs Gained)				
Assume No Current Service				
3% Discount Rate	2,079	1,849	3,915	
0% Discount Rate	4,888	4,272	8,993	
<b>CE</b> (\$/QALY)				
3% Discount Rate 0% Discount Rate	-\$8,719 -\$11,177	-\$10,287 -\$11,971	-\$6,781 -\$7,998	

## **Preventive Medication**

#### Fluoride Varnish and Fissure Sealants for Dental Health in Children

United States Preventive Service Task Force Recommendations (2014)

Dental caries is the most common chronic disease in children in the United States. According to the 1999–2004 National Health and Nutrition Examination Survey (NHANES), ~ 42% of children ages 2 to 11 years have dental caries in their primary teeth. After decreasing from the early 1970s to the mid-1990s, the prevalence of dental caries in children has been increasing, particularly in young children ages 2 to 5 years.

The U.S. Preventive Services Task Force recommends that primary care clinicians prescribe oral fluoride supplementation starting at age 6 months for children whose water supply is deficient in fluoride. (B recommendation)

The U.S. Preventive Services Task Force recommends that primary care clinicians apply fluoride varnish to the primary teeth of all infants and children starting at the age of primary tooth eruption. (B recommendation)

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of routine screening examinations for dental caries performed by primary care clinicians in children from birth to age 5 year. (I Recommendation)<sup>318</sup>

Canadian Task Force on Preventive Health Care Recommendations (1994)

Lower dental caries prevalence and the need for efficiency in the provision of preventive and therapeutic dental services require selective use of dental caries preventives and targeting of services toward persons at greatest risk. The following recommendations are based on a review of the available evidence.

*There is good evidence of effectiveness of the following measures in preventing dental caries (A Recommendation):* 

1. Water fluoridation for preventing coronal and root caries;

2. Fluoride supplements in low fluoride areas with careful adherence to low dosage schedules;

3. Professional topical fluoride applications and self-administered fluoride mouth rinses for those with very active decay or at high future risk for dental caries;

4. Fluoride dentifrices, with special supervision and the use of small amounts for young children;

5. Professionally-applied fissure sealants for selective use on permanent molar teeth soon after their eruption.

*There is poor evidence of effectiveness for the following measures in preventing dental caries (C Recommendation):* 

<sup>&</sup>lt;sup>318</sup> Moyer VA. Prevention of dental caries in children from birth through age 5 years: US Preventive Services Task Force recommendation statement. *Pediatrics*. 2014; 133(5): 1-10.

1. Professional topical fluoride applications and self-administered fluoride mouth rinses for the majority of children and for adults who are not at high risk for dental caries;

2. Toothbrushing (without a fluoride dentifrice) and flossing;

3. The traditional prophylaxis prior to a topical fluoride application or given at a dental recall visit;

4. Dietary counselling to the general population about cariogenic foods.<sup>319</sup>

Utilization of This Clinical Preventive Service

## **Currently in British Columbia**

In 2012/13, 91.8% of B.C. kindergarten children were screened for dental health. Of these, 67.3% were caries free, 18.1% had treated caries and 14.6% had visible decay.<sup>320</sup>

## Relevant British Columbia Population in 2013

The USPSTF uses a range of primary tooth eruption to age 5 in its guideline. In 2013, BC Stats estimates that there are 226,682 children aged 1-5 in British Columbia.

## Modelling CPB and CE - Fluoride Varnish

No model is available from the Partnership for Prevention and HealthPartners Research Foundation to calculate the CPB and CE of preventing dental caries in children less than five years old. In this section, we will calculate the CPB and CE associated with preventing dental caries in children less than five years old based on the following assumptions for CPB and CE.

In estimating CPB, we made the following assumptions:

- The effectiveness of fluoride varnish in reducing decayed, missing and filled teeth is 37% with a 95% CI of 24% to 51% (Table 8-1, row *b*).<sup>321</sup>
- An adherence rate of 70% with the intervention. This assumption will be modified from 50% to 90% in the sensitivity analysis (Table 8-1, row *c*).
- Numerous studies have assessed oral health related quality of life.<sup>322</sup> The USPSTF review notes that early childhood caries are associated with "pain and tooth loss, as well as impaired growth, decreased weight gain, and negative effects on speech, appearance, self-esteem, school performance, and quality of life."<sup>323</sup> We were not, however, able to find a value that we could use for our model. We therefore assumed a 0.03 reduction in quality of life associated with severe dental caries (with a range

<sup>&</sup>lt;sup>319</sup> Lewis DW and Ismail AI. *Canadian Guide to Clinical Preventive Health Care: Chapter 36: Prevention of Dental Caries*. 1994. Available at http://canadiantaskforce.ca/wp-

content/uploads/2013/03/Chapter36\_dental\_caries94.pdf?0136ff. Accessed November 2013.

<sup>&</sup>lt;sup>320</sup> Healthy Development and Women's Health Directorate - BC Ministry of Health. *BC Dental Survey of Kindergarten Children 2012-2013: A Provincial and Regional Analysis* 2014. Available at

http://www.health.gov.bc.ca/women-and-children/pdf/provincial-kindergarten-dental-survey-2012-13.pdf. Accessed July 2014.

<sup>&</sup>lt;sup>321</sup> Marinho VC, Worthington HV, Walsh T et al. Fluoride varnishes for preventing dental caries in children and adolescents. *Cochrane Database of Systematic Reviews*. 2013; 7.

<sup>&</sup>lt;sup>322</sup> Chou R, Cantor A, Zakher B et al. Preventing dental caries in children <5 years: systematic review updating USPSTF recommendation. *Pediatrics*. 2013; 132(2): 332-50.

<sup>&</sup>lt;sup>323</sup> Allen PF. Assessment of oral health related quality of life. *Health and Quality of Life Outcomes.* 2003; 1: 40.

from 0.01 to 0.05, as in the vision screening for amblyopia model) (Table 8-1, row h).

Based on these assumptions, the CPB associated with preventing decayed, missing and filled teeth in children less than five years old is 407 (Table 8-1, row *i*).

We also modified several major assumptions and recalculated the CPB as follows:

- Assume the effectiveness of fluoride varnish in reducing decayed, missing and filled teeth is reduced from 37% to 24% (Table 8-1, row *b*): CPB = 264
- Assume the effectiveness of fluoride varnish in reducing decayed, missing and filled teeth is increased from 37% to 51% (Table 8-1, row *b*): CPB = 560
- Assume adherence with the intervention is reduced from 70% to 50% (Table 8-1, row *c*): CPB = 290
- Assume adherence with the intervention is increased from 70% to 90% (Table 20-1, row *c*): CPB = 523
- Assume the change in QoL associated with improved oral health is reduced from 0.03 to 0.01 (Table 8-1, row *h*): CPB = 136
- Assume the change in QoL associated with improved oral health is increased from 0.03 to 0.05 (Table 8-1, row *h*): CPB = 678

Table	Table 8-1: CPB of Preventing Dental Caries in Children < 5 Years of Age in a Birth				
	Cohort of 40,000 (B.C.)				
Row					
Label	Variable	Base Case	Data Source		
а	Proportion of B.C. kindergarten children caries free	67.3%	V		
b	Effectiveness of fluoride varnish in reducing decayed, missing and filled tooth surfaces	37.0%	٧		
с	Adherence with intervention	70%	Assumed		
d	Children with treated caries or visible decay	13,080	= (1-a)*40,000		
е	Children benefitting from intervention	3,388	= (d * c) * b		
f	Years of benefits (from ages 1 to 5) per child	4.0	V		
g	Life-years lived with poor oral health	13,551	= e * f		
h	Change in QoL associated with improved oral health	0.03	Assumed		
i	Potential QALYs gained, CPB	407	= g * h		

*√* = Estimates from the literature

In estimating CE, we made the following assumptions:

- Fluoride varnish would be available for application to all children in B.C. (Table 8-2, row *a*) with a 70% adherence rate (Table 8-2, row *b*).
- The cost of applying fluoride varnish is \$13.80 (Table 8-2, row d).<sup>324</sup>
- For patient time costs, we assumed an hourly wage of \$24.39 (the B.C. average in 2013)<sup>325</sup> plus 18% benefits applied to the estimated hour of patient time required for a cost per dental visit of \$28.78 (Table 8-2, row *e*).

<sup>&</sup>lt;sup>324</sup> Based on the B.C. Dental Association fee guide.

- Assume fluoride varnish would need to be applied once every six months from age 1 to age 5 for a total of 9 applications (Table 8-2, row f).<sup>326</sup>
- Assume 2.9 new carious surfaces per untreated 5 year-old (Table 8-2, row g). $^{327}$
- Cost per filling would be \$121.00 (Table 8-2, row *i*).<sup>328</sup> This assumes a composite (white) filling in primary teeth. An amalgam (silver) filling would be \$85.30.
- The prevalence for day surgery for dental cavities in B.C. is estimated to be 1.38% of children (Table 8-2, row *l*).<sup>329</sup>
- The cost per day surgery for dental cavities in B.C. is estimated at \$1,782 which includes \$1,415 for hospital and \$267 for anaesthesia costs (Table 8-2, row *o*).<sup>330</sup>
- For patient time costs associated with dental day surgery, we assumed an hourly wage of \$24.39 (the B.C. average in 2013)<sup>331</sup> plus 18% benefits applied to the estimated three hours of patient time required for a cost of \$86.34 (Table 8-2, row *p*). The average dental day surgery in B.C. lasts 83 minutes.<sup>332</sup>
- Discount rate of 3%.

Based on these assumptions, the CE associated with preventing dental caries in children less than five years old is 19,292 per QALY (Table 8-2, row *y*).

We also modified several major assumptions and recalculated the cost per QALY as follows:

- Assume the effectiveness of fluoride varnish in reducing decayed, missing and filled teeth is reduced from 37% to 24% (Table 8-1, row *b*): \$/QALY = \$33,589
- Assume the effectiveness of fluoride varnish in reducing decayed, missing and filled teeth is increased from 37% to 51% (Table 8-1, row *b*): \$/QALY = \$12,046
- Assume adherence with the intervention is reduced from 70% to 50% (Table 8-1, row *c*): \$/QALY = \$16,450
- Assume adherence with the intervention is increased from 70% to 90% (Table 20-1, row *c*): \$/QALY = \$20,870

<sup>&</sup>lt;sup>325</sup> Statistics Canada. Average Hourly Wages of Employees by Selected Characteristics and Occupation, Unadjusted Data, by Province (Monthly) (British Columbia). 2013. Available at http://www.statcan.gc.ca/tablestableaux/sum-som/l01/cst01/labr69k-eng.htm. Accessed December 2013.

<sup>&</sup>lt;sup>326</sup> Fluoride Recommendations Work Group. Recommendations for using fluoride to prevent and control dental caries in the United States. *Morbidity and Mortality Weekly Report Recommendations and Reports*. 2001; 50(RR-14): 1-42.

<sup>&</sup>lt;sup>327</sup> Ramos-Gomez FJ and Shepard DS. Cost-effectiveness model for prevention of early childhood caries. *Journal of the California Dental Association*. 1999; 27(7): 539-44.

<sup>&</sup>lt;sup>328</sup> Based on the B.C. Dental Association fee guide.

<sup>&</sup>lt;sup>329</sup> Canadian Institute for Health Information. *Treatment of Preventable Dental Cavities in Preschoolers: A Focus on Day Surgery Under General Anesthesia*. 2013. Available at

https://secure.cihi.ca/free\_products/Dental\_Caries\_Report\_en\_web.pdf. Accessed January 2014.

<sup>&</sup>lt;sup>330</sup> Canadian Institute for Health Information. *Treatment of Preventable Dental Cavities in Preschoolers: A Focus* on Day Surgery Under General Anesthesia. 2013. Available at

https://secure.cihi.ca/free\_products/Dental\_Caries\_Report\_en\_web.pdf. Accessed January 2014.

<sup>&</sup>lt;sup>331</sup> Statistics Canada. Average Hourly Wages of Employees by Selected Characteristics and Occupation,

*Unadjusted Data, by Province (Monthly) (British Columbia).* 2013. Available at http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/labr69k-eng.htm. Accessed December 2013.

<sup>&</sup>lt;sup>332</sup> Canadian Institute for Health Information. *Treatment of Preventable Dental Cavities in Preschoolers: A Focus on Day Surgery Under General Anesthesia*. 2013. Available at

https://secure.cihi.ca/free\_products/Dental\_Caries\_Report\_en\_web.pdf. Accessed January 2014.

- Assume the change in QoL associated with improved oral health is reduced from 0.03 to 0.01 (Table 8-1, row *h*): \$/QALY = \$57,875
- Assume the change in QoL associated with improved oral health is increased from 0.03 to 0.05 (Table 8-1, row *h*): \$/QALY = \$11,575
- Assume that the application of fluoride varnish is equally effective if applied annually (versus every six months) (Table 8-2, row *f*). The evidence on frequency of applications is inconclusive<sup>333</sup>: AQALY = 7,561
- Assume that fluoride varnish needs to be applied four time per year to achieve maximum effectiveness (Table 8-2, row *f*): \$/QALY = \$51,552
- Change the cost per filling from \$121.00 for a composite filling to \$85.30 for an amalgam filling (Table 8-2, row *i*): \$/QALY = \$20,524.

Table	8-2: CE of Preventing Dental Caries in Childrer (B.C.) Cohort of 40,000	1 < 5 fears o	of Age in a Birth
Row Label	Variable	Base Case	Data Source
а	Children eligible for intervention	40,000	V
b	Adherence with intervention	70%	= Table 8-1 row o
С	Children with treated caries or visible decay	13,080	= Table 8-1 row c
	Costs of intervention		
d	Cost of flouride varnish application	\$13.80	٧
е	Value of patient time and travel for office visit	\$28.78	V
f	# of times flouride varnish applied from age 1 to 5	9	V
g	Estimated cost of intervention over lifetime of birth cohort	\$10,730,160	=(d+e)*f*a*b
	Cost avoided		
h	New carious surfaces per untreated 5 year-old	2.9	٧
i	Dental caries avoided	14,035	= g * c * Table 8-1 ro
j	Cost per filling	\$121.00	V
k	Value of patient time and travel for office visit	\$57.56	V
1	Filling costs avoided	-\$2,506,061	= (i + j) * h
m	Prevalence of day surgery for caries	1.38%	V
n	Day surgeries without intervention in birth cohort	552	= a * m
0	Day surgeries avoided with intervention in birth cohort	204	= m * Table 8-1 rov
р	Cost of day surgery	\$1,782	V
q	Value of patient time and travel for day surgery	\$86.34	V
r	Day surgery costs avoided	-\$381,590	= (p + q) * o
	CE calculation		
S	Cost of intervention over lifetime of birth cohort	\$10,730,160	= g
t	Costs avoided	-\$2,887,651	= +r
u	QALYs saved	407	Table 8-1 row i
v	Cost of intervention over lifetime of birth cohort (3% discount)	\$10,123,044	Calculated
w	Costs avoided (3% discount)	-\$2,724,267	Calculated
х	QALYs saved (3% discount)	384	Calculated
y	CE (\$/QALY saved)	\$19,292	= (v + w) / x

*√* = *Estimates from the literature* 

<sup>&</sup>lt;sup>333</sup> Marinho VC, Worthington HV, Walsh T et al. Fluoride varnishes for preventing dental caries in children and adolescents. *Cochrane Database of Systematic Reviews*. 2013; 7.

## Summary - Fluoride Varnish

Table 8-3: Fluoride Varnish in a Birth Coł			ars of Age
Sum	mary		
	Base		
	Case	Ra	nge
<b>CPB</b> (Potential QALYs Gained)			
Assume No Current Service			
3% Discount Rate	384	128	639
0% Discount Rate	407	136	678
Gap between B.C. Current and	Best in the Wo	orld	
3% Discount Rate	Current Sci	reening at 9	2% in B C
0% Discount Rate	current sci		2/6 III B.C.
CE (\$/QALY) including patient time	costs		
3% Discount Rate	\$19,292	\$7,561	\$57,875
0% Discount Rate	\$19,292	\$7,561	\$57,875
<b>CE</b> (\$/QALY) <b>excluding</b> patient time	costs		
3% Discount Rate	\$3,482	-\$320	\$10,445
0% Discount Rate	\$3,482	-\$320	\$10,445

## Modelling CPB and CE – Dental Sealants

While the focus of the USPSTF is on improving dental health in preschool children, there is also a body of evidence indicating that the use of dental sealants is effective in preventing decayed, missing and filled teeth in children six years of age and older with permanent teeth.<sup>334</sup> In this section, we will calculate the CPB and CE associated with preventing dental caries in children with permanent teeth based on the following assumptions for CPB and CE.

In estimating CPB, we made the following assumptions:

- In a birth cohort of 40,000, a total of 39,827 children would survive to age 6 (Table 8-4, row *a*).<sup>335</sup>
- An estimated 70% of parents would accept dental sealants for their children. This assumption will be modified from 50% to 90% in the sensitivity analysis (Table 8-4, row *b*).
- Dental sealants would be placed on the 1<sup>st</sup> molars at age six, the 1<sup>st</sup> and 2<sup>nd</sup> bicuspids at age 10 and the 2<sup>nd</sup> molars at age 12.
- The effectiveness of dental sealants in reducing decayed, missing and filled teeth is 84% at year 1, decreasing to 55% at year 9. Effectiveness beyond nine years is unknown.<sup>336</sup>
- An estimated 12.2% of Canadians avoid certain foods because of problems with their teeth or mouth, and 11.6% of Canadians sometimes or always have pain in their

<sup>&</sup>lt;sup>334</sup> Ahovuo-Saloranta A, Forss H, Walsh T et al. Sealants for preventing dental decay in the permanent teeth. *Cochrane Database of Systematic Reviews*. 2013; 3.

<sup>&</sup>lt;sup>335</sup> See <u>http://www.statcan.gc.ca/pub/84-537-x/2013005/tbl-eng.htm</u>. Accessed December 2013.

<sup>&</sup>lt;sup>336</sup> Ahovuo-Saloranta A, Forss H, Walsh T et al. Sealants for preventing dental decay in the permanent teeth. *Cochrane Database of Systematic Reviews*. 2013; 3.

mouth.<sup>337</sup> Based on this information, we assumed that 12% of children/youth with caries would have significant enough pain to reduce their quality of life (Table 8-4, row j).

- We assumed a 0.03 reduction in quality of life associated with severe dental caries (with a range from 0.01 to 0.05, as in the fluoride varnish model above) (Table 8-4, row *l*).
- We assumed that 30% of children in B.C. currently have dental sealants.<sup>338</sup>

Based on these assumptions, the CPB associated with preventing decayed, missing and filled teeth in children with permanent teeth is 558 (Table 8-4, row *m*). The CPB of 558 represents the gap between no coverage and improving coverage to 70%. The CPB of 319 life years saved (see Table 8-4, row *n*) represents the gap between the estimated current coverage of 30% and 70%.

lable	Table 8-4: CPB of Preventing Dental Carles in Children with Permanent Teeth in a			
	Birth Cohort of 40,000 (B.C.)			
Row				
Label	Variable	Base Case	Data Source	
а	# of 6-year olds in a birth cohort of 40,000	39,827	V	
b	Adherence with intervention	70%	Assumed	
с	Children 'accepting' intervention	27,879	=a*b	
d	Estimated new caries between ages 6-20 per child - untreated	7.69	Calculated	
е	Estimated new caries between ages 6-20 per child - treated	2.46	Calculated	
f	Estimated new caries without intervention	214,340	=c*d	
g	Estimated new caries with intervention	68,495	=c*e	
h	New caries avoided with intervention	145,845	=f-g	
i	Life-years lived without caries due to intervention	155,036	Calculated	
j	Proportion of children living with caries with significant pain	12%	V	
k	Life-years lived without caries or pain due to intervention	18,604	=i*j	
I	Change in QoL associated with improved oral health	0.03	Assumed	
m	Potential QALYs gained, Intervention increasing from 0% to 70%	558	=k*l	
n	Potential QALYs gained, Intervention increasing from 30% to 70%	319	=d18/7*4	

√ = Estimates from the literature

We also modified several major assumptions and recalculated the CPB as follows:

- Assume adherence with the intervention is reduced from 70% to 50% (Table 8-4, row *b*): CPB = 399
- Assume adherence with the intervention is increased from 70% to 90% (Table 8-4, row *b*): CPB = 718
- Assume the change in QoL associated with improved oral health is reduced from 0.03 to 0.01 (Table 8-4, row *l*): CPB = 186
- Assume the change in QoL associated with improved oral health is increased from 0.03 to 0.05 (Table 8-4, row *l*): CPB = 930

<sup>338</sup> Dye B, Tan S, Smith V et al. Trends in oral health status: United States, 1988-1994 and 1999-2004. *National Center for Health Statistics*. 2007; 11(248): 1-104.

<sup>&</sup>lt;sup>337</sup> Canadian Dental Association. *Dental Health Services in Canada: Facts and Figures 2010*. 2010. Available at http://www.med.uottawa.ca/sim/data/Dental/Dental\_Health\_Services\_in\_Canada\_June\_2010.pdf. Accessed January 2014.

In estimating CE, we made the following assumptions:

- The cost of applying sealants is estimated at \$26.10 per single tooth with an additional \$14.40 per tooth on the same quadrant.<sup>339</sup> The costs of applying dental sealants on the 1<sup>st</sup> molars at age six would therefore be \$104.40, the 1<sup>st</sup> and 2<sup>nd</sup> bicuspids at age 10 would be \$162.00 and the 2<sup>nd</sup> molars at age 12 would be \$104.40 for a total cost of \$370.80 (Table 8-5, row *d*).
- For patient time costs, we assumed an hourly wage of \$24.39 (the B.C. average in 2013)<sup>340</sup> plus 18% benefits applied to the estimated two hours of patient time required for a cost per dental visit of \$57.56 (Table 8-5, row *e* & *k*).
- Cost per filling would be \$145.00 (Table 8-5, row *j*).<sup>341</sup> This assumes a composite (white) filling in permanent teeth. An amalgam (silver) filling would be \$105.00.
- An average of 1.84 fillings would be treated each time fillings are required (Table 8-5, row *l*).<sup>342</sup>
- Discount rate of 3%.

Based on these assumptions, the CE associated with preventing dental caries in children with permanent teeth is -\$15,140 per QALY (Table 8-5, row v).

We also modified several major assumptions and recalculated the cost per QALY as follows:

- Assume adherence with the intervention is reduced from 70% to 50% (Table 8-4, row *b*): \$QALY = -\$15,140
- Assume adherence with the intervention is increased from 70% to 90% (Table 8-4, row *b*): \$QALY = -\$15,140
- Assume the change in QoL associated with improved oral health is reduced from 0.03 to 0.01 (Table 8-4, row *l*): \$QALY = -\$45,421
- Assume the change in QoL associated with improved oral health is increased from 0.03 to 0.05 (Table 8-4, row *l*): \$QALY = -\$9,084
- Change the cost per filling from \$145 for a composite filling to \$105 for an amalgam filling (Table 8-5, row *j*): \$/QALY = -\$4,706.

<sup>&</sup>lt;sup>339</sup> Based on the B.C. Dental Association fee guide.

<sup>&</sup>lt;sup>340</sup> Statistics Canada. Average Hourly Wages of Employees by Selected Characteristics and Occupation, Unadjusted Data, by Province (Monthly) (British Columbia). 2013. Available at http://www.statcan.gc.ca/tablestableaux/sum-som/101/cst01/labr69k-eng.htm. Accessed December 2013.

<sup>&</sup>lt;sup>341</sup> Based on the B.C. Dental Association fee guide.

<sup>&</sup>lt;sup>342</sup> Dye B, Tan S, Smith V et al. Trends in oral health status: United States, 1988-1994 and 1999-2004. *National Center for Health Statistics*. 2007; 11(248): 1-104.

Table	Table 8-5: CE of Preventing Dental Caries in Children with Permanent Teeth in a			
Row	Birth Cohort of 40,000 (B.C			
Label	Variable	Base Case	Data Source	
а	Children eligible for intervention	39,827	= Table 8-4 row a	
b	Adherence with intervention	70%	= Table 8-4 row b	
С	Children 'accepting' intervention	27,879	= Table 8-4 row c	
	Costs of intervention			
d	Cost of dental sealant applications	\$370.80	V	
е	Value of patient time and travel for office visit	\$57.56	V	
f	# of sealant applications (at age 6, 10 and 12)	3	V	
g	Estimated cost of intervention over lifetime of birth cohort	\$10,337,496	=c*d	
h	Estimated cost of patient time over lifetime of birth cohort	\$4,814,128	=c*e*f	
	Cost avoided			
i	Dental caries avoided with intervention	145,845	Calculated	
j	Cost per filling	\$145.00	V	
k	Value of patient time and travel for office visit	\$57.56	V	
I	# of fillings per visit	1.84	V	
m	# of dental visits avoided	79,264	=i/l	
n	Filling costs avoided	-\$21,147,577	=i*j	
0	Patient costs avoided	-\$4,562,423	=m*k	
	CE calculation			
р	Cost of intervention over lifetime of birth cohort	\$15,151,625	= g+h	
q	Costs avoided	-\$25,710,001	= n+o	
r	QALYs saved	558	Table 8-4 row k	
S	Cost of intervention over lifetime of birth cohort (3% discount)	\$13,735,242	Calculated	
t	Costs avoided (3% discount)	-\$20,476,934	Calculated	
u	QALYs saved (3% discount)	445	Calculated	
v	CE (\$/QALY saved)	-\$15,140	= (s-t) / u	

√ = Estimates from the literature

## Summary – Dental Sealants

Table 8-6: Dental Sealants for Children with PermanentTeeth in a Birth Cohort of 40,000					
Sum	imary				
	Base				
	Case	Rar	nge		
<b>CPB</b> (Potential QALYs Gained)					
Assume No Current Service					
3% Discount Rate	445	148	930		
0% Discount Rate	558	186	742		
Gap between B.C. Current and	Best in the Wo	orld			
3% Discount Rate	254	85	531		
0% Discount Rate	319	106	532		
CE (\$/QALY) including patient time	costs				
3% Discount Rate	-\$15,140	-\$45,421	-\$4,706		
0% Discount Rate	-\$18,917	-\$56,752	-\$8,465		
<b>CE</b> (\$/QALY) <b>excluding</b> patient time costs					
3% Discount Rate	-\$16,804	-\$50,411	-\$6,369		
0% Discount Rate	-\$19,368	-\$58,105	-\$8,916		

Population of British Columbia					
Males and Females					
2013					
Age Group	Male	Female	Total		
<1	22,579	21,537	44,116		
1	22,568	21,195	43,763		
2	23,254	21,863	45,117		
3	23,652	22,175	45,827		
4	23,708	22,285	45,993		
5	23,653	22,330	45,982		
6	23,576	21,996	45,571		
7	23,380	21,938	45,318		
8	23,556	21,976	45,532		
9	23,648	21,953	45,601		
10	23,309	21,396	44,705		
11	23,713	21,939	45,652		
12	23,988	22,444	46,432		
13	24,366	23,007	47,374		
14	24,817	23,328	48,144		
15-17	81,088	74,831	155,919		
18-19	57,055	55,256	112,311		
20-24	170,920	160,566	331,486		
25-29	171,871	163,865	335,736		
30-34	158,096	161,445	319,541		
35-39	144,494	149,657	294,151		
40-44	157,391	161,534	318,925		
45-49	170,875	172,858	343,733		
50-54	181,231	185,179	366,410		
55-59	166,581	174,945	341,526		
60-64	145,796	152,873	298,669		
65-69	119,415	124,046	243,461		
70-74	85,898	90,709	176,607		
75-79	62,816	69,757	132,573		
80-84	46,626	56,566	103,192		
85-89	26,597	40,507	67,104		
90+	13,640	28,911	42,551		
Total	2,314,156	2,354,866	4,669,022		
BCStats, Population Projections . Avaliable at http://www.bcstats.gov.bc.ca/StatisticsBySubject/Demograp hy/PopulationProjections.aspx					

## Appendix A: British Columbia Population by Age and Sex in 2013

Routine Immunization Schedule <sup>343</sup>											
Age Group → Vaccine ↓	2 Months	4 Months	6 Months	12 Months	18 Months	Starting at 4 Years of Age (Kindergarten Entry)	Grade 6	Grade 9	Adult	65 Years and Over	High Risk Program *
Diphtheria, Tetanus, Pertussis, Hepatitis B, Polio, and Haemophilus influenza type b (DTaP-HB- IPV-Hib) Vaccine	~	~	~								
Diphtheria, Tetanus, Pertussis, Polio, Haemophilus influenza Type b (DTaP- IPV-Hib) Vaccine					~						
Pneumococcal Conjugate (PCV 7) Vaccine	~	~		~							√*
Rotavirus Vaccine	~	~									
Hepatitis A Vaccine [a]			Aboriginal infants only		✓ Aboriginal infants only	Aboriginal children not previously immunized					√*
Hepatitis B Vaccine [b]							✓ If eligible		✓ If eligible		√*
Measles, Mumps, Rubella (MMR) Vaccine [c]				~		~			If susceptible		
Meningococcal C Conjugate (Men-C) Vaccine [d]	~			~			~		✓ If eligible		√*
Chickenpox (Varicella) Vaccine <mark>[e]</mark>				~		~	✓ If eligible		If susceptible		
Human Papillomavirus (HPV) Vaccine [f]							~	✓	Susceptione		
Diphtheria, Tetanus, Pertussis, Polio (DTaP-IPV) Vaccine						$\checkmark$					
Tetanus, Diphtheria, Pertussis (Tdap) Vaccine								~			√*
Tetanus and Diphtheria (Td) Vaccine [g]									Every 10 years	Every 10 years	
Inactivated Influenza (Flu) Vaccine <mark>[h]</mark>			Annually for	✓ r infants 6 mont	hs to 4 years					~	√*
Live Attenuated Influenza (Flu) Vaccine [h]			Annually for	of age	ns to 4 years					annually	annually
Pneumococcal Polysaccharide Vaccine										✓ 1 time only	√*

## Appendix B: B.C. Immunization Schedule

[a] The hepatitis A vaccine is provided free to aboriginal children and adolescents aged 6 months to 18 years living both on-reserve and off-reserve. Infants will receive the first dose at 6 months of age and the second dose at 18 months of age. Older children and adolescents need 2 doses of the vaccine. The second dose needs to be given at least 6 months after the first dose.

<sup>&</sup>lt;sup>343</sup> HealthLink BC. *BC Immunization Schedule*. 2013. Available at http://www.healthlinkbc.ca/pdf/routine-immunization-schedule.pdf. Accessed November 2013.

[b] The hepatitis B vaccine is provided free to babies in B.C. as a series of 3 doses at 2, 4 and 6 months of age in combination with other routine childhood vaccines. Children who did not complete their infant hepatitis B vaccine series or have never received the vaccine will be offered hepatitis B vaccine for free in grade 6. The hepatitis B vaccine is provided free to people born in 1980 or later who have never received the vaccine or have not received the recommended number of doses for their age.

[c] Anyone born after 1956 that has not been immunized or does not have immunity to measles, mumps and rubella should get 2 doses of the MMR vaccine.

[d] The Men-C vaccine is provided free to people born in 1988 or later who have never received the vaccine.

[e] The chickenpox vaccine is provided free as a series of 2 doses. The first dose of vaccine is given at 12 months of age and the second starting at 4 years of age before a child enters kindergarten. A second dose of the vaccine is offered to students in grade 6 who did not receive 2 doses when they were younger. People 13 years of age and over who have never received the vaccine also need 2 doses. It is not necessary for those who had chickenpox or shingles disease at 1 year of age or older to get the vaccine.

[f] Two doses of the HPV vaccine, Gardasil®, are provided free to girls in grade 6. A 3rd dose is given to girls in grade 9. The HPV vaccine is also offered to girls in grade 9 who have not received the vaccine. Girls born in 1994 or later who were eligible for the HPV vaccine but did not receive it may contact their local health unit to get vaccinated at no cost. Although the HPV vaccine, Gardasil®, is only provided free to eligible girls in B.C., the vaccine is recommended for females 9 to 45 years of age and males 9 to 26 years of age. The vaccine is also recommended for men 27 years of age and older who have sex with men. Contact your health care provider for more information.

[g] A person with a deep dirty wound or bite may need a dose of tetanus vaccine if it has been 5 or more years since they received their last dose of vaccine.

[h] Annual influenza immunization is recommended for people at high risk of serious illness from influenza and people able to transmit or spread influenza to those at high risk of serious illness from influenza. For a complete list, see HealthLinkBC File #12d Influenza (Flu) Vaccine and HealthLinkBC File #12e Live Attenuated Influenza (Flu) Vaccine.

\* High Risk Program: British Columbia provides many vaccines free of charge to some groups of people, such as those with chronic illness or weakened immune systems. Contact your health care provider or doctor, or call 8-1-1 for more information.

## Appendix C: Perinatal Services and Other PHSA Guidelines

The 2013 Perinatal Services BC document titled *Guidelines and Standards: Statement of Provincial Guideline Adoption in British Columbia* notes that

Perinatal Services BC develops evidence-based, clinical practice guidelines that include recommendations for care of the woman during pregnancy, labour/birth, and after birth for the mother and newborn in British Columbia. These guidelines assist the practitioner and patient in making decisions about health care practices (choices) with a goal of better patient care across health care settings. Evidence-based guidelines hold the promise of improving health care quality and outcomes yet should not be interpreted as policy. It should be recognized that one size does not fit all. Individual practitioners use both clinical expertise and the best available external evidence in day-to-day patient care; neither of which when used alone is enough.<sup>344</sup>

The following provides a summary of PSBC and other Provincial Health Services Authority (PHSA) guidelines that are applicable to clinical prevention. The full text of most of these guidelines can be found on the PSBC website.<sup>345</sup> Some of the guidelines described may not be the most recent version, as several of the guidelines were under revision at the time this document was written. Many of these guidelines have not gone through the same rigor or economic modelling as the maneuvers being considered for the Lifetime Prevention Schedule. They are, however, evidence-based and are supported by evidence statements and grading of recommendations according to the ranking of the Canadian Task Force on Preventative Health Care (CTFPHC). Though the definitions of CTFPHC evidence statements and recommendations have changed through the years, below we have included a version most commonly used in the following guidelines. PSBC also recommends guidelines produced by other organizations who are the content experts in the condition, for example, the Oak Tree Clinic for HIV in Pregnancy guidelines.

Key to evidence statements and grading of recommendations,				
using the ranking of the Canadian Ta	sk Force on Preventative Health Care			
Quality of Evidence Assessment	<b>Classification of Recommendations</b>			
I: Evidence obtained from at least one	A. There is good evidence to recommend			
properly randomized controlled trial	the clinical preventive action			
II-1: Evidence from well-designed	<b>B</b> . There is fair evidence to recommend the			
controlled trials without randomization.	clinical preventive action			
<b>II-2</b> : Evidence from well-designed cohort	C. The existing evidence is conflicting and			
(prospective or retrospective) or case-	does not allow to make a recommendation			
control studies, preferably from more than	for or against use of the clinical preventive			
one centre or research group.	action; however, other factors may influence			
<b>II-3</b> : Evidence obtained from comparisons	decision-making			
between times or places with or without the	<b>D</b> . There is fair evidence to recommend			
intervention. Dramatic results in	against the clinical preventive action			
uncontrolled experiments (such as the	E. There is good evidence to recommend			
results of treatment with penicillin in the	against the clinical preventive action			
1940s) could also be included in this	<b>I.</b> There is insufficient evidence (in quantity			

 <sup>&</sup>lt;sup>344</sup> Perinatal Services BC. *Guidelines and Standards: Statement of Provincial Guideline Adoption in British Columbia*. 2013. Available at http://www.perinatalservicesbc.ca/Guidelines/default.htm. Accessed February 2014.
 <sup>345</sup> PSBC guidelines are available at http://www.perinatalservicesbc.ca/Guidelines/Guidelines/default.htm. Accessed February 2014.

category. III: Opinions of respected authorities,	or quality) to make a recommendation; however, other factors may influence
based on clinical experience, descriptive	decision-making
studies, or reports of expert committees.	

## Screening for Asymptomatic Disease or Risk Factors

#### Gestational Diabetes Mellitus Screening & Diagnosis (Last updated October, 2010)<sup>346</sup>

"Strong, continuous associations of maternal glucose levels below those diagnostic of GDM [gestational diabetes mellitus] with increased birthweight and increased cord blood C-peptide. No obvious thresholds at which risk is increased. The results were applicable to all centres. Consensus was required to translate these results into clinical practice."

Tests/Values: New guideline as of October 1, 2010

- Elimination of the 3 hr 100 g OGTT
- 50 g GCT optional
- 2hr 75g OGTT using IADPSG diagnostic criteria

Current Recommendations <sup>347</sup>					
Diagnostic Criteria	Canadian Diabetes Association recommendations (2008) <sup>348</sup>	International Association of Diabetes and Pregnancy Study Groups recommendations (2010)			
<ul> <li>Screening</li> <li>in women at high risk in their first trimester</li> <li>all women at 24-28 wks pregnant</li> </ul>	<ul> <li>50 g glucose screen followed by 1 hr PG</li> <li>If 1 hr PG:</li> <li>7.8 mmol/L = normal, retest only if risk factors increase</li> <li>7.8 - 10.2 mmol/L = perform an OGTT</li> <li>≥ 10.3 mmol/L = diagnosis is GDM</li> </ul>	Eliminated 50 g glucose screen			
Diagnostic Test:	75 g OGTT	75 g OGTT			

Maternity Care Pathway (Last updated February, 2010)<sup>349</sup>

In addition to the recommendations below for the Maternity Care Pathway, PSBC offers a Pregnancy Passport to help women understand what to expect with their pregnancy care and help them think about how to care for themselves and their baby.<sup>350</sup>

http://www.perinatalservicesbc.ca/NR/rdonlyres/FEA4D154-7871-4284-BA54-

<sup>&</sup>lt;sup>346</sup> Perinatal Services BC. Gestational Diabetes Mellitus Screening and Diagnosis: An Update for Guideline 10B that is no longer available. 2010. Provincial Health Services Authority. Available at

http://www.perinatalservicesbc.ca/NR/rdonlyres/FEA4D154-7871-4284-BA54-

<sup>6</sup>F575A7B683D/0/OBGuidelinesDiabetesScreening10B.pdf. Accessed January 2014.

<sup>&</sup>lt;sup>347</sup> Perinatal Services BC. Gestational Diabetes Mellitus Screening and Diagnosis: An Update for Guideline 10B that is no longer available. 2010. Provincial Health Services Authority. Available at

<sup>6</sup>F575A7B683D/0/OBGuidelinesDiabetesScreening10B.pdf. Accessed January 2014.

<sup>&</sup>lt;sup>348</sup> Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2008 clinical practice guidelines for the prevention and management of diabetes in Canada. *Canadian Journal of Diabetes*. 2008; 32(suppl 1): S1-S201.

<sup>&</sup>lt;sup>349</sup> British Columbia Perinatal Health Program. BCPHP Obstetric Guideline 19: Maternity Care Pathway. 2010. Available at http://www.perinatalservicesbc.ca/NR/rdonlyres/4C4892B0-BF43-496A-B113-5A50471B9C4B/0/OBGuidelinesMaternityCarePath19.pdf. Accessed January 2014.

Screening Test	Recommendation	Level of Recommendation
Blood group, rhesus D status and red cell antibodies	Recommend in every pregnancy within the first trimester and again at 28 weeks in Rh negative women with only one previous type and screen done by Canadian Blood Services	С
Hb, MCV	Recommend	В
HIV	Recommend	A
Rubella antibody titre	Recommend if no known history of disease or immunization	В
Hepatitis C testing	<ul> <li>Recommend screening to women with risk factors:</li> <li>Injection drug use (even once)</li> <li>Hemodialysis</li> <li>Persistent elevated AST</li> <li>Receipt of blood products or organs before 1992 or clotting factors before 1988</li> <li>Exposure to blood of high-risk individual</li> <li>Prison inmates</li> <li>HIV positive</li> <li>Tattoos not carried out in properly regulated premises</li> </ul>	A
Standard Test for syphilis (STS)	Recommend in every pregnancy	А
Hepatitis B surface antigen	Recommend	A
Other investigations: such as parovirus B19	Routine screening for Toxoplasmosis, B19, mumps should be done	Ι
serology (B19, IgG and IgG), mumps, CMV	Offer serology testing to women exposed to or with symptoms of parovirus, mumps or CMV to determine prior immunity (IgG) or current infection (IgM)	В
Chlamydia screening	Offer screening to all women Recommend screening to women with increased risk factors	В
Gonorrhoea screening	Offer screening to all women Recommend screening to women with increased risk factors	А
Midstream urine for C&S	Recommend screening for asymptomatic bacteruria in early pregnancy and	A
	screening in each trimester in women with known history of recurrent UTI	С
GTT or Fasting Blood Glucose	Offer to diagnose (case finding) Type 2 Diabetes for patients with risk factors: obesity and/or strong family history	А
Thyroid Stimulating	Offer to all women	В

<sup>350</sup> Perinatal Services BC. *Pregnancy Passport*. 2012. Available at http://www.perinatalservicesbc.ca/familyresources/pregnancypassport/default.htm. Accessed February 2014.

Hormone	Recommend to women with a history or symptoms of thyroid disease or other conditions associated with thyroid disease	
Pap Test	Offer Pap testing if indicated	В
TWEAK screening for pregnancy risk- drinking	Recommend screening questionnaire	В

## **Routine Prenatal Care at each Appointment**

Procedure	Recommendation	Level of
	itteominentauton	Recommendation
Blood pressure		С
Assess Fetal	Recommend that healthy women without	В
Movement	risk factors for adverse perinatal outcomes be	
	aware of fetal movements beginning at 26-32	
	weeks and to perform a fetal movement	
	count if they perceive decreased movements	
	Recommend daily fetal movements counting	A
	starting at 26 weeks to 32 weeks in all	
	pregnancies with risk factors for adverse	D
	outcomes, and recommend that women who	В
	do not perceive six movements in an interval	
	of two hours seek further antenatal testing as	
T + 11 + +	soon as possible	0
Fetal heart tones	Offer at each visit, to confirm a viable fetus	C
Symphysis-fundus	Recommend measuring from symphysis	В
height	pubis to top of the fundus in centimeters.	
OTI	Plot on graph in Antenatal Record	D
STIs	Recommend screening in each trimester for	В
	women with ongoing risk factors for STI	
	acquisition: Hep B, Hep C, HIV, Chlamydia,	
I Inin a mar alim ati ala	syphilis, gonorrhea	В
Urinary dipstick	Recommend all pregnant women be assessed	В
testing for proteinuria	for proteinuria in early pregnancy to screen	
	for preexisting renal disease	С
	Recommend urinary dipstick testing for screening for proteinuria when the suspicion	C
	of preeclampsia is low	А
	Recommend more definitive testing for	A
	proteinuria (by urinary protein:creatinine	
	ratio (UPCR) or 24-hour urine collection)	
	when there is a suspicion of preeclampsia	
Weight measurement	Recommend for women who are	Ι
The organ measurement	underweight or overweight. Monitor weight	1
	relative to the individual goal	
	Consider recommending little to no weight	В
	gain for obese women	D
	Sum for obese women	l

#### Routine Care at 28 – 36 Weeks

Procedure/Test	Recommendation	Level of Recommendation
Blood group, rhesus D status and red cell antibodies	Recommend for every pregnancy within the first trimester and again at 28 weeks in Rh negative women with only one previous type and screen done by Canadian Blood Services	С
CBC, HgB, MCV	Offer re-screening for anaemia If HgB less than 105g/l investigate and consider iron supplements	С
1-hour 50-g glucose screen for gestational diabetes (GDM)	Offer screening for gestational diabetes. The discretion to screen and how to screen is at the discretion of the care provider and the woman given the current lack of evidence for any one approach	Ι
Edinburgh Postnatal Depression Scale (EPDS)	Recommend the EPDS be administered to all women between 28-32 weeks	В
Vaginal anal swab for GBS	Offer all women screening for presence of group B streptococcus (GBS) to determine carrier status	В
Suppressive therapy for recurrent genital HSV	Recommended Valacyclovir 500 mg BID from 36 weeks to delivery or Acyclovir 400 mg TID	А
ECV for Breech Presentation	Confirm presentation with detailed ultrasound at 34 weeks. Offer ECV if available	А

## Prenatal Screening for Down Syndrome, Trisomy 18 and Open Neural Tube Defects (Last updated February, 2014)

"After a discussion of the pros and cons, all pregnant women regardless of age should be offered prenatal screening for Down syndrome, trisomy 18, and ONTDs. Ideally this discussion needs to occur prior to 10 weeks gestational age (GS) so that the best possible screen for the patient is available. After receiving the information, it is the woman's choice to proceed with or decline screening."<sup>351</sup>

### Group B Streptococcal Screening in the Perinatal Period (Last updated November, 2013)<sup>352</sup>

- "Offer all women screening for colonization with group B streptococcus at 35 to 37 weeks gestation including women with planned cesarean delivery.
- Provide intravenous antibiotic prophylaxis for group B streptococcus at the onset of labour or rupture of membranes to 1) any woman + for GBS by vaginal/rectal swab done at 35 37 weeks gestation 2) any woman with an infant previously infected with GBS 3) any woman with documented GBS bacteriuria in the current pregnancy.
- Manage all women who are less than 37 weeks gestation and in labour or with ruptured membranes with IV GBS antibiotic prophylaxis for a minimum of 48 hours unless there

<sup>&</sup>lt;sup>351</sup> See <u>http://www.perinatalservicesbc.ca/NR/rdonlyres/91324196-DBAF-4CE2-978E-41ED290F9FB1/0/GuidelineMarch.pdf</u>. Accessed April 2014.

<sup>&</sup>lt;sup>352</sup> See <u>http://www.perinatalservicesbc.ca/NR/rdonlyres/325C4D6C-DE66-4C42-AE22-2308119D766C/0/OBGuidelinesGBSPerinatalPeriod12.pdf</u>. Accessed April, 2014.

has been a negative vaginal/rectal swab or rapid nucleic acid-based test within the previous 5 weeks.

- Treat all women with intrapartum fever and signs of chorioamnionitis with broad spectrum intravenous antibiotics targeting chorioamnionitis and including coverage for group B streptococcus, regardless of group B streptococcus status and gestational age.
- Request antibiotic susceptibility testing on group B streptococcus-positive urine and vaginal/rectal swab cultures in women who are thought to have a significant risk of anaphylaxis from penicillin.
- If a woman with pre-labour rupture of membranes at ≥ 37 weeks' gestation is positive for group B streptococcus by vaginal/rectal swab culture screening, has had group B streptococcus bacteriuria in the current pregnancy, or has had an infant previously affected by group B streptococcus disease, administer intravenous group B streptococcus antibiotic prophylaxis. Immediate obstetrical delivery (such as induction of labour) is indicated, as described in the Induction of Labour guideline published by the Society of Obstetricians and Gynaecologist in September 2013.
- At ≥ 37 weeks' gestation, if group B streptococcus colonization status is unknown and the 35- to 37-week culture was not performed or the result is unavailable and the membranes have been ruptured for greater than 18 hours, administer intravenous group B streptococcus antibiotic prophylaxis.
- If a woman with pre-labour rupture of membranes at < 37 weeks' gestation has an unknown or positive group B streptococcus culture status, administer intravenous group B streptococcus prophylaxis for 48 hours, as well as other antibiotics if indicated, while awaiting spontaneous or obstetrically indicated labour."

#### Herpes in the Perinatal Period (Last updated June, 2008)<sup>353</sup>

### Recommendations

- 1. Women's history of genital herpes should be evaluated early in pregnancy. (III-A)
- 2. Women with known recurrent genital herpes simplex virus (HSV) should be counselled about the risks of transmission of HSV to their neonates at delivery. (III-A)
- 3. At delivery, women with recurrent HSV should be offered a Caesarean section if there are prodromal symptoms or in the presence of a lesion suggestive of HSV. (II-2A)
- 4. Women with known recurrent genital HSV infection should be offered acyclovir or valacyclovir suppression at 36 weeks' gestation to decrease the risk of clinical lesions and viral shedding at the time of delivery and therefore decrease the need for Caesarean section. (I-A)
- 5. Women with primary genital herpes in the third trimester of pregnancy have a high risk of transmitting HSV to their neonates and should be counselled accordingly and should be offered a Caesarean section to decrease this risk. (II-3B)
- 6. A pregnant woman who does not have a history of HSV but who has had a partner with genital HSV should have type-specific serology testing to determine her risk of acquiring genital HSV in pregnancy before pregnancy or as early in pregnancy as possible. Testing should be repeated at 32 to 34 weeks' gestation. (III-B)

<sup>&</sup>lt;sup>353</sup> Money D and Steben M. Guidelines for the management of herpes simplex virus in pregnancy. *Journal of Obstetrics and Gynaecology Canada*. 2008; 30(6): 514-9.

#### Newborn Screening (Last updated December, 2010)<sup>354</sup>

"The goal of BC's Newborn Screening (NBS) Program is to identify babies who have a treatable disorder detectable through a blood test. These babies appear normal at birth and, unless they are screened, might otherwise not be diagnosed with one of these disorders before irreversible damage has occurred. If not treated, these conditions are associated with recurrent illnesses and/or developmental disabilities and/or death. Early detection of these disorders allows treatment that may prevent severe mental handicap, growth problems, health problems and sudden infant death.<sup>355,356</sup>

Babies born in British Columbia and the Yukon are screened for the following 22 disorders:

### **Metabolic Disorders**

Amino Acid Disorders

- Phenylketonuria (PKU)
- Maple Syrup Urine Disease (MSUD)
- Citrullinemia (CIT)
- Argininosuccinic Acidemia (ASA)
- Homocystinuria (Hcy)
- Tyrosinemia (Tyr 1)

Fatty Acid Oxidation Disorders:

- Medium-chain Acyl-CoA
   Dehydrogenase Deficiency (MCAD)
- Long-chain Hydroxyacyl-CoA Dehydrogenase Deficiency (LCHAD)
- Trifunctional Protein Deficiency (TFP)
- Very-long chain AcylCoA Dehydrogenase Deficiency (VLCAD)

Organic Acid Disorders:

- Propionic Acidemia (PROP)
- Methylmalonic Acidemia (MUT)
- Cobalamin Disorders (Cbl A,B)
- Glutaric Aciduria Type 1 (GA 1)
- Isovaleric Acidemia (IVA)

Galactosemia (GALT)

Nine secondary disorders that are not primary targets of the screening program will be identified as "byproducts" of the screening process:

<sup>356</sup> Perinatal Services BC. *Perinatal Services BC Neonatal Guideline 9: Newborn Screening*. 2010. Available at http://www.perinatalservicesbc.ca/NR/rdonlyres/5DF1127B-9015-4714-9B31-

01E52BC3747D/0/NBGuidelinesScreening9.pdf. Accessed January 2014.

## **Endocrine Disorders**

- Congenital Hypothyroidism (CH)
- Congenital Adrenal Hyperplasia (CAH)

## Hemoglobinopathies

- Sickle Cell Disease (HbSS)
- Sickle Cell/Hemoglobin C (HbSC)
- Sickle Cell/β-thalassemia (HbS/β-thal)

## **Cystic Fibrosis (CF)**

<sup>&</sup>lt;sup>354</sup> Perinatal Services BC. *Perinatal Services BC Neonatal Guideline 9: Newborn Screening*. 2010. Available at http://www.perinatalservicesbc.ca/NR/rdonlyres/5DF1127B-9015-4714-9B31-

<sup>01</sup>E52BC3747D/0/NBGuidelinesScreening9.pdf. Accessed January 2014.

<sup>&</sup>lt;sup>355</sup> Dietzen DJ, Rinaldo P, Whitley RJ et al. National Academy of Clinical Biochemistry laboratory medicine practice guidelines: follow-up testing for metabolic disease identified by expanded newborn screening using tandem mass spectrometry; executive summary. *Clinical Chemistry*. 2009; 55(9): 1615-26.

- a. Amino Acid Disorders
  - i. Hypermethioninemia (MET)
  - ii. Citrin Deficiency (CIT II)
  - iii. Mild Hyperphenylalaninemia (H-Phe)
  - iv. Biopterin Biosynthesis Deficits (BIOPT BS)
  - v. Biopterin Recycling Deficits (BIOPT REC)
- b. Organic Acid Disorders
  - i. Cobalamin C/D (Cbl C/D)
  - ii. 2-methylbutyrylglycinuria (2MBG)
- c. Fatty Acid Oxidation Disorders
  - i. Multiple Acyl-CoA Dehydrogenase Deficiency (MAD)
- d. Hemoglobinpathies
  - i. Variant Hemoglobinpathies (Var Hb)

#### Newborn Hearing Screening (Last updated September, 2009)<sup>357</sup>

"The BC Early Hearing Program (BCEHP) is a province-wide program for early hearing screening and intervention. The BCEHP is a service of BC Children's Hospital and the Provincial Health Services Authority (PHSA) in partnership with the regional health authorities and the Ministry of Children and Family Development and their funded agencies. [...] BCEHP, which was announced in March 2005 by the provincial government, is the first province-wide screening program to check the hearing of newborns in British Columbia."

"Prior to the introduction of the BCEHP, the average age of identification of hearing loss in children was approximately two and a half years. Without hearing screening, age of identification is very variable, and is dependent on the degree of hearing loss, whether there is a known risk factor, and whether there is parental concern. Typically, the more severe the hearing loss, the earlier the diagnosis occurred."

"With the introduction of newborn hearing screening, diagnosis of hearing loss occurs in the majority of healthy babies by three months of age. Hearing devices are fit within one month of the confirmed diagnosis. Extended stays in the NICU may lengthen the timeframes."

"With the BCEHP, babies with hearing loss are identified earlier and have intervention and supports in place by the age of six months. In many cases, this is happening at much earlier ages. Studies show that in the absence of other complicating factors, early intervention and support can help children with hearing loss have skills similar to their hearing peers by the time they start kindergarten."

Goals of the program:

- Hearing screening completed before one month of age
- Diagnostic hearing assessment completed before three months of age
- Medical assessment commenced by three months of age
- Early intervention and communication supports commenced before six months of age

<sup>&</sup>lt;sup>357</sup> Public Health Services Authority. *BCEHP Background*. 2009. Available at

http://www.phsa.ca/AgenciesAndServices/Services/BCEarlyHearing/ForPhysicians/BCEHP-Background.htm. Accessed January 2014.

**Behavioural Counselling Interventions** 

# Alcohol Use During the Perinatal Period & Fetal Alcohol Spectrum Disorder (Last updated August, 2010) $^{\rm 358}$

## **Summary Statements**

- 1. There is evidence that alcohol consumption in pregnancy can cause fetal harm. (II-2) There is insufficient evidence regarding fetal safety or harm at low levels of alcohol consumption in pregnancy. (III)
- 2. There is insufficient evidence to define any threshold for low-level drinking in pregnancy. (III)
- 3. Abstinence is the prudent choice for a woman who is or might become pregnant. (III)
- 4. Intensive culture-, gender-, and family-appropriate interventions need to be available and accessible for women with problematic drinking and/or alcohol dependence. (II-2)

## Recommendations

- 1. Universal screening for alcohol consumption should be done periodically for all pregnant women and women of child-bearing age. Ideally, at-risk drinking could be identified before pregnancy, allowing for change. (II-2B)
- 2. Health care providers should create a safe environment for women to report alcohol consumption. (III-A)
- 3. The public should be informed that alcohol screening and support for women at risk is part of routine women's health care. (III-A)
- 4. Health care providers should be aware of the risk factors associated with alcohol use in women of reproductive age. (III-B)
- 5. Brief interventions are effective and should be provided by health care providers for women with at-risk drinking. (II-2B)
- 6. If a woman continues to use alcohol during pregnancy, harm reduction/treatment strategies should be encouraged. (II-2B)
- 7. Pregnant women should be given priority access to withdrawal management and treatment. (III-A)
- 8. Health care providers should advise women that low-level consumption of alcohol in early pregnancy is not an indication for termination of pregnancy. (II-2A)

# Antidepressant Use During Pregnancy: Considerations for the Newborn Exposed to SSRIs/SNRIs (Last updated May, 2013)<sup>359</sup>

### Recommendations

- 1. Parents should be educated prior to delivery about the increased risks for neonatal adaptation syndrome, congenital heart defects, and PPHN. This includes being informed of the screening their newborn will receive in the first 24 hours. (A)
- 2. Differential diagnosis and assessment is required for symptoms and signs of neonatal irritability, poor feeding and respiratory difficulties to rule out infectious, metabolic, circulatory and neurological conditions. Other withdrawals should also be ruled out. (A)
- 3. Focus on supportive care and emphasize that neonatal adaptation syndrome symptoms are usually mild and transient. (A)

<sup>&</sup>lt;sup>358</sup> Carson G, Cox L, Crane J et al. Alcohol use and pregnancy consensus clinical guidelines. *Journal of Obstetrics and Gynaecology Canada*. 2010; 32(8 Suppl 3): S1-S27.

<sup>&</sup>lt;sup>359</sup> Perinatal Services BC. Antidepressant Use During Pregnancy: Considerations for the Newborn Exposed to SSRIs/SNRIs. 2013. Available at http://www.perinatalservicesbc.ca/NR/rdonlyres/F97DB04E-4031-440F-BFA0-D52090E0C9ED/0/NBGuidelinesConsiderationsNBexposedtoSSRIs\_SNRIsMay2013.pdf. Accessed January 2014.

- 4. Newborns exposed to SSRIs/SNRIs in utero should have their vitals assessed every 4 hours for the first 24 hours including the use of pulse oximetry at each assessment. The first SpO2 should be at approximately 1 hour post delivery. Newborns with a low SpO2 should undergo consultation with a pediatrician if available. If a pediatrician is not available, consult BC Women's NICU. (A)
- 5. All newborns born after in utero exposure to SSRI/SNRI require a complete clinical exam immediately after delivery and prior to discharge from hospital. (A)
- 6. Serious congenital heart defects will likely be discovered through use of clinical examination and pulse oximetry (see recommendation 4). A low SpO2 should undergo consultation with a pediatrician if available. If a pediatrician is not available, consult BC Women's NICU. If a congenital heart defect is suspected, discuss with Pediatric Cardiology and consider echocardiography. (A)
- 7. The one-month visit should include a complete newborn clinical exam with particular attention paid to the possibility of septal defects that may not have been detected by initial screening. (A)
- 8. Discharge after 24 hours can be considered if the newborn has stable vital signs, a normal SpO2 at discharge, a normal physical exam, is feeding well, maintaining their temperature, and has no symptoms of NAS. Prior to discharge parents should be advised to see their PCP in 3 to 5 days to ensure the newborn weight is within normal parameters and there are no NAS symptoms. (B)
- 9. Encourage and support breastfeeding. (A)

### Breastfeeding the Healthy Term Infant (Last updated June, 2013) <sup>360</sup>

"Exclusive breastfeeding for the first six months of an infant's life and continued breastfeeding for two years and beyond was recommended by Health Canada in 2004 and subsequently promoted and supported by health professional associations and organizations. To promote breastfeeding initiation and increase breastfeeding longevity for attaining this goal, implementation of evidence-based best practices by all health care professionals is critical. A strategy for promoting best practice is the Baby-Friendly Initiative (BFI)."

"These guidelines are based on current evidence and BFI best practices. They are consistent with the *Canadian Baby-Friendly Initiative*; the recommendations of the BC Ministry of Health; Perinatal Services BC (PSBC) education *Breastfeeding: Making a Difference*<sup>©</sup>; the *BC Baby-Friendly Network Resource Binder*; and the Canadian documents, *Nutrition for Healthy Term Infants and Family-Centred Maternity and Newborn Care: National Guidelines.*"

"Breastfeeding contributes to improved health outcomes for infants, children, and women who breastfeed and it has long-term positive health effects for individuals who were breastfed. Evidence also shows that the protective effects of breastfeeding are associated with substantial health care savings, decreased parental absenteeism from work, and advantages to the environment."

<sup>&</sup>lt;sup>360</sup> Perinatal Services BC. *Perinatal Services BC Health Promotion Guideline: Breastfeeding Healthy Term Infants*. 2013. Available at http://www.perinatalservicesbc.ca/NR/rdonlyres/B34C2802-3478-4CBE-BDAE-19D1A960814F/0/BFGuidelinesBreastfeedingHealthyTermInfants06Feb2013.pdf. Accessed January 2014.

#### Breastfeeding Multiples (Last updated January, 2007)<sup>361</sup>

"Six general principles and corresponding guidelines for breastfeeding multiple birth infants have been developed for use by health care providers. The principles and guidelines are shaped by the Declaration of Rights and Statement of Needs of Twins and Higher Order Multiples, a document endorsed by Multiple Births Canada and The Society of Obstetricians and Gynecologists of Canada. The guidelines suggest 'best practices' in hospital and community settings and are based on current findings from multiple birth and breastfeeding research as well as empirical and anecdotal evidence from health professionals and multiple birth families. The guidelines are in concert with the Canadian Baby-Friendly<sup>TM</sup> Initiatives, national breastfeeding guidelines, and the BCRCP guidelines for breastfeeding healthy term and preterm infants. As the preterm birth rate for multiples born in Canada is approaching 60%, practitioners are encouraged to also review the BCRCP Guideline: Breastfeeding the Healthy Preterm Infant."

Six principles for optimizing breastfeeding success for families expecting and parenting multiple birth infants:

- 1. Families need opportunities to become informed about and prepare for breastfeeding term and preterm multiple birth infants.
- 2. Families require access to multiple-specific and general breastfeeding resources.
- 3. Families should be supported to initiate lactation and provide breast milk to their infants at the earliest opportunity.
- 4. Families should be assisted in the ongoing development of a breast feeding plan that considers the needs of the mother, each infant, and the family as a whole.
- 5. Families should receive evidence-based and skilled breastfeeding assistance throughout the postpartum and early childhood periods.
- 6. Families should receive coordinated, comprehensive, consistent, and seamless breastfeeding care throughout pregnancy and early childhood.

#### Breastfeeding the Preterm Infant (Last updated October, 2001)<sup>362</sup>

"Breastfeeding is universally accepted as the best method of feeding term infants, and the nutritional and immunological superiority of breast milk is well documented in the literature. Short-term and long-term health benefits associated with feeding breast milk to preterm infants include:

- Reduced incidence of infections
- Reduced incidence of necrotizing enterocolitis
- Improved feeding tolerance
- Enhanced neurodevelopment
- Decreased number of hospital readmissions
- Enhanced family bonding, maternal involvement and interaction
- Enhanced maternal self-esteem and maternal role attainment"

<sup>&</sup>lt;sup>361</sup> British Columbia Reproductive Care Program. *Nutrition, Part III. Breastfeeding Multiples.* 2007. Available at http://www.perinatalservicesbc.ca/NR/rdonlyres/D72E27F9-11A1-4E97-8E7D-

DF60B5EFE57C/0/BFGuidelinesBreastfeedingMultiplesPartIII3.pdf. Accessed January 2014. <sup>362</sup> British Columbia Reproductive Care Program. *Nutrition Part II. Breastfeeding the Healthy Preterm Infant* ≤37 *Weeks.* 2001. Available at http://www.perinatalservicesbc.ca/NR/rdonlyres/05B1B442-C800-4FF2-9311-762A2FC320C9/0/BFGuidelinesBreastfeedingPretermPartII3.pdf. Accessed January 2014.

"Health Care facilities and community agencies can support breastfeeding preterm infants by providing the necessary support, education, and resources to ensure that these guidelines can be enacted.

- Breastfeeding support services are effective in preventing hospital breastfeeding failures in mothers and preterm infants.
- In-hospital support services and preparation for the post discharge breastfeeding experience enhance success.
- Specialized support services specific to breastfeeding preterm infants are necessary and should be provided."

### Breastfeeding Recommendations for Healthy, Full Term Infants (Last updated June, 2013)

- 1. Infants are exclusively breastfed for the first six months of life and breastfeeding, with introduction of complementary foods continues for up to two years and beyond. (A)
- 2. Evidence-based best practices based on the Baby-Friendly Initiative should be used by health care providers when caring for women and their infants. (A)
- 3. Initiate breastfeeding education in the first prenatal visits providing the parents with information that builds on their knowledge and needs. (A)
- 4. Place the infant skin-to-skin on the mother following birth so the infant has full access to the mother's breast and nipple and remains skin-to-skin until completion of the first feeding.
- 5. Exclusive breastfeeding should be encouraged and facilitated in the early postpartum period. (A)
  - a. Early and frequent feedings should be supported
  - b. Encourage skin-to-skin contact
  - c. Keep mothers and infants together
  - d. Parents should be shown how to recognize feeding cues
  - e. Parents should be taught how to recognize the signs of adequate breastmilk intake
- 6. A Breastfeeding assessment of mother and infant should be carried out at key timeframes through discussion and observation. (A)
- 7. Provide support for infants identified with specific challenges. (A)
- 8. Provide support for mothers identified with specific challenges. (A)

### Best Practice Guidelines for Mental Health Disorders in the Perinatal Period (March, 2014)

### "Recommendations common to all perinatal mental health disorders

- 1. Encourage women with a personal or family history of a mental health disorder to plan their pregnancy, ideally timed when their mood (and physical condition) is as stable as possible.
- 2. For women with a chronic mental health disorder:
  - a. Share decision-making with the woman and her healthcare providers before and during pregnancy to plan individualized treatment that takes into consideration the severity of her illness, previous response to medication and any supports that might be available to her.
  - b. Consider referral to a psychiatrist before or during pregnancy to assist with treatment planning and monitoring of the woman's mental health status.
  - c. Where a woman decides to stop taking medications before or during pregnancy without consultation, pay particular attention to her mental status throughout pregnancy and especially in the postpartum period because of the high risk of relapse.

- 3. For women requiring psychotropic medications in the perinatal period:
  - a. Support informed decision-making by discussing the risks and benefits of medications as well as the risks of not treating symptoms with the woman. Involve partners and other family members whenever possible and where appropriate.
  - b. Use the minimum number of psychotropic medications at the lowest effective dose.
- 4. Encourage women with severe mental health disorders requiring multiple psychotropic medications to deliver in a hospital (versus a home birth). This will facilitate closer monitoring of mother and baby. See Perinatal Services BC guideline on Antidepressant Use During Pregnancy: Considerations for the Newborn Exposed to SSRIs/SNRIs.
- 5. Where possible encourage breastfeeding (psychotropic medications are not usually a contraindication to breastfeeding):
  - a. Maximize the breastfeeding support to women to increase the probability of success. Refer to a lactation consultant and/or public health nurse.
  - b. Where exclusive breastfeeding is not possible (e.g., medical reasons for the mother/baby or challenges for the mother with breastfeeding, including significant psychological stress), support options that promote optimal nutrition for the baby and support the health and wellbeing of the mother. This may include supplementation with the mother's expressed breast milk, pasteurized donor milk, formula or fully formula feeding.
  - c. Women with premature babies or babies with significant health problems are encouraged to discuss their psychotropic medications with the baby's pediatrician if they want to breastfeed.
- 6. Educate partners and family members about recognizing the symptoms of mental health disorders and ways to support women during pregnancy and after the birth. Support should include ways to maximize the woman's opportunity for adequate sleep."<sup>363</sup>

#### Safe Sleep Environment Guideline for Infants 0-12 Months (Last updated February, 2011)<sup>364</sup>

"It is important for health care providers to model and discuss safe sleep practices at every contact. [...] It is also important that care providers do **not** model behaviours in the hospital or community setting that carry risk – such as swaddling, covering the infant's head (bedding, hat or toque use indoors), bed sharing when the mother wishes to sleep after cuddling or nursing, or using a car seat, swing, bouncy chair etc. for infant sleep."

The following are seven key recommendations to support safe infant sleep.

- 1. Infants must be placed on their back to sleep (supine). (A)
- 2. The fetus and infant should not be exposed to tobacco and secondhand smoke. (A)
- 3. Infants and parents/caregivers should sleep in close proximity in the same room (on a separate safe sleep surface) for the first six months; having the infant in close proximity has been found to reduce SIDS. (B)

http://www.perinatalservicesbc.ca/NR/rdonlyres/D799441C-3E00-49EE-BDF7-

<sup>&</sup>lt;sup>363</sup> See

http://reproductivementalhealth.ca/sites/default/files/uploads/resources/files/best\_practice\_guidelines\_for\_mental\_health\_disorders\_in\_the\_perinatal\_period.pdf. Accessed April 2014.

<sup>&</sup>lt;sup>364</sup> Perinatal Services BC. Perinatal Services BC Health Promotion Guideline 1: Safe Sleep Environment Guideline for Infants 0 to 12 Months of Age. 2011. Available at

<sup>2</sup>A3196B971F0/0/HPGuidelinesSafeSleep1.pdf. Accessed January 2014.

- 4. Breastfeeding is recommended as it is a protective measure against SIDS. (A)
- 5. Infant overheating should be avoided. (A)
- 6. Infant sleep surfaces must be firm and free of hazards. (A)
- Cribs, cradles and bassinets must meet standards as per the Crib and Cradle Regulations. (A)

#### Tobacco Use in the Perinatal Period (Last updated June, 2006)<sup>365</sup>

"Effective screening and intervention with women prior to pregnancy, during pregnancy and in the postpartum period can support cessation or reduction in women's tobacco use and improvement in the health of women and their infants."

"It is recommended that physicians talk about tobacco use with **all women**. ASK women of childbearing age about their smoking status; ADVISE those who smoke how important it is to stop and avoid exposure to second hand smoke; ASSESS those who smoke to determine their level of tobacco addiction and readiness to quit; ASSIST by providing assistance in quitting by offering support, appropriate use of nicotine replacement therapy, referral to cessation support programs, forming a quit and a social support plan; ARRANGE follow-up to match the woman's readiness to quit. All pregnant smokers should be followed."

"With **all pregnant women** (and where appropriate, their partners and support systems) it is recommended that physicians provide information on the risks associated with tobacco use in pregnancy, and discuss their level of tobacco addiction (including level of addiction before and after pregnancy) using nonjudgmental approaches."

"Using non-judgmental, empathetic approaches with **pregnant women who identify they are smokers**, it is recommended that physicians increase awareness of the risks of smoking during pregnancy, encourage and support change and directly support or make referrals to tobacco cessation programs. It is important to support women to improve their health in the many ways known to reduce risk, such as: good nutrition, reducing stress, recognizing and addressing signs of depression, anxiety, or other mental health issues, participating in regular physical activity and abstaining from or reducing alcohol and other drug use."

"With **postpartum women** it is recommended that physicians continue to educate and monitor tobacco use to support changes and provide information to recognize and take action on warning signals that may precede relapse. Continue to monitor related health areas that will support the health of women and infants."

"It is recommended that physicians monitor and educate regarding **infant health** as it relates to exposure to second hand smoke. Exclusive breastfeeding for the first six months of the infant's life followed by the addition of nutrient-rich foods with continued breastfeeding for up to two years and beyond is also recommended."

<sup>&</sup>lt;sup>365</sup> British Columbia Reproductive Care Program. BCRCP Guideline: Tobacco Use in the Perinatal Period. 2006. Available at http://www.perinatalservicesbc.ca/NR/rdonlyres/8A2EEC6D-DB7C-4BA9-9840-13F752B899AE/0/SUGuidelinesTobacco7.pdf. Accessed January 2014.

### **Preventative Medication**

#### Eye Care and Prevention of Ophthalmia Neonatorum (Last updated March, 2001)<sup>366</sup>

"A physician, or other qualified person, assisting at the birth of a baby must within one hour of the birth treat the eyes of the baby with a prophylactic solution of 1% tetracycline, 0.5% erythromycin, or 1% silver nitrate dispensed in single use containers."<sup>367</sup>

# Folic Acid & the Prevention of Neural Tube Defects & Other Congenital Anomalies (Last updated January, 2007)<sup>368</sup>

## **Recommendations:**

- 1. Women in the reproductive age group should be advised about the benefits of folic acid supplementation during wellness visits (birth control renewal, Pap testing, yearly examination), especially if pregnancy is contemplated. (III-A)
- 2. Women should be advised to maintain a healthy nutritional diet, as recommended in *Canada's Food Guide to Healthy Eating* (good or excellent sources of folic acid: broccoli, spinach, peas, Brussels sprouts, corn, beans, lentils, oranges). (III-A)
- 3. Women who could become pregnant should be advised to take a multivitamin containing 0.4 mg to 1.0 mg of folic acid daily. (II-1A)
- 4. Women taking a multivitamin with folic acid supplement should be advised *not* to take more than 1 daily dose of vitamin supplement, as indicated on the product label. (II-2A)
- 5. Women in intermediate- to high-risk categories for NTDs (NTD-affected previous pregnancy, family history, insulin-dependent diabetes, epilepsy treatment with valproic acid or carbamazepine) should be advised that high-dose folic acid (4.0 mg-5.0 mg daily) supplementation is recommended. This should be taken as folic acid *alone*, not in a multivitamin format, due to risk of excessive intake of other vitamins such as vitamin A. (I-A)
- 6. The choice of a 5 mg folic acid daily dose for women considering a pregnancy should be made under medical supervision after minimizing the risk of undiagnosed vitamin B<sub>12</sub> deficiency (hypersegmentation of polymorphonuclear cells, macrocystic indices, large ovalocytes, leucopenia, thrombocytopenia, markedly elevated lactate dehydrogenase level, confirmed red blood cell folate level). (II-2A)
- 8. Signs or symptoms of vitamin  $B_{12}$  deficiency should be considered before initiating folic acid supplementation of doses greater than 1.0 mg. (III-A)
- 9. A three-generation pedigree on the families of both the pregnant woman and the biological father should be obtained to identify increased risk for congenital birth defects (i.e., NTD, cardiac, chromosomal, genetic). (III-A)
- 10. Women who become pregnant should be advised of the availability of noninvasive screening tests and invasive diagnostic tests for congenital birth defects (including NTDs): maternal serum "triple marker screen" at 15 to 20 weeks, ultrasound at 16 to 20 weeks, and amniocentesis after 15 weeks of pregnancy if a positive screening test is present. (I-A)

<sup>&</sup>lt;sup>366</sup> British Columbia Reproductive Care Program. *Newborn Guideline 11: Eye Care and Prevention of Opthalmia Neonatorum*. 2001. Available at http://www.perinatalservicesbc.ca/NR/rdonlyres/DC56AD11-C5ED-4288-91B2-215A8CD9A836/0/NBGuidelinesEyeCare11.pdf. Accessed January 2014.

<sup>&</sup>lt;sup>367</sup> Government of British Columbia. *Health Act Communicable Disease Regulation, B.C Reg. 4/83, section 17.* 2013. Available at http://www.bclaws.ca/Recon/document/ID/freeside/12\_4\_83#section17. Accessed January 2014.

<sup>&</sup>lt;sup>368</sup> Wilson R, Davies G, Desilets V et al. The use of folic acid for the prevention of neural tube defects and other congenital anomalies. *Journal of Obstetrics and Gynaecology Canada*. 2003; 25(11): 959-73.

#### Vitamin K<sub>1</sub> Prophylaxis (Last updated March, 2001)<sup>369</sup>

"Vitamin K Deficiency Bleeding or VKDB (also known as Hemorrhagic Disease of the Newborn or HDN) is bleeding due to inadequate activity of Vitamin K-dependent coagulation factors. There is considerable evidence that infants at birth present with low levels of Vitamin K which places them at a higher risk for VKDB and that the risk for VKDB is increased for those infants exclusively breastfed. Prophylactic Vitamin K administration to newborns has been utilized since the 1950's as a therapy to decrease the incidence of VKDB."

### Recommendations

- 1. Vitamin K<sub>1</sub> should be given within the first 6 hours after birth following initial stabilization of the baby and an appropriate opportunity for maternal (family) baby interactions.
- 2. Vitamin  $K_1$  should be given as a single intramuscular dose of:
  - 0.5 mg for birth weight 1500 g or less
  - 1.0 mg for birth weight greater than 1500 g
- 3. For newborn infants whose parents refuse an intramuscular injection, the following is recommended:
  - An oral dose of 2.0 mg of vitamin  $K_1$  at the time of the first feeding
  - This dose should be repeated at 2-4 weeks and 6-8 weeks of age
  - The parenteral form of vitamin K for oral administration is all that is currently available
  - Parents should be advised of the importance of baby receiving follow-up doses and be cautioned that their infants remain at an increased risk of late VKDB
- 4. The IM route should be used for preterm and sick infants. The IV route may be necessary for extremely low birth weight (ELBW) babies.

<sup>&</sup>lt;sup>369</sup> British Columbia Reproductive Care Program. *Newborn Guideline 12: Vitamin K1 Prophylaxis*. 2001. Available at http://www.perinatalservicesbc.ca/NR/rdonlyres/2658455A-B0EF-45EF-B06C-9AC67CC45949/0/NBGuidelinesVitaminK12.pdf. Accessed January 2014.

## The Lifetime Prevention Schedule for Children and Youth

Establishing Priorities among Effective Clinical Prevention Services in British Columbia for Children and Youth Summary and Technical Report

July 2014 Update

## Participating partner organizations:

