

CDMS TO DRIVE SMOKING CESSATION COUNSELLING IN PRIMARY CARE

A CONTROLLED CLUSTER RANDOMIZED PILOT STUDY OF THE EFFECT
OF A NEW SMOKING CESSATION MANAGEMENT MODULE ON RATES OF
INITIATION AND CONTINUATION OF SMOKING CESSATION COUNSELLING
IN ONTARIO PRIMARY CARE PRACTICES USING P-PROMPT CHRONIC
DISEASE MANAGEMENT SYSTEM (CDMS)

By

NATALIE T. MACLEOD, B.Sc. (Hons.)

A Thesis

Submitted to the School of Graduate Studies

in Partial Fulfillment of the Requirements

for the Degree

Master of Science

McMaster University

© Copyright by Natalie T. MacLeod, September 2010

Master of Science (2010)
(Health Research Methodology)

McMaster University
Hamilton, Ontario

TITLE: A controlled cluster randomized pilot study of the effect of a new smoking cessation management module on rates of initiation and continuation of smoking counselling in Ontario primary care practices using P-PROMPT Chronic Disease Management System (CDMS)

AUTHOR: Natalie T. MacLeod, Hons.B.Sc. (University of Toronto)

SUPERVISOR: Rolf J. Sebaldt, BSc, MD, CM, FRCPC, FACP

NUMBER OF PAGES: xv, 175

Abstract

Multi-faceted interventions that include some form of a clinical information system have been shown to improve primary care physicians' management of chronic diseases. The objective of this pilot study was to assess the feasibility of a cluster randomized controlled trial of a multi-faceted intervention, which includes a clinical information system, to improve the management of the chronic disease of tobacco use by physicians. Feasibility was assessed with respect to the use of a measurement tool (Smoking Status Identification Card) and use of a new smoking cessation management module in the clinical information system.

Letters of invitation were sent out to the 65 primary care physicians (in 38 primary care practices) who were subscribed to the web-based clinical information system (P-PROMPT CDMS). Five physicians from 5 primary care practices agreed to participate, who were stratified and then randomized to the intervention (2 primary care practices) or control group (3 primary care practices).

Following the 12-week study period, SSIC completion reached the 90% threshold success criterion in 2 of the 5 primary care practices (one each from the intervention and control group). The intervention group demonstrated basic use of the new smoking cessation management module that reached 21.9% and 19.0% in each of the respective practices, which was below the 30% threshold success criterion. A preliminary evaluation of physician delivery of smoking cessation counselling demonstrated a trend to a higher percentage of Ministry of Health and Long-Term Care (MOHLTC) physician service billing codes submitted

among the physicians in the intervention group, which may be indicative of greater smoking cessation counselling.

It is concluded that a randomized controlled trial to test a multi-faceted intervention is not feasible with the current study design. Significant modifications to the current study design are required that can potentially be tested prior to progression to a larger trial.

Acknowledgements

This thesis was an incredible learning experience that would not have been possible without the instrumental contributions of my supervisors, thesis supervisory committee, colleagues and family. I would like to begin by thanking my primary supervisor, Dr. Rolf Sebaldt, for his outstanding guidance, kind support, unwavering commitment and incredible generosity. His pragmatic advice and meticulous reviews of my work were invaluable to my success. Dr. Sebaldt took on the responsibility of a thesis supervisor with great diligence and true enthusiasm that effectively fostered my progress and current achievement. For all of this I am extremely grateful.

A debt of gratitude is owed to my secondary supervisor, Dr. Peter Selby, whose leadership in the field of nicotine research presented the opportunity for the current research. Dr. Selby provided both stipend support and study funding that enabled me to complete the study for this thesis. I cannot articulate how grateful I am for the opportunity to conduct this research and would like to thank him for his mentorship and vision.

I want to thank the other members of my thesis supervisory committee whose individual expertise were assets to my research. Dr. Brian Haynes provided great insight throughout the process and played a significant role during the development of my research methodology. Dr. Eleanor Pullenayegum helped me through the statistical issues of my study and provided me with great

guidance and support. Jim Bowen guided me through the details of executing a trial and was an outstanding source of help and encouragement.

I have learned a great deal from each member of my committee. Their critiques, reviews, words of encouragement, continuous support and exceptional mentorship were essential to my achievement. They helped me develop my current understanding and knowledge of health research methodology and have guided me in my journey to be an active contributor to the research community. For all of this I am extremely grateful.

Also instrumental were the contributions of Dr. Sebaldt's Fig.P Software and P-PROMPT CDMS team, each of whom always jumped at the opportunity to help me. The current research would not have been possible without their generosity and guidance. To this end I would like to thank Jenny Galan, Annie Petrie, Shirley Marshall, Andrew Head, Allison Mark, David Beardwood, and Dan Vandermolen.

I would also like to thank Rosa Dragonetti and Dr. Laurie Zawertailo at the Centre for Addiction and Mental Health's Nicotine Dependence Clinic. Both Rosa and Laurie provided me with important resources and great advice during my thesis for which I am very thankful.

As well, I am grateful for the vision and leadership of the Ontario Tobacco Research Unit (OTRU) that supported this research through an Ashley Studentship for Research in Tobacco Control.

While my research would not have been possible without the above individuals, my family played an equally instrumental role in my current achievement. I am forever indebted to my mother, Najanda MacLeod, who single-handedly instilled in me a passion for learning and has always nurtured my ambition and perseverance with her encouragement and support. Her own determination and strength are exemplary and continue to astound me. My mother is my role model - she is my inspiration and the reason I am where I am today.

I am equally blessed with an incredible future father-in-law and mother-in-law, Dr. Artin and Eky Ternamian - they are truly one-of-a-kind. My father-in-law's outstanding work ethic, inquisitiveness and innovative thinking inspire me; while my mother-in-law's extraordinary problem-solving skills and true benevolence in her family and community involvement never fail to impress me. I have learned a great deal from them that I have applied during my studies and thesis. Together they have provided unconditional support, encouragement, and guidance over the years, for which I am truly indebted to them.

I would also like to thank my brothers, Charles and Alexander MacLeod, my fiancé's brothers, Joseph and Paul Ternamian, and my sister-in-law, Tzoline Ternamian, for their patience and support. Their understanding allowed me to focus on my goals and to complete my thesis in a timely manner.

Finally, I would like to express my sincere gratitude to my exceptional fiancé, Miran Ternamian, for his unparalleled support and understanding. Your advice and humour were integral to my success during this journey. You have supported and encouraged me from the very beginning - my love and gratitude for this is beyond measure.

Table of Contents

Abstract	iii
Table of Contents.....	ix
List of Tables.....	xiii
List of Figures.....	xiv
List of Abbreviations.....	xv
1.0 Introduction.....	- 1 -
2.0 Background.....	- 2 -
2.1 The Health Issue	- 2 -
2.1.1. Prevalence	- 4 -
2.1.2. Morbidity.....	- 4 -
2.1.3. Mortality.....	- 5 -
2.1.4. Economic Costs	- 7 -
2.2. Smoking Cessation Counselling.....	- 8 -
2.2.1. Screening and Brief Interventions for Substance Abuse	- 9 -
2.2.2. Screening for Tobacco Use	- 10 -
2.2.3. Brief Tobacco Interventions.....	- 11 -
2.2.3.1. The 5A's and Pharmacotherapy	- 13 -
2.3. Primary Care Physicians' Delivery of Smoking Cessation Counselling ...	- 15 -
2.3.1. The Quality Gap	- 15 -
2.3.2. Challenges Faced by Primary Care Physicians.....	- 16 -
2.3.3. Ontario Fee Incentives for Physician Delivery of Smoking Cessation Counselling.....	- 17 -
2.4. Quality Improvement	- 18 -
2.4.1. Clinical Practice Guidelines	- 19 -
2.4.2. Quality Improvement Strategies	- 21 -
2.4.2.1. Multi-Faceted Strategies.....	- 22 -
2.5. Disease Management	- 24 -

2.5.1.	Clinical Information Systems	- 26 -
2.6.	Quality Improvement Efforts in Smoking Cessation Treatment	- 28 -
2.7.	P-PROMPT Chronic Disease Management System	- 32 -
2.8.	Need for a Study	- 35 -
3.	Study Objective	- 38 -
3.1.	Brief Overview of Research Question	- 38 -
3.2.	Study Objectives	- 39 -
4.	Methods.....	- 40 -
4.1.	Description and Justification of the Pilot Study Design.....	- 40 -
4.2.	Pilot Trial Sample Size	- 42 -
4.2.1.	Determining the Feasibility of the Main Trial: Sample Size Considerations	- 42 -
4.2.1.1.	Probability of Accessing the Smoking Cessation Management Module in P-PROMPT CDMS.....	- 43 -
4.2.1.2.	Adjusting Sample Size for Clustering Effect.....	- 45 -
4.3.	Establishing Threshold Criteria.....	- 47 -
4.3.1.	Objective 1	- 47 -
4.3.2.	Objective 2	- 48 -
4.3.3.	Objective 3	- 49 -
4.3.4.	Inclusion Criterion.....	- 49 -
4.3.5.	Exclusion Criteria	- 50 -
4.3.6.	Justification of the Eligibility Criteria and Generalizability of the Study....-	50 -
4.4.	P-PROMPT CDMS Smoking Cessation Management Module Changes -	51 -
4.5.	Multifaceted Smoking Cessation Management Intervention.....	- 52 -
4.5.1.	Cues for physicians to deliver smoking cessation counselling	- 55 -
4.5.2.	Patient Letters inviting “potential smokers” to present for Smoking Cessation Counselling.....	- 56 -

4.5.3.	The Patient Care Status and Update Form in P-PROMPT CDMS ..	- 57 -
4.5.4.	The Smoking Registry	- 57 -
4.6.	Smoking Status Identification Cards (SSICs)	- 58 -
4.7.	Characteristics of Physicians and Primary Care Practices.....	- 59 -
4.8.	Measurement Timepoints.....	- 60 -
4.9.	End-point for Early Withdrawal	- 61 -
5.	Study Timeline.....	- 61 -
5.1.	Phase I	- 61 -
5.1.1.	Recruitment.....	- 62 -
5.1.2.	Informed Consent.....	- 64 -
5.1.3.	Assessment of Eligibility	- 64 -
5.1.4.	Baseline Evaluations	- 65 -
5.2.	Phase II	- 66 -
5.2.1.	Stratification and Randomization.....	- 66 -
5.2.2.	Randomization Procedure	- 67 -
5.2.3.	On-Site Module Orientation Sessions and Study Kits	- 68 -
5.2.4.	Patient Letter Prompts inviting to present for Smoking Cessation Counselling.....	- 69 -
5.2.5.	Smoking Status Identification Cards (SSICs)	- 70 -
5.3.	Phase III	- 70 -
5.3.1.	Site Wrap-up Visits.....	- 70 -
6.	Measurements.....	- 71 -
6.1.	Outcome Measures	- 71 -
6.2.	Statistical Methods	- 73 -
7.	Ethics.....	- 75 -
7.1.	Research Ethics Board Review and Approval.....	- 75 -
7.2.	Subject Consent.....	- 75 -
7.3.	Data Management and Confidentiality	- 76 -
7.3.1.	Health Information Custodians and their Agents	- 77 -

7.3.2.	Collection of Personal Health Information	- 77 -
7.3.3.	Disclosure for Research	- 78 -
8.	Results	- 79 -
8.1.	Physician Interviews to Guide Development of the New (Improved) Smoking Cessation Management Module in P-PROMPT CDMS....	- 79 -
8.2.	Study Outcomes.....	- 80 -
8.2.1.	Baseline Use of the Smoking Cessation Management Module	- 84 -
8.2.2.	Pre-Study Questionnaire	- 85 -
8.2.3.	Utilization of the SSICs.....	- 89 -
8.2.4.	P-PROMPT CDMS Access and Utilization.....	- 93 -
8.2.5.	Delivery of Smoking Cessation Counselling.....	- 98 -
8.2.6.	Post-Study Informal Staff Interviews	- 101 -
8.2.7.	Post-Study Physician Questionnaire	- 102 -
9.	Discussion	- 104 -
10.	Future Directions.....	- 127 -
	References.....	- 137 -
	Appendices	- 162 -

List of Tables

Table 1: The “5A’s” model for screening for and treating tobacco use and dependence.....	- 11 -
Table 2: A Sample of definitions for disease management.....	- 25 -
Table 3: Main study sample size calculations per arm with 80% Power.....	- 45 -
Table 4: Participating physicians’ and primary care practices’ characteristics-	83 -
Table 5: Baseline use of the original smoking cessation management module-	85 -
Table 6: Summary of Pre-Study Questionnaire Responses by Physicians ...	- 86 -
Table 7: SSIC completion and patient attendance over the 3-month active study period	- 91 -
Table 8: Summary of data collected from SSICs	- 92 -
Table 9: Registrations and changes to smoking information fields over the 3-month active study period.....	- 95 -
Table 10: Physician and staff use of P-PROMPT CDMS over the 3-month active study period.....	- 97 -
Table 11: Rates of delivery of smoking cessation counselling over 3-month active study period.....	- 100 -

List of Figures

- Figure 1:** The multi-faceted intervention tested in this pilot trial..... - 53 -
- Figure 2:** Study timeline - 63 -
- Figure 3:** Physician recruitment flow chart..... - 82 -

List of Abbreviations

CAMH	Centre for Addiction and Mental Health
CCM	Chronic Care Model
CCSA	Canadian Centre for Substance Abuse
CDC	Centre for Disease Control
CDM	Chronic disease management
CDMS	Chronic disease management system
CDSS	Clinical decision support system
CI	Confidence interval
DALY	Disability adjusted life year
EMR	Electronic medical record
FHT	Family health team
GEE	Generalized estimating equation
HIC	Health information custodian
ICC	Intracluster correlation coefficient
IOM	Institute of Medicine
MOHLTC	Ontario Ministry of Health and Long-Term Care
OMA	Ontario Medical Association
OR	Odds ratio
OTRU	Ontario Tobacco Research Unit
PEM	Patient Enrolment Model
PHIPA	Personal Health Information Protection Act
REB	Research Ethics Board
RCT	Randomized controlled trial
SSIC	Smoking Status Identification Card
STOP	Stop Smoking Treatment for Ontario Patients
USPSTF	U.S. Preventive Services Task Force

1.0 Introduction

The societal burden that is caused by tobacco use is considerable and potentially preventable. In particular, smoking is a prevalent public health hazard that causes excess morbidity and mortality.¹⁻³ Tobacco use is considered a chronic disease because it is a long-term disorder with periods of remission and relapse and requires sustained, continuing care much like other chronic diseases.^{4,5} While interventions do exist to help smokers escape the cycle of this chronic disease to achieve long-term cessation, they still remain inadequately implemented.⁶ An ideal setting for smoking cessation interventions is the primary care office.⁶ Primary care physicians are at the front line of health care delivery, and smoking cessation interventions can be provided as a part of their daily practice. However, various barriers prevent primary care physicians from consistently providing smoking cessation counselling to their patients who smoke.⁶⁻⁸ As a result, many patients with this chronic disease do not receive an important health care service that can potentially prevent future morbidity and mortality. This failure has been identified as a health care quality gap⁹ and has been the subject of quality improvement efforts that include the publication of clinical practice guidelines¹⁰ and various multi-faceted approaches.^{11,12} One such multi-faceted approach is disease management,^{13,14} a concept that acknowledges the long-term relationship patients endure with various diseases and aims to help physicians consistently address patients' health care needs in the context of these chronic diseases. One potential component of disease management that

has emerged is the clinical information system, which collects, summarizes and informs the health care provider of each patient's health care deliverables.¹⁵ This type of system may have utility in improving the quality of health care that tobacco dependent patients receive by increasing physicians' delivery of smoking cessation treatment. In order to understand how these clinical information systems may have utility, it is necessary to review the relevant background literature and available evidence.

2.0 Background

2.1 The Health Issue

The use of tobacco has long been a global phenomenon that has come to be referred to as the global tobacco epidemic.¹⁶ Tobacco dependence is a chronic disease that is experienced over an extended period of time and is characterized by periods of remission and relapse that require sustained treatment to ensure long-term abstinence.⁴ This fits the US Centre for Disease Control and Prevention's definition of chronic diseases as "illnesses that are prolonged, do not resolve spontaneously and are rarely cured completely."¹⁷

Tobacco contains the addictive drug nicotine, which makes both short-term and long-term cessation hard to achieve.¹⁸ The addiction is caused by the pharmacologic effects of nicotine, as well as by conditioned behaviour.¹⁹ One such effect is the positive reaction, such as an enhancement in function or mood or a reduction in stress, which are experienced with tobacco use.¹⁸ A second

pharmacologic effect of nicotine is the negative consequences experienced when tobacco use is stopped. Once the nicotine level in an individual's blood diminishes and is not replaced, withdrawal symptoms are experienced that can include irritability, restlessness and an inability to concentrate, among other things.¹⁸ A final contributing factor to nicotine addiction is the conditioning that occurs during tobacco use. An individual comes to associate certain situations, moods or environmental factors (which come to serve as cues) with the positive effects of tobacco use¹⁹ – for example, the association between a cup of coffee and smoking. In this example, a cup of coffee will cue the smoker who will then experience an urge to smoke, before which no immediate urge existed. This conditioning, together with the pharmacologic effects of nicotine, creates a cycle that makes it very hard to abstain from tobacco use. The pharmacologic mechanisms and conditioned behaviour described above are similar to other drug dependencies, including those seen with the use of cocaine and heroin.²⁰ In fact, the progressive, chronic and relapsing nature of tobacco dependence has led to its classification as a drug dependency.²¹ While the negative effects of tobacco use are to a large extent the multiple medical complications that become increasingly severe over the long term rather than immediate and debilitating as other drug dependencies, the human body is similarly susceptible to a dependence on tobacco that can cause compulsive smoking behaviour.

2.1.1. Prevalence

It is estimated that 1.3 billion people around the world, or about 20% of the human population, smoke daily.²² Trends since the 1960s demonstrate decreasing tobacco use in developed countries. In the United States, the proportion of adult smokers declined from 24.1% in 1998 to 20.6% in 2008.²³ A similar downward trend is evident among adult smokers in Canada. In 2008, 21.9% of Canadians reported current daily or occasional smoking, with British Columbia and Ontario each having the two lowest prevalence estimates of 18.9% and 20.4% respectively.²⁴ While developed countries have made progress and have succeeded in decreasing tobacco use, the number of smokers worldwide continues to increase, due to population growth and the targeted advertising of tobacco products in the lucrative markets of developing countries and towards groups who have not historically been avid smokers, such as women.^{16,25}

2.1.2. Morbidity

As the number of smokers worldwide increases, the burden of tobacco-related diseases will rise accordingly. Smokers expose themselves to an extraordinary number of adverse health consequences that affect the cardiovascular, respiratory, pulmonary, digestive, reproductive and central nervous systems.^{1,26,27} Research demonstrates that smoking causes a substantially increased risk of several cancers, heart disease, stroke and chronic

respiratory diseases, among others.²⁸ In fact, the 1989 Report of the Surgeon General summarized extensive evidence that conclusively showed that smoking was causally related to cancer of the lung, larynx, esophagus, and oral cavity in men and women.¹ Cigarette smoking was also a contributory factor for bladder, kidney, pancreatic and cervical cancer.¹ Also well-established is the causative relationship between smoking and coronary heart disease.¹ Furthermore, longitudinal studies demonstrate that cigarette smoking causes a progressive decline and clinical impairment in lung function that qualifies for a diagnosis of chronic obstructive pulmonary disease.¹ As well, a recent prospective longitudinal cohort study has shown that middle-age smokers had lower health-related quality of life following 26 years of follow-up.²⁹ The study assessed 1658 men of similar socioeconomic status in 1974 and then re-evaluated them using a mailed questionnaire in the year 2000. The heavy smokers in the cohort lost 10 years of life on average and experienced a serious decline in health-related quality of life as measured by the RAND 36-item health survey scale.²⁹ The men who were current, and likely life-long, smokers in 2000 reported poorer scores on all 8 of the RAND 36 subscales.²⁹

2.1.3. Mortality

The long-term use of tobacco in any form can be lethal. Indeed, the tobacco epidemic threatens more lives than any infectious disease.²⁵ Approximately a third to a half of all tobacco users die as a result of it.³⁰ The

World Health Organization has reported that on average, a tobacco user's life is ended 15 years prematurely.³ Indeed, tobacco is a risk factor for six of the eight leading causes of death in the world.³¹ The tobacco smoke produced from smoking contains thousands of deadly chemicals, of which at least 50 are suspected or known carcinogens. In addition, in the form of second-hand smoke, it is a true environmental health hazard that unfairly exposes non-smokers to many of the same health risks that smokers subject themselves to. The far-reaching adverse health consequences of smoking are highlighted by the fact that indoor second-hand smoke is more lethal than indoor air contaminants such as asbestos particles, radon, or particles produced from wood fires in a household fireplace.³¹

In 1997 Murray and Lopez published a groundbreaking paper that projected mortality and disability by cause as part of the Global Burden of Disease Study. The report cites tobacco-related morbidity and mortality as the most important determinant of health trends.³² It estimated that in 1990, there were 3 million tobacco-related deaths around the world, and the report projected 8.4 million tobacco-related deaths would occur globally in the year 2020.³² Peto et al. estimated that in 1990, the average loss of life for an individual who died of a tobacco-related disease was 16 years.³⁰ Updated global projections newer than those provided by Murray and Lopez were prepared by Mathers and Loncar in 2006 that estimated that the total of tobacco-attributable deaths will increase from 5.4 million in 2005 to 6.4 million in 2015 and then to 8.3 million in 2030.³³

Significantly, tobacco-related deaths are expected to decline by 9% between 2002 and 2030 in high-income countries yet will double in low- and middle-income countries over the same time period.³³

2.1.4. Economic Costs

The use of tobacco is associated with staggering societal costs, including direct health care costs and indirect costs of productivity losses.³⁴ Positive economic contributions of the tobacco industry to any national economy can be in the form of jobs and tax revenues. Yet on balance, the World Health Organization's Report on the Global Tobacco Epidemic clearly states that despite the tobacco industry's economic contributions, "...its overriding contribution to any country is suffering, disease, death – and economic losses."³³ Tobacco use poses a huge financial burden on a country's economy with the various direct and indirect costs that are related to it. A measurement of Disability Adjusted Life Years (DALYs) attributes a 4% global burden of disease to tobacco.³⁵ According to the third edition of The Tobacco Atlas, tobacco costs the world economy \$500 billion annually, which is more than all low- and middle-resource countries, taken together, spend annually on health.³¹ The Canadian Centre on Substance Abuse (CCSA) used 2002 data to estimate a nearly \$40 billion social cost of substance abuse in Canada. The study revealed that tobacco accounted for nearly 43% of this cost.³⁵ A fragment of this cost is illustrated in a 2007 study that considered

smoking-attributable acute care hospital days in Canada, which was estimated to cost over \$2.5 billion in 2002 alone.³⁶

2.2. Smoking Cessation Counselling

The economic and social burdens caused by tobacco use could be alleviated by smoking cessation. Most importantly, the majority of the negative health consequences that result from tobacco use can be reversed, at least in part, by smoking cessation.³⁷ Indeed, accumulated research over the past several decades confirms that smoking cessation results in immediate and life-long health benefits by significantly reducing the risk of developing smoking-related diseases.^{1,37}

While smoking is an addiction that makes long-term cessation difficult to achieve, a number of strategies and approaches have been developed and implemented in efforts to help people quit smoking. Smokers consider a physician's advice to stop smoking an important motivator to attempt smoking cessation.⁶ However, since physicians do not consistently provide smoking cessation counselling,^{6,38,39} there is a need to enhance capacity in primary care settings to assist people with stopping or reducing tobacco use. Research clearly demonstrates that, within the context of a primary care setting, screening and brief intervention is an effective method to treat tobacco use.^{6,8,40} Moreover, tobacco screening and brief intervention has been identified as one of the top 3 priorities among effective clinical preventive services that address equally

preventable burdens and are equally cost-effective, the two others being aspirin chemoprophylaxis for the primary prevention of cardiovascular disease and childhood immunizations.⁴¹ It should be noted that the advisability of aspirin chemoprophylaxis for the primary prevention of cardiovascular disease has recently been brought into question in patients with diabetes.⁴²

2.2.1. Screening and Brief Interventions for Substance Abuse

Decades of research have demonstrated the efficacy of screening and brief interventions for the abuse of various substances – including tobacco.⁴³ Considerable evidence demonstrates that screening and brief interventions can result in both short-term and long-term smoking cessation.^{6,8,40} Research demonstrates that brief interventions that are less than 3 minutes in length increase overall tobacco abstinence rates.⁶ Moreover, studies have shown that tobacco use interventions are highly cost-effective.⁶ Since the implementation of screening and brief intervention is not costly or time intensive, it is suitable for the primary care setting.⁶

Screening for substance abuse is “a preliminary procedure to evaluate the likelihood that an individual has a substance use disorder or is at risk of negative consequences from use of alcohol or other drugs.”⁴⁴ This means that the individual is asymptomatic at the time he/she presents at the physician’s office. The goal of screening is to identify persons with unhealthy substance use before dependence and its accompanying symptoms or negative consequences are

established. Once an individual is identified as an unhealthy user through screening, a time-limited and structured brief intervention follows. While there are various slightly differing definitions of “brief intervention,” generally it is considered to be one to four 5-15 minute counselling sessions that include feedback about the substance abuse, advice, goal setting, and follow-up appointments.^{44,45}

2.2.2. Screening for Tobacco Use

Screening for tobacco use contributes to increased rates of physician intervention, and, as such, is a critical component of treating tobacco use.⁴⁶⁻⁴⁹ According to the U.S. Department of Health and Human Services and the Centre for Disease Control’s *Treating Tobacco Use and Dependence Clinical Practice Guideline* (CDC Guideline), a consistent pattern of findings obtained through multiple well-designed randomized controlled trials supports the efficacy of screening for tobacco use.^{6,50,51} In a primary care setting, treating tobacco use through brief intervention involves the fulfillment of the 5A’s model (Table 1). The first A requires the healthcare provider to **Ask** the patient about tobacco use, which is the screening component of the intervention. The question can be as simple as “What is your tobacco use status: current, former, never?” To help clinicians incorporate this first A into routine practice, the CDC Guideline provides strategies for implementation, which include expanding the vital signs to include tobacco use, using tobacco use stickers on all patient charts, or indicating

tobacco use status either through the physician’s electronic medical record or any other form of computerized reminder system employed by the physician. In short, a system that will ensure systematic identification of all tobacco users at every visit is advocated.

Table 1: The “5A’s” model for screening for and treating tobacco use and dependence⁶

Ask about tobacco use	Identify and document tobacco use status for every patient at every visit.
Advise to quit	In a clear, strong and personalized manner, urge every tobacco user to quit.
Assess willingness to make a quit attempt	Is the tobacco user willing to make a quit attempt at this time?
Assist in quit attempt	For the patient willing to make a quit attempt: offer medication and provide or refer for counseling or additional treatment to help the patient quit. For the patient unwilling to quit at the time: provide interventions designed to increase future quit attempts.
Arrange follow-up	For the patient willing to make a quit attempt: arrange for follow-up contacts, beginning within the first week after the quit date. For the patient unwilling to quit at the time: address tobacco dependence and willingness to quit at next clinic visit.

2.2.3. Brief Tobacco Interventions

An important study on brief tobacco interventions dates from the 1980’s.⁵² It demonstrated that brief physician advice influenced a small yet noteworthy number of patients to stop smoking and set the stage for a number of similar

studies with positive findings.⁵² Subsequent accumulated evidence has led the U.S. Preventive Services Task Force (USPSTF) and the CDC Guideline to recommend brief interventions to assist patients with smoking cessation.^{6,53}

As mentioned above, brief tobacco intervention follows the 5A's model summarized in Table 1. Once a tobacco user has been identified (first A: **A**sk), he/she must be **A**dvised by strongly being urged to quit. Following this second A, the patient should be **A**ssessed for willingness to make a quit attempt. In the case that the patient is willing to quit, the physician must **A**ssist him/her by helping the patient develop a quit plan, recommending the use of medication as long as it is not contraindicated, and providing practical counselling that will help the patient with problem solving and skills training. Also, as part of Assisting, the physician should provide the patient with intra-treatment social support and supplementary materials and resources that may include telephone-based smoking cessation counselling through “quitlines”⁵⁴, among other options. Finally, the brief intervention is completed by **A**rranging a follow-up appointment, either in-person or in the form of a phone call.

The Ontario Guidelines Advisory Committee and the Ontario Tobacco Strategy's Clinical Tobacco Intervention program, which was established by the Ontario Medical Association (OMA) and its collaborators, recommend this same widely accepted strategy for smoking cessation counselling, as set forth in the CDC Guideline.⁶

Meta-analyses included in the CDC Guideline demonstrate a dose-response relationship between session length and abstinence rates, an increase in abstinence rates with increasing “total amount of contact time” up to a maximum of 90 minutes, and a dose-response relationship between number of sessions and treatment effectiveness.^{6,55,56} However, although the intensity of the clinical intervention positively affects abstinence rates⁵⁵⁻⁶⁰, it is important to consider the feasibility of interventions of greater intensity in primary care settings because time constraints limit the services that primary care physicians can provide.⁶¹

2.2.3.1. The 5A’s and Pharmacotherapy

According to the 5A’s Model, the fourth A requires “Assisting” the patient who has made the decision to quit. This assistance can take the form of counselling, development of a quit plan, and/or a referral to a public health unit or other agency that provides smoking cessation counselling resources. As well, physicians are encouraged to assist their patients to quit smoking by prescribing the appropriate pharmacotherapy. Recently, Bader and colleagues used a modified Delphi approach to identify and rank the “best practices” used by 37 international experts in their tailoring of pharmacotherapy prescriptions for smoking cessation.⁶² This research led to the development of an algorithm to help clinicians prescribe pharmacotherapy for smoking cessation.

Pharmacotherapy can take the form of over-the-counter nicotine replacement therapy, such as nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, or nicotine patch. Other pharmacotherapy includes the prescription drugs bupropion (Zyban®) and varenicline (Champix®). Bupropion is a norepinephrine and dopamine reuptake inhibitor and nicotinic acid receptor antagonist that reduces cravings and symptoms of nicotine withdrawal, while in contrast, varenicline is a nicotinic acetylcholine receptor partial agonist that acts to reduce cravings and the pleasurable effects of nicotine.^{63,64} These over-the-counter and prescription drugs are listed as first-line medications in the CDC Guideline.⁶ If any of nicotine replacement therapy, bupropion or varenicline is prescribed to an Ontario patient in 2010, there are three ways by which the prescribed drug can be acquired: (1) fill the prescription at a pharmacy and pay for the drug out-of-pocket; (2) fill the prescription and have it paid for in full or in part by their private drug benefits insurance plan; or (3) receive the prescribed pharmacotherapy free of charge through the STOP (Stop Smoking Treatment for Ontario Patients) Study, which is part of the Ontario government's Smoke-Free Ontario Initiative and is primarily funded by its Ministry of Health Promotion.⁶⁵ The STOP study has been implemented to increase the accessibility of this form of smoking cessation aid to the public.

2.3. Primary Care Physicians' Delivery of Smoking Cessation Counselling

A survey of national tobacco dependence treatment services in 36 countries found that few countries promoted adequate treatment for tobacco dependence.⁶⁶ Patients around the world receive suboptimal care for their chronic disease of tobacco dependence.³ This section reviews the literature pertaining to this health care quality gap and identifies quality improvement strategies relevant to this study.

2.3.1. The Quality Gap

In a random-digit-dialed survey of adult Ontarians, Brewster et al. reported that about two-thirds of the 2,421 respondents considered physicians to be a good source of advice for smoking cessation.⁶⁷ Of the 22.8% of respondents who reported current smoking, 52.5% indicated that they would be very likely to seek advice about smoking cessation from a physician. Yet in the preceding year, only 41.7% of the current smokers reported receiving smoking cessation advice. The Canadian Tobacco Use Monitoring Survey 2006 reported that only 48% of Ontarian smokers aged 15 or older who had visited a doctor in the past 12 months were advised by their doctor to quit smoking,³⁹ and this figure remains little changed at 47% in the most recent data.⁶⁸ Due to this suboptimal delivery of smoking cessation intervention by primary care physicians, the majority of

smokers who present at a primary care practice have a far-reaching health threat that is being left unaddressed.

2.3.2. Challenges Faced by Primary Care Physicians

Attempts have been made to understand the paradox of physicians' relative neglect of their patients' hazardous smoking behaviour. Physicians have cited a number of reasons for their inconsistent delivery of smoking cessation counselling.^{6,69} Barriers include inadequate knowledge about treatment and how to identify smokers efficiently, inadequate support for routine assessment and treatment, time constraints, limited training in tobacco cessation interventions and inadequate payment for providing treatment.⁶ Additionally, primary care physicians consider the unreceptive nature of patients a barrier to the provision of smoking cessation counselling.⁷⁰ Yet a patient's motivation and likelihood of a future quit attempt are increased with the provision of smoking cessation counselling by a physician.^{8,71} Conroy et al. have demonstrated that, even among smokers not ready to quit, the delivery of smoking cessation counselling (considered to be any of the 5A's) by a physician during a visit to the primary care practice increased patient satisfaction with their health care.⁷² Finally, while time constraints have been cited by physicians as a barrier, research has demonstrated that *perceived* barriers may be greater than actually exist.⁷ Consistent with this hypothesis are the results of Meredith et al. that primary care physicians' delivery of smoking cessation counselling is associated with their

attitude toward it.⁷ In their study of 280 primary care physicians, those who had a favorable attitude toward smoking cessation counselling provided significantly more such counselling to their patients.⁷

2.3.3. Ontario Fee Incentives for Physician Delivery of Smoking Cessation Counselling

To increase physician delivery of smoking cessation counselling by the 5A's model, fee incentives were established in Ontario. In the 2004 Memorandum of Agreement between the Ontario Ministry of Health and Long-Term Care and the Ontario Medical Association for physician services,⁷³ a set of financial incentives was introduced for primary care physicians to provide a targeted set of preventive care and chronic disease management services, including smoking cessation counselling. In their present form, the smoking cessation counselling incentives include (a) an Add-On Initial Smoking Cessation Fee Code E079A with an eligible billing amount of \$15.40 for physicians who talk to their patients about their smoking behaviour and (b) a Smoking Cessation Follow-up Visit Fee Code K039A with an eligible billing amount of \$33.45 for physicians who provide smoking cessation counselling to patients within 12 months of providing the patient with the services defined and billed for by the E079A. Additionally, physicians practicing in a Patient Enrolled Model (PEM) are entitled to a Smoking Cessation Counselling Fee Code Q042A with an eligible

billing amount of \$7.50 that can be billed together with the K039A if the patient to whom they provided the service is one who is enrolled on the physician's roster.⁷⁴

Delivery of complete smoking cessation treatment by a PEM physician would result in eligibility for a billing pattern of one E079A, two K039As and two Q042As over a period of 12 months. The E079A must be submitted independently and before the other codes can be submitted. It encompasses the delivery of up to all of the 5A's. The K039A and Q042A are submitted together as long as the patient is enrolled to the PEM physician and committed to quit smoking. Thus, a physician may annually receive five incentive payments totaling \$97.30 per patient who has been counselled on three different occasions. It is conceivable, however, that it could be logistically difficult for physicians and their office staff to efficiently keep track of their rolling per-patient eligibility for regularly claiming these fees to full potential eligibility.

2.4. Quality Improvement

The discrepancy between ideal care and usual care, the health care quality gap, is an opportunity to seek to improve medical providers' adherence to recommended quality standards for health care delivery.⁷⁵ To address and bridge such health care quality gaps, research about the quality of health care has developed over the decades into quality improvement research. As the widely held "father of quality assurance"⁷⁶ and renowned author of the "Seven Pillars of Quality," Avedis Donabedian emphasized the importance of defining quality

before proceeding with discussions of it.^{77,78} While no definition of quality of health care has been standardized, efforts range from narrow definitions that are limited to health care providers' technical performance to broader definitions that may include the health care setting, access to care and related social dimensions.⁷⁹ A widely accepted definition set forth by the Institute of Medicine (IOM) proposes that "quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."⁹ In 1999, the IOM Quality of Health Care in America committee released a report that concluded that the quality of health care in America was unacceptable and proposed a four-tier strategy to combat the issues that plagued its health care system.⁸⁰ Two years later, a report from the same committee was released with a much more urgent tone that highlighted how great the discrepancy was between the health care that currently existed and the health care that could exist.⁸¹ These two ground-breaking reports greatly increased interest in patient safety and quality of health care and spurred a number of innovative strategies to improve quality and safety.

2.4.1. Clinical Practice Guidelines

One quality improvement strategy that exists is the publication and dissemination of clinical practice guidelines. Generally, clinical practice guidelines are the product of a comprehensive, systematic effort to compile, analyse and

summarize the available scientific evidence in a concentrated area of clinical care. The result is an authoritative document that outlines the actions that need to be taken to ensure that the best standard of care is delivered to patients. The ideal care that should be provided to patients who smoke is summarized in the comprehensive CDC Guideline (see section 2.2.2 above), which is a Public Health Service-sponsored Clinical Practice Guideline.⁶ Unfortunately, the CDC Guideline, along with most other clinical practice guidelines, are not solely by their existence effective in attracting consistent adherence by health care providers in actual clinical practice.^{82,83}

Although clinical practice guidelines would appear to contain important recommendations to be followed under ideal circumstances, in the context of a physician's busy daily routine, publication alone of a clinical practice guideline is a dissemination of information but does not guarantee implementation of its recommendations in all patients to whom they may apply.⁸⁴ In a review of systematic reviews that investigated various interventions to promote the implementation of research findings by physicians, Bero and colleagues found that passive efforts to disseminate information, publications and mailings were ineffective, while educational outreach visits, reminders, multi-faceted interventions and interactive educational meetings were consistently effective.⁸⁵

Ultimately, changing provider behavior is a complex endeavour that has proven to be challenging.¹² In the context of health care quality improvement, frequent non-adherence of physicians to clinical practice guidelines, beyond an

expected extent that might readily be explained by particular modulating factors, considerations or extenuating circumstances of individual patients, has instigated significant research to understand barriers and strategies to help and enable physicians to change their practices to better adhere to recommended guidelines.^{82,86-88}

2.4.2. Quality Improvement Strategies

Alongside changing provider behavior, a number of quality improvement strategies aimed at the patient and/or health care organizations currently exist and are used in various combinations. These strategies include provider education, provider reminders, provider decision support systems, financial incentives, regulation and policy, audit and feedback, patient education, promotion of patient self-management, patient reminders, and disease and case management programs.⁸⁹ While these approaches have shown inconsistent effects that range from small to modest,^{11,12} caution has been expressed about the interpretation of published results.^{90,91} For example, Ting and colleagues have identified three reasons for the relatively poor performance of these commonly used quality improvement strategies, which include: a) inadequate emphasis on an evaluation of the degree to which the selected strategy matches the target quality problem; b) tendency for intuition rather than prior evidence to guide quality improvement interventions; and c) disregard for contextual factors related to the implementation setting and components of the intervention itself that may cause important mediating effects.⁹² Furthermore, quality improvement research

has been characterized as generally lacking the rigour of clinical research, with omission of key data, poor design, suboptimal analysis and reporting, and a lack of evidence-based selection of implementation strategies.^{91,93}

2.4.2.1. Multi-Faceted Strategies

While inconsistencies exist about the effectiveness of each of the quality improvement strategies mentioned above, systematic reviews have shown that the use of two or more of the above strategies often lead to better outcomes than the use of any single strategy. In the first major systematic review of interventions to improve professional practice, Oxman et al. identified 102 trials that used one or more interventions targeted at improving the performance of health care professionals.¹¹ The interventions were along the lines of the quality improvement strategies mentioned above. An analysis of the strategies demonstrated that the use of two or more improved provider performance. A few years later, in a broader systematic review that synthesized information from 41 systematic reviews of professional behaviour change strategies, Grimshaw et al. also concluded that provider behavior was more likely to change under the influence of multi-faceted interventions rather than a single intervention, however no interventions consistently produced large improvements.⁹⁴

In the face of uncertainty, determining the effectiveness and efficiency of guideline dissemination and implementation strategies was identified as a priority by the United Kingdom's National Health Service Research & Development

Health Technology Assessment Programme's Methodology Panel.⁹⁵ They funded a project to undertake a systematic review of the effectiveness and costs of different guideline development, dissemination and implementation strategies. In this synthesis of 235 evaluations of strategies to promote the implementation of guidelines, consistently modest evidence of improvements in care were observed.⁹⁵ Notably, multi-faceted interventions had median effect sizes that were not significantly greater than single-faceted interventions.⁹⁵ Thus, this systematic review did not show that multi-faceted interventions are more effective than single-faceted interventions. Furthermore, the effects of multi-faceted interventions did not increase as the number of component interventions increased.⁹⁵

In the three reviews cited above, the complexity and heterogeneity of the interventions and their contexts prevented direct comparisons and definitive conclusions about the effects of each component intervention alone.^{11,12,95} Moreover, most of the implementation strategies, both single- and multi-faceted, showed wide variations in effect size.^{11,12,95} Thus, general conclusions about which strategies are effective (and perhaps variably so, in a context-specific fashion) cannot be made without further methodologically rigorous research.⁹⁶

Nevertheless, the USPSTF has compiled a group of implementation strategies to assist the successful implementation of multi-faceted smoking cessation treatment recommendations in primary care practice. The identified strategies include instituting a tobacco user identification system, promoting

clinician intervention through education, resources and feedback, and dedicating staff to provide treatment and assessing the delivery of treatment in staff performance evaluations.⁵³

2.5. Disease Management

One multi-faceted strategy that has emerged over the decades to improve the quality of care received by patients with chronic diseases is disease management⁹⁷ or chronic disease management (CDM). In general, disease management is a concept that involves shifting the health care system's current focus from acute care to chronic care and emphasizes integrated care, which is organized around patients.¹³ Twenty years since the term was first coined, disease management remains an elusive term with multiple definitions (Table 2).^{14,98-104}

The heterogeneity in its definition is reflected in the diversity of disease management programs that have been researched and implemented.^{14,101} The variability in program characteristics and in studies of them has prevented meaningful comparisons between programs and the specific components that comprise each program. In the face of meager evidence, there is no clarity regarding the specific components that a disease management program must have.

Table 2: A Sample of definitions for disease management

Authors	Definition
Epstein and Sherwood, 1996 ⁹⁸	“[disease management] refers to the use of an explicit systematic population-based approach to identify persons at risk, intervene with specific programs of care, and measure clinical and other outcomes.”
Dellby, 1996 ⁹⁹	<p>“Disease management is an approach to patient care which coordinates resources across the entire health-care delivery system and throughout the life cycle of the disease. The three primary elements of disease management are:</p> <ol style="list-style-type: none"> 1. A knowledge base that quantifies the economic structure of the disease and describes care guidelines (what care should be provided, by whom, and in what setting) for discrete patient segments; 2. A care delivery system without traditional boundaries between medical specialties and institutions; 3. A continuous improvement process which consistently builds the knowledge base and develops the care guidelines and delivery system.”
Ellrodt et al., 1997 ¹⁰⁰	“Disease management is an approach to patient care that emphasizes coordinated, comprehensive care along the continuum of disease and across health care delivery systems.”
Weingarten et al., 2002 ¹⁴	“[disease management is] an intervention designed to manage or prevent a chronic condition using a systematic approach to care and potentially employing multiple treatment modalities.”
Faxon et al. AHA 2004 ¹⁰¹	“The term disease management programs typically refers to multidisciplinary efforts to improve the quality and cost-effectiveness of care for select patients with chronic illness.”
Shrijvers, 2009 ¹⁰²	“Disease management consists of a group of coherent interventions designed to prevent or manage one or more chronic conditions using a systematic, multidisciplinary approach and potentially employing multiple treatment modalities. The goal of disease management is to identify persons at risk for one or more chronic conditions, to promote self management by patients and to address the illnesses or conditions with maximum clinical outcome, effectiveness and efficiency regardless of treatment setting(s) or typical reimbursement patterns.”
Peytremann-Bridevaux and Burnand, 2009 ¹⁰³	“[chronic disease management]...consists of a group of coherent interventions, designed to prevent or manage one or more chronic conditions using a community-wide, systematic and structured multidisciplinary approach potentially employing multiple treatment modalities. The goal of [chronic disease management] is to identify persons with one or more chronic

	<p>conditions, to promote self-management by patients and to address the illness or conditions according to disease severity and patient needs and based on the best available evidence, maximizing clinical effectiveness and efficiency regardless of treatment setting(s) or typical reimbursement patterns. Routine process and outcome measurements should allow feedback to all those involved, as well as to adapt the programme.”</p>
<p>DMAA, 2010¹⁰⁴</p>	<p>“Disease management is a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant. Disease management:</p> <ul style="list-style-type: none"> • Supports the physician or practitioner/patient relationship and plan of care; • Emphasizes prevention of exacerbations and complications utilizing evidence-based practice guidelines and patient empowerment strategies; and • Evaluates clinical, humanistic, and economic outcomes on an on-going basis with the goal of improving overall health.”

2.5.1. Clinical Information Systems

Over a decade ago, Wagner and colleagues conducted a review of the literature about reorganizing health care delivery with an aim to improve outcomes in chronic illness care.¹⁰⁵ In their literature review that considered RCTs, chronic disease management programs or clinics and European programs to improve the primary care of chronic illness, they concluded that the common components of each paper considered fell into five areas that collectively comprised their proposed Model for Effective Chronic Illness Care. One of these five areas was Supportive Information Systems that included reminders, outcomes, feedback and care planning. It is this concept of a Supportive Information System that is believed to help physicians integrate clinical practice guidelines into their practice, thereby enhancing “... the likelihood of sustained

adherence to the guideline.”¹⁰⁶ Based on their findings from this literature review and following review and revision by a group of experts, Wagner and colleagues refined the original model and developed the current model for improvement of chronic illness care known as the Chronic Care Model (CCM).¹⁰⁷ In this refined model, the concept of a Supportive Information System evolved into that of Clinical Information Systems, which are computerized database management systems that organize patient and population data to facilitate efficient and effective care.¹⁵ Elements of such systems include: provision of timely reminders for patients and physicians, identification of relevant subpopulations for proactive care, facilitation of individual patient care planning, sharing of information with patients and providers for coordinated care, monitoring performance of the practice team and the care system.¹⁵

As an essential feature of an effective program to manage chronic diseases, clinical information systems have disease registries (of the above-mentioned “patient subpopulations”) at their core. A disease registry would “...include information about the performance and results of important elements of care. Health care teams that have access to a registry can call in patients with specific needs, deliver planned care, receive feedback on their performance, and implement reminder systems.”¹⁰⁸

In this manner, clinical information systems allow the primary care practice to take an active, rather than a passive opportunistic, role in the management of chronic diseases, equitably across their entire practice. The importance of such

information systems is highlighted by the belief that “effective chronic illness care is virtually impossible without information systems that assure ready access to key data on individual patients as well as populations of patients.”¹⁵

Although clinical information systems have demonstrated success, there is evidence that, in their current incarnations, they may impart little or no benefit.¹⁰⁹ In a review that examined strategies for improving the quality of care for adult type 2 diabetic patients, clinical information systems did not demonstrate significant benefit in terms of patient or provider outcomes.¹¹⁰ However, the authors acknowledged the presence of publication bias and methodological issues within the individual studies included in the review. Further methodologically rigorous research is required to determine the effectiveness of clinical information systems to improve patient and provider outcomes.¹¹⁰ Substantial changes in existing clinical information systems so as to more completely provide the above set of stipulated essential features may well also be required after developing a clearer understanding of the distinguishing features between health records systems and chronic disease management systems.¹¹¹

2.6. Quality Improvement Efforts in Smoking Cessation Treatment

Various quality improvement efforts have been investigated to improve the quality of health care that tobacco dependent patients receive. These efforts tend to focus on increasing provider adherence to the comprehensive clinical practice

guidelines so that both the provider and patient may take advantage of the evidence-based recommendations.

One quality improvement strategy that has been investigated in the treatment of tobacco dependence is the systematic identification of a physician's patients who use tobacco. The CDC Guideline has identified multiple well-designed randomized control trials that consistently demonstrate that a clinic screening system to identify tobacco users significantly increases rates of clinician intervention. The meta-analysis of 9 relevant studies demonstrates that, with a screening system in place to identify smoking status, the rate of clinician intervention was 65.6 (95% CI; 58.3-72.6), with an estimated OR of 3.1 (2.2-4.2), compared to an estimated rate of 38.5 with no screening system in place to identify smokers (OR of 1.0). However, in a study of the effects of adding smoking status as a vital sign in 2 primary care clinics, Boyle and Solberg demonstrated that implementation of a smoking status screening system is not sufficient to increase cessation support actions in clinical practice.¹¹² In fact, while chart documentation of patients' tobacco use more than doubled from 38% to 78%, documentation of advice decreased by nearly half from 34% to 19%.¹¹² Similarly, Piper et al. demonstrated that the rate at which physicians advised or assisted smokers to quit did not increase with the implementation of a smoking status screening system.¹¹³ Both papers concluded that while a smoker identification system is essential, greater environmental or system-wide changes are required to gain better adherence to the clinical practice guidelines.^{112,113}

Once a patient's smoking status is determined through the smoker identification system in a clinical office, this information can be used to appropriately prompt providers and patients about interventions to manage the chronic disease. Research demonstrates that reminder systems and prompts can increase the rates of physician delivery of various health services.¹¹⁴⁻¹¹⁷ However, the clinic screening systems whose use has been investigated by most studies are paper-based.^{48,51,118,119} Paper-based systems limit the provider's ability to gauge the portion of the patient population that requires treatment and does not allow real-time assessment of the physician's progress in treating the patient population. Thus, the data collected using a paper-based system cannot be maximized, or its use optimized, in the way a computer-based system would enable.¹²⁰ Notably, computerized reminder systems have generally increased provider compliance with practice guidelines.¹²¹⁻¹²³ McAfee and colleagues demonstrated the success and feasibility of adopting such a computerized reminder system in the context of treating tobacco dependence.¹²⁰ Tobacco use status was captured on a standard paper form that is regularly used to document the health services provided during a patient encounter. The data from the form is entered into a database for billing. As part of the study's computerized tobacco control initiative, tobacco status was also entered into the database. McAfee and colleagues reported that both automated performance feedback and senior-level incentives reinforced provider compliance and led to a ten-fold increase in the

rate of tobacco-user identification and an over three-fold increase in the documentation of provider advice and intervention.¹²⁰

The measurement of provider performance is important because providers typically overestimate the quality of care they provide when data is not available.^{38,72} The positive influence of performance feedback on provider behavior was demonstrated by Andrews and colleagues, who tested a multicomponent intervention to improve primary care providers' adherence to smoking cessation guidelines.¹²⁴ While the provider education component of the multicomponent intervention did not significantly impact provider adherence to the guidelines, the individual and team performance feedback did show significant improvement in providers' delivery of smoking cessation counseling compared to the control group ($p=0.001$).¹²⁴ As well, a cluster randomized clinical trial by Bentz and colleagues showed that provider-specific monthly feedback reports created from data entered into an electronic health record significantly improved smoking cessation counselling in the intervention group compared to the control group ($p<0.001$).¹²⁵ In a study to assess the impact of comparative feedback versus general reminders on physician rates of referral to telephone smoking cessation counselling, Wadland et al. showed that performance feedback reports in the intervention group significantly increased the number of referrals compared to the control group (484 vs. 220; $p<0.001$).¹²⁶

In an effort to investigate the potential role of a computerized decision support system (CDSS) to increase provider adherence to the tobacco use

treatment guidelines, Marcy et al. surveyed a random sample of 600 primary care and subspecialty physicians.⁷⁰ They concluded that if a CDSS is designed with a physician's cost, space and time limitations in mind, then it may improve physician knowledge of tobacco treatment guidelines and resources.

To date, the single most comprehensive quality improvement study in tobacco dependence treatment has been completed by Hung and Shelley who performed a multi-level analysis of the use of the Chronic Care Model as a framework for improving provider delivery of the 5A's model's tobacco cessation services.¹²⁷ Using cross-sectional surveys completed by 497 health care providers, associations were examined between provider delivery of the 5A's services, clinic implementation of CCM elements tailored for treating tobacco use, and the degree of CCM integration in the clinics.¹²⁷ They found that physicians practicing in clinics with enhanced delivery system design, clinical information systems and self-management support for cessation were more likely to provide complete smoking cessation treatment of the 5A's ($p < 0.05$).¹²⁷ As well, implementation of one to six elements of the CCM increased the odds of providers delivering all 5A's of smoking cessation treatment ($p < 0.01$).¹²⁷

2.7. P-PROMPT Chronic Disease Management System

In Ontario, an existing clinical information system that is designed to be a guidelines-based and clinical data-driven chronic disease management system (CDMS) integrated with preventive care and population screening management,

is P-PROMPT® CDMS. It is a multi-faceted clinical practice management tool designed to facilitate and increase the delivery of preventive care and chronic disease management services in primary care practice.¹²⁸ P-PROMPT CDMS is a web-based electronic patient data and disease registry management system with multi-source data integration. It is based at core on a system of multiple patient disease registries within each physician's roster of patients. As a multi-faceted tool, it includes an online record of each patient's chronic disease and preventive care history, as well as online physician reminders/prompts, real-time reports on measures of practice-wide performance measures of timeliness of service delivery (health care processes) and of at-goal disease control (health care outcomes), overview dashboards of patient care status, and mailed patient prompts/reminders. In a demonstration project funded by the Ministry of Health and Long Term Care through its Primary Health Care Transition Fund, P-PROMPT aimed to increase the delivery of four preventive care services. The study recruited 249 physicians across Ontario whose patient rosters totaled 350,000 people.¹²⁹ After one year as a *preventive care* delivery intervention, P-PROMPT facilitated the increased delivery of pap testing and screening mammograms from 67% and 68% respectively, at baseline, to 75% post-intervention.¹²⁹ To a lesser degree, immunizations also increased.¹²⁹ However, the ability of the subsequently expanded P-PROMPT CDMS to increase the processes or improve the outcomes of physicians' management of *chronic*

diseases, specifically smoking, has not been determined and is the subject of an ongoing study centered on diabetes management.¹³⁰

P-PROMPT CDMS in its current form has guidelines-based modules for a series of preventive care services and chronic diseases, but some are implemented more comprehensively and completely than others. Its original smoking cessation management module, available through the Patient Care Status and Update Form, is abbreviated and currently hardly used or populated with patient data by P-PROMPT CDMS subscribers. Thus, it is evident that the smoking cessation management module is not known to and/or not meeting the needs of the primary care practices.

One of the strengths of P-PROMPT CDMS is its ability to import patient-specific information about medical conditions and diagnostic tests from multiple external provincial database sources. This obviates the need for tedious, duplicate manual entry by clinicians and automatically equips physicians and their health care teams with various automatically pre-populated registries. This critical strength of P-PROMPT CDMS is currently not fully exercisable for the context of the chronic disease of smoking, since a database of smokers in the province of Ontario does not exist from which P-PROMPT CDMS could import the necessary information to fully populate each physician's smoking registry. Recently, P-PROMPT CDMS has begun to automatically construct a partial smokers' registry by regularly adding all those patients for whom any of the smoking cessation service billing codes have been billed by the physician. It is

plausible that the data-limited inability to fully automatically assemble a complete physician's smoking registry may present a sufficient barrier and contribute to the underuse to date of the smoking registry in P-PROMPT CDMS.

In parallel, P-PROMPT CDMS also facilitates efficient tracking of physician incentive billings alongside the tracking delivery of the elements of chronic disease patient care to which they correspond.

2.8. Need for a Study

To briefly summarize the foregoing, research demonstrates that the quality of health care that patients with tobacco dependence currently receive needs to be improved. Quality improvement and disease management strategies have been investigated in the context of a variety of chronic diseases, particularly diabetes and cardiovascular disease, yet not as extensively for tobacco dependence.^{75,89} The available literature underscores the importance of clinical information systems in the management of various chronic diseases.¹³¹⁻¹³³ Specifically, the need for systematic identification of patients with a particular health concern and the importance of their compilation into a patient disease registry is emphasized.¹⁰⁸ However, the use of a multi-faceted intervention that includes a clinical information system and a smoking status identification system to compile a patient Smoking Registry from the patients on a physician's roster has not been investigated in the context of the chronic disease of tobacco dependence.

This research is a pilot study that assessed the feasibility of conducting a cluster randomized controlled trial to evaluate the efficacy of a multi-faceted intervention to increase delivery of smoking cessation counselling by primary care physicians. The assessment of feasibility aimed to test a measurement tool (SSICs) and explore various implementation issues in the primary care setting. The multi-faceted intervention included a clinical information system (P-PROMPT CDMS) that displayed provider smoking cessation counselling delivery cues and was equipped with a new smoking cessation management module in the registries-based P-PROMPT CDMS chronic disease management system. This multi-faceted intervention also consisted of patient care reminder letters and a Smoking Registry that was populated with information obtained through a clinical smoking status identification system. This identification system required the dissemination and collection of smoking status identification cards (SSICs) from patients who presented at the primary care practice.

Currently, there is no process to systematically identify smoking status of patients in a primary care setting. This presents as a challenge during any research that intends to investigate physician delivery of smoking cessation counselling because the total population of smokers (all possible recipients of the treatment to be measured) in the physician's roster is unknown. Since a populated registry is part of the advantage that P-PROMPT CDMS can bring but that is currently lacking in the context of smoking cessation counselling, this study intends to (a) actively identify smokers and (b) enable primary care offices to

efficiently populate the physician's smoking registry as part of the intervention. Also, the clinical information system to be tested in this trial (P-PROMPT CDMS) currently has a smoking cessation management module that is not easily accessible or user-friendly and, thus, has remained nearly empty to date. Finally, the delivery of the 5A's by primary care physicians has not explicitly been measured and so is not well understood.

This study intends to address the issues presented above. Logistic concerns associated with conducting such a trial in a busy primary care setting included the staff's ability to disseminate and collect the SSICs, patient acceptance of the SSICs to collect their smoking status information, as well as, the physicians' and staff's use of a critical component of the multi-faceted intervention - the clinical information system. It is thought that the multi-faceted intervention will help primary care practices collect the smoking status of most of each physician's patients who present at the practice during the study. As well, it is thought that the improved interface will be used more often and that this increased use will lead to increased delivery of smoking cessation counselling by primary care physicians.

3.0 Study Objective

3.1. Brief Overview of Research Question

Most, if not all, aspects of the future trial were replicated in the design and execution of the pilot trial. The primary differences between the two are the set of objectives and the sample size. To determine the feasibility of the future trial, this pilot tested a data collection tool and the adoption of the new smoking disease management module in the clinical information system. The research question for the main study for which the current study is a pilot is as follows:

Among primary care physicians who are subscribers to the P-PROMPT CDMS, does a multi-faceted intervention that includes a new smoking cessation management module added to the existing P-PROMPT CDMS increase initiation of smoking cessation counselling and its continuation according to the OMA's 5A's standard, compared with use of P-PROMPT CDMS with its currently existing smoking cessation management module?

The current research is a pilot trial intended to inform the design and execution of the main study. The pilot trial's research question is as follows:

Among primary care physicians who are subscribers to the P-PROMPT CDMS, what is the percentage of use of Smoking Status Identification Cards (SSICs), how often do physicians and staff access the smoking

cessation management module, and does the use of the new enhanced smoking cessation management module affect the percentage of delivery of smoking cessation counselling?

3.2. Study Objectives

The purpose of this pilot trial is to assess the feasibility of conducting a cluster randomized controlled trial to evaluate the efficacy of a multi-faceted smoking cessation management intervention that is based on an existing electronic clinical information system (P-PROMPT CDMS).

The 3 feasibility objectives of this pilot study are:

- (1) To evaluate whether Smoking Status Identification Cards (SSICs) will collect the smoking status of at least 90% of unique patients 15 years of age or older who present at the primary care practice for the study duration.
- (2) To determine whether the smoking cessation management module is used for at least 30% of patients who present at the primary care practice.
- (3) To conduct a preliminary evaluation of the smoking cessation counselling events delivered by each primary care physician.

4.0 Methods

4.1. Description and Justification of the Pilot Study Design

The health care research community has increasingly realized the value of conducting pilot trials.¹³⁴ Pilot trials help to ensure that larger randomized controlled trials are feasible and methodologically rigorous.¹³⁵ This pilot study aims to determine the feasibility of a future trial by evaluating both the use of the intervention and a data collection tool. Ultimately, the results of this pilot trial will help ensure optimal study conduct and provide a stronger justification for the final study design.

This pilot study was an interventional study designed as a controlled cluster randomized trial. The target population was the 65 physicians (belonging to 38 primary care practices) in Ontario who subscribe to and consequently have access to the web-based, systematic and multi-faceted chronic disease management system, P-PROMPT CDMS. These physicians have their entire patient roster held within the system, together with their demographics, key clinical data, and assignments to preventive care and chronic disease registries and to one of the guidelines for their care. The study setting was the primary care offices of each physician who consented to participate. The participating physicians were randomly divided into two groups. Using a between-group design, one group received the intervention to be tested and the other group received no active intervention and acted as the control. The multi-faceted

intervention included a clinical information system (P-PROMPT CDMS) with provider health care delivery cues, patient prompts and a clinical smoking status screening system to populate the physician's Smoking Registry in the clinical information system in their P-PROMPT CDMS. Baseline measurement of each physician's use of the original (currently existing) smoking cessation management module in P-PROMPT CDMS was used to stratify the primary care practices into low and high frequency of use. This step was followed by 1:1 randomization. Each physician who consented to participate was fully aware that there was a 50% chance of being randomized to receive the intervention and that they were free to choose not to participate at any point during the study.

An operationally feasible study design was employed in this pilot study in a manner to mimic and potentially prepare for conducting a study that will reflect and investigate the use of the intervention in typical clinical settings in Ontario. A cluster randomized controlled trial design was employed which, in the main study, will reduce the effect of treatment contamination that would arise since a number of physician subscribers to P-PROMPT CDMS work in primary care offices alongside each other, often as part of a family health team. If physicians who work in the same practice were assigned to different arms of the study, they would likely communicate about the intervention. As well, these physicians tend to share staff, who would then be exposed to both the intervention and control P-PROMPT CDMS, which would also contribute to contamination. In such a cluster randomized controlled trial design, the unit of randomization is a group, in this

case, a primary care practice that may include more than one doctor. However, this diminishes the study's power. A statistical technique used to account for this effect is discussed under Sample Size Adjustments and Estimates. A randomized controlled trial design is the best way to answer the main study's question because it will potentially demonstrate causality. A key feature of this design is randomly assigning the intervention to participants, which helps to eliminate the confounding variables inherent in a sample of, in this case, primary care physicians.

4.2. Pilot Trial Sample Size

This study was a pilot trial that aimed to inform the design and execution of a future, larger trial to be based on an evaluation of the feasibility objectives of this pilot. Since the study's target population is physician subscribers to P-PROMPT CDMS and currently comprises only 65 individuals across 38 primary care practice settings, it was unrealistic to recruit more than 10-15% of the target population to this pilot trial. Thus, a sample size of 6 to 10 physicians was set.

4.2.1. Determining the Feasibility of the Main Trial: Sample Size

Considerations

As part of the assessment of the main study's feasibility, preliminary sample size of the main study was calculated in two steps. To begin, a regular sample size calculation was computed that considered the range of probabilities

of accessing the smoking cessation management module in P-PROMPT CDMS. These sample sizes were then adjusted for the clustering effect expected due to the potential of having more than one physician participant from each primary care practice.

4.2.1.1. Probability of Accessing the Smoking Cessation Management Module in P-PROMPT CDMS

It is hypothesized that access to and use of the smoking cessation management module in P-PROMPT CDMS will lead to increased rates of smoking cessation counselling in primary care practices. It is also expected that the greater the access to and use of the module in P-PROMPT CDMS, the more smoking cessation counselling will be delivered. Thus, the probability of accessing the smoking cessation management module in P-PROMPT CDMS must be considered to determine the overall probability of delivery of counselling. The differences in probabilities between the intervention and control groups must then be used to calculate the range of potential sample sizes of the main trial.

The current pattern and frequency of use of P-PROMPT CDMS varies markedly among the 65 physician subscribers and their staff. In the intervention group, it is estimated that if the primary care practice accesses the new smoking cessation management module of P-PROMPT CDMS during a patient visit, there will be a nearly 100% probability that the patient will be counselled for smoking cessation. In the control group, the rate of counselling is expected to reflect

provincial estimates of physician delivery of smoking cessation counselling, since there is no data available about whether physicians with P-PROMPT CDMS have other than average activity in this form of chronic disease management.

Since 48% of Ontarian smokers aged 15 or older who had visited a doctor over a 12 month period were advised by their doctor to quit smoking,³⁹ this percentage will be applied as the expected percentage of counselling expected to be observed in the control group (the probability of counselling when not using the registry is 0.48). If the probability of not using the registry for a given patient is (1-p), the probability of counselling when using the registry is 1, and the probability of using the registry is p, then the overall probability of counselling is: $[P(\text{counselling}|\text{use registry}) * P(\text{use registry})] + [P(\text{counselling} | \text{not use registry}) * p(\text{not use registry})] = p + 0.48 * (1-p)$.

Using a range of probabilities of access from 10% to 100%, the above equation was used to calculate a range of rates of counselling in the intervention group from 0.53 to 1.0. The standard deviation of counselling rates in the intervention group can be estimated by taking +/- 2 standard deviation units from the middle of the range of rates of counselling to get a standard deviation estimate of 11.75. Effect size was then calculated over the range of probabilities of access to allow sample size calculation for the main study (Table 3).

Table 3: Main study sample size calculations per arm with 80% Power

Probability of Access to Smoking Cessation Management Module in P-PROMPT CDMS (%)	Rate of Counselling (%) (Intervention group)	Difference in Counselling Rates Compared to Control	Main Study Sample Size of Physicians Per Arm (Standard deviation=11.75)	Adjusted for Clustering: Main Study Sample Size of Physicians Per Arm
10	53.2	5.20	107	131.61
20	58.4	10.4	26.8	32.96
30	63.6	15.6	11.91	14.65
40	68.8	20.8	6.70	8.24
50	74.0	26.0	4.29	5.28
60	79.2	31.2	2.97	3.32
70	84.4	36.4	2.19	2.69
80	89.6	41.6	1.67	2.05
90	94.8	46.8	1.32	1.62
100	100	52.0	1.07	1.32

4.2.1.2. Adjusting Sample Size for Clustering Effect

The unit of randomization in this study is the primary care practice, while the unit of analysis is the physician. It is expected that the rates of smoking cessation counselling delivered by physicians in the same primary care practice cluster will be more similar to one another than the rates observed in physicians of different primary care practice clusters.

To account for this similarity among physicians within the same primary care practice, an intra-cluster correlation coefficient (ICC) must be used to calculate the sample size.¹³⁶ An ICC is a measure of how related data is within specified clusters.¹³⁷ It serves to inflate the sample size required for cluster randomized trials to account for the net loss of independent data.¹³⁸

In a study of the effect of cluster randomization on sample size in prevention research, an ICC of 0.23 was calculated for smoking cessation counselling among physicians within the same cluster.¹³⁹ An ICC reflects the proportion of variance that is attributable to a cluster.¹⁴⁰ It is a parameter that is estimated from data collected in a trial and depends on the study's outcomes, clustering units and population. Once an ICC is estimated, it can be applied in future, similar research that has comparable outcomes, clustering units and study population as the research findings from which the ICC was originally calculated. The ICC is then used in the equation for design effect, which is a variance inflation factor or adjustment.¹⁴¹ In this context, the use of the above ICC in the equation for the design effect yields the sample size correction factor.

$$\text{Design effect} = [1+(m-1)*\text{ICC}]$$

$$= [1+(2-1)*0.23]$$

= 1.23; where m=2 is the average number of physicians expected in each cluster (actual value calculated in this study is 2.3).

To determine the adjusted or effective sample size, the original sample size calculation for each probability of accessing the smoking cessation

management module in P-PROMPT CDMS (Table 3) must be multiplied by the above design effect of 1.23. The resulting sample sizes account for the clustering effect that will be observed due to similarities of physicians working in the same practice (Table 3).^{136,140}

4.3. Establishing Threshold Criteria

As a pilot trial that aimed to determine the feasibility of a larger trial, each study objective was accompanied by an *a priori* threshold criterion to claim success.¹³⁴

4.3.1. Objective 1

To evaluate whether SSICs will collect the smoking status of at least 90% of unique patients 15 years of age or older who present at the primary care practice for the study duration.

The role of the SSICs is so fundamental to the primary outcome of the larger trial, which is to determine the percentage of smoking patients who are counselled (it will provide a denominator) that the threshold criterion for claiming success of this device must be set relatively high. If SSICs are ineffective at sufficiently accurately capturing the number of smokers who present at the physician's office, the validity of the outcome measure determining the rate of smoking cessation counselling in each physician's practice will be seriously threatened. In the extreme case, the calculation would yield a paradoxical result

for rates of smoking cessation counselling if more smokers were counselled than were initially identified by the SSICs. Thus, a value of at least 90% was chosen for patients aged 15 or over whom present at the physician's office during the study period who must complete and return the SSIC to claim success of this device.

4.3.2. Objective 2

To determine whether the smoking cessation management module is used for at least 30% of patients who present at the primary care practice.

A threshold value for accessing P-PROMPT CDMS can be set from the feasibility of the sample size of the main study that is associated with the probability of access (Table 3). For example, using the ICC of 0.23 with 80% power at the 0.05 significance level and 20% probability of access would require a cluster-adjusted sample size of 33 physicians in each arm of the study for a total sample size of 66 physicians (with an expected average of 2 physicians belonging to 1 primary care practice cluster). With a target population of 65 physicians, this is not a feasible recruitment rate of over 100%. However, a 30% probability of access would require 15 physicians in each arm and a total sample size of 30 physicians, which is realistic. Thus, a threshold value of 30% probability was chosen for accessing the P-PROMPT CDMS smoking cessation management module that must be observed in the pilot trial to render the main trial feasible (Table 3). This threshold value will be applied in the analysis of both

basic and advanced use of P-PROMPT CDMS separately. Basic use of P-PROMPT CDMS requires entering each patient's smoking status (current smoker, previous smoker, never smoker). Advanced use of P-PROMPT CDMS requires changing a smoking related information field other than smoking status for only "current smoker" patients who present at the primary care practice.

4.3.3. Objective 3

To conduct a preliminary evaluation of the smoking cessation counselling events delivered by each primary care physician.

This objective is to measure the treatment effect and is proposed to be the primary outcome in the main trial. A limitation of conducting a pilot trial is that it is underpowered and cannot be used to determine treatment effect. Thus, a threshold value could not be chosen for this objective because neither success nor failure can be claimed due to the insufficient power of the pilot trial. However, a cautious preliminary evaluation of the results might be able to informally suggest *potential* success or failure.¹³⁴

4.3.4. Inclusion Criterion

The inclusion criterion was:

- (i) Primary care physicians who currently subscribe to P-PROMPT CDMS

4.3.5. Exclusion Criteria

The exclusion criteria were:

- (i) Subscribers to a paper-based version of P-PROMPT CDMS
- (ii) Physicians who are expected to retire during the course of the study
- (iii) Physicians whose billing information is not readily accessible through P-PROMPT CDMS's automated data synchronization done through either its automated "Data Synch" or an alternative method that allows electronic scanning of the physician's service billing codes

4.3.6. Justification of the Eligibility Criteria and Generalizability of the Study

The participants chosen for this study is a group of primary care physicians who are likely sufficiently homogeneous in their approach to chronic disease management that their responses to the intervention may be expected to be similar. Their putative homogeneity is based on the fact that they belong to a highly specific, self-selected group of primary care practitioners who have taken the active step in the management of chronic diseases in their practice of electing to pay for a patient healthcare delivery support tool out-of-pocket, and unlike for an electronic medical record system, without prospects of receiving reimbursement for it by the MOHLTC. This homogeneity, in turn, negatively affects the generalizability of the study. For practical reasons, the

inclusion/exclusion criteria were designed to be narrow and to limit the study sample to physicians who are already subscribers of P-PROMPT CDMS.

4.4. P-PROMPT CDMS Smoking Cessation Management Module Changes

Since the use of the current smoking cessation management module in P-PROMPT CDMS was limited, as a part of the intervention for the study, the module was enhanced to facilitate utilization and functionality. To inform this modification, various sources of information were used, including the accumulated knowledge gathered from relevant literature, personal use and review of P-PROMPT CDMS, and a series of semi-structured interviews with current P-PROMPT CDMS primary care practices were undertaken. The semi-structured interviews with primary care practice subscribers to P-PROMPT CDMS were conducted to gain an understanding of their needs, opinions, and work flows as it pertained to their normal use of P-PROMPT CDMS. The Principal Investigator, Natalie MacLeod, held semi-structured interviews that collected information about two key areas: (a) the user's understanding and use of P-PROMPT CDMS in the practice and (b) the user's opinions regarding P-PROMPT CDMS (Appendix 1). A convenience sample of subscribers was chosen. Those who accepted an invitation were met in-person at their primary care office. The corresponding re-design was specified by the Principal Investigator, Natalie MacLeod, and performed by a P-PROMPT CDMS programmer for use in this pilot study. Since P-PROMPT CDMS is a web-based

program, the changes could be implemented to become automatically available in the P-PROMPT CDMS of the physicians in the intervention group at the time of commencement of the study.

4.5. Multifaceted Smoking Cessation Management Intervention

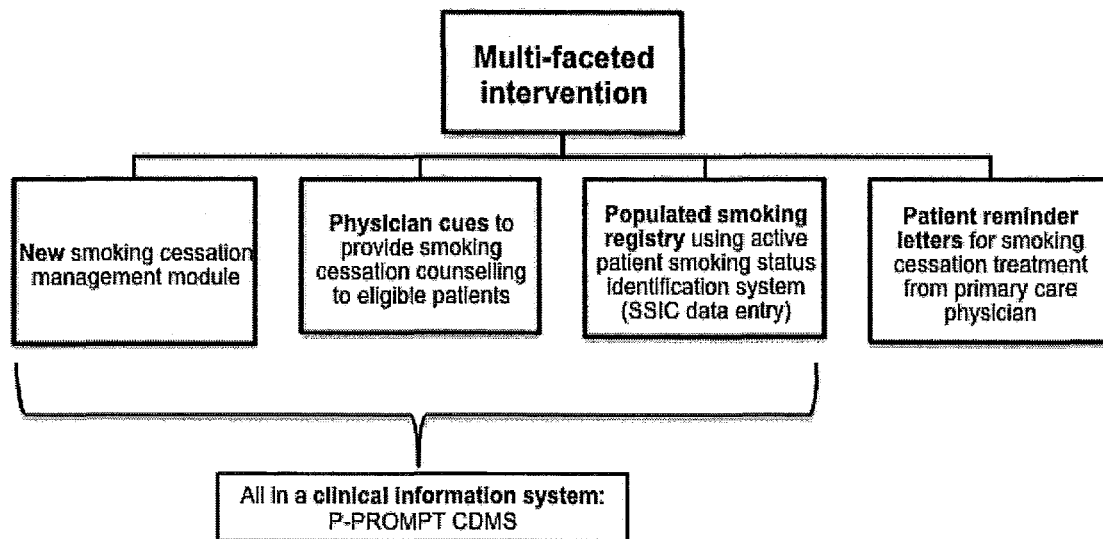
The intervention that was tested in the treatment group of this study was multi-faceted and consisted of 4 components (Figure 1):

- Access to the new (improved) Smoking Cessation Management Module
- Cues for physicians to deliver smoking cessation counselling
- Letters sent to patients who are “potential smokers,” prompting and inviting them to present for smoking cessation counseling
- A proactively populated patient smoking registry that used the information collected on SSICs; SSICs were handed out in the primary care practices by each practice’s administrative assistant to all patients 15 years of age or older who presented at the physician’s office during the study.

The multifaceted intervention had at its core a new (improved) smoking cessation management module in P-PROMPT CDMS. This new module included the following components: a) easy access and visible smoking status data entry box and b) default setting for each patient of the full Ontario Medical Association (OMA) Clinical Tobacco Intervention program’s Smoking Progress

Notes Annual Patient Profile as part of the Patient Care Status and Update Form for all patients registered in the smoking disease registry.

Figure 1: The multi-faceted intervention tested in this pilot trial



The primary care practices of **control group** physicians maintained their usual access to the previously existing smoking cessation management module in P-PROMPT CDMS. They were instructed to identify smokers and to deliver smoking cessation counselling to the best of their ability given their usual resources.

Study elements that were common in both the intervention group and control group included the audit-and-feedback feature of P-PROMPT CDMS, an orientation session at the initial site visit, study kits and the *handing-out* of SSICs

in the primary care practices. The details of these common elements are as follows:

- As part of P-PROMPT CDMS, physicians have access to an audit-and-feedback feature that informs them of how up-to-date their patient population is on a particular health care measure (for example, pap test, screening mammogram, smoking cessation counselling, etc.), together with a corresponding drill-down list of patients. Since this is standard, both control and intervention group physicians had access to this feature.
- To ensure that the control group had as heightened an awareness as the intervention group to their respective versions of the smoking cessation management module, the Principal Investigator, Natalie MacLeod, conducted a brief, in-person orientation session with each of the intervention and control group primary care practices. In the intervention group, this session was used to introduce and help implement the improved smoking cessation management module in the primary care practices. In the control group, this session reviewed the standard smoking cessation module in the primary care practices. All study-related materials were delivered to each participating primary care practice at these orientation sessions.
- Each physician was provided with a standard Study Kit.

- SSICs were handed out in the primary care practices by each practice's administrative assistant to all patients 15 years of age or older who presented at the physician's office. However, information on the SSICs was *not* used by the control group physicians' primary care practices to proactively populate their smoking registry during the course of the study. The information collected on the SSICs was used to provide the investigator with an estimate of the number of smokers who presented at the physician's office. The information obtained from the SSICs in the control group at the end of the study was used to create a Smoking Registry for future use by the practice/physician.

4.5.1. Cues for physicians to deliver smoking cessation counselling

As part of its design, P-PROMPT CDMS provides physician prompts. These are in the form of overall physician practice performance reports and regularly updated patient drill-down lists that track patients according to preventive care and/or chronic disease services and colour-code them relative to guidelines. Critically, these lists highlight all overdue patients. While these features were not removed when the new smoking cessation management module was added for the intervention group, a variation of the traditional prompt was integrated into the module. Six evidence-based statements from the CDC's Tobacco Guideline⁶ about the nature and value of physician-delivered smoking

cessation counselling were prepared and displayed prominently on the main, initially nearly empty, entry page of P-PROMPT CDMS for each physician in the intervention group (Appendix 2). The statements were displayed individually and changed on a daily basis. Appendix 3 is a screenshot of the P-PROMPT CDMS page with the physician prompt as it would have appeared during the study.

4.5.2. Patient Letters inviting “potential smokers” to present for Smoking Cessation Counselling

P-PROMPT CDMS offers the mailing of patient prompts as part of its services. However, a prerequisite of this service is the existence of a specific registry of patients to whom the letters can be targeted. To take advantage of this health care quality improvement strategy, a list was compiled of patients who could reasonably be believed to have an above-average likelihood of being smokers. Potential smokers were identified as individuals for whom MOHLTC physician service billing codes were submitted for the delivery of smoking cessation counselling at any time since their inception in January 2007. In addition, male and female patients 40-44 years of age were identified and also included in this list of potential smokers. This is because the Ontario Tobacco Research Unit (OTRU), in 2005, identified this age-bracket as having one of the highest overall prevalence of smoking: it includes the highest prevalence of smoking in females (23%) and the second-highest in males (29%) in Ontario.³⁹

This list of potential smokers served as a target sample to which a letter was mailed on behalf of the physician, inquiring about their smoking behaviour, one month following randomization of the primary care practices. The letter prompted smoking patients to consider their health and invited them to make an appointment to visit the physician's practice to talk about their smoking behaviour (Appendix 4).

4.5.3. The Patient Care Status and Update Form in P-PROMPT CDMS

The standard smoking cessation Patient Care Status and Update Form within P-PROMPT CDMS defaults to a *brief* version of the Ontario Medical Association (OMA) Clinical Tobacco Intervention program's Smoking Progress Notes Annual Patient Profile. As part of the intervention for physicians in the intervention group, this default setting for the Patient Care Status and Update Form in their P-PROMPT CDMS was changed to be the new *comprehensive* Smoking Progress Notes Annual Patient Profile, which is a flow sheet specifically designed to facilitate effective smoking cessation interventions by physicians and fully incorporates the components of the 5A's model.

4.5.4. The Smoking Registry

To develop a target patient registry, a smoking status identification system was used that included SSICs intended to identify current smokers from among

the patients who presented at the physician's clinical practice during the study period. SSICs are discussed in further detail below.

Accessibility, user-friendliness and brevity of the data input process were addressed to enable primary care offices to efficiently populate the physician's smoking registry. Previously in P-PROMPT CDMS, the process of strictly registering a patient as a smoker without entering any other data related to their smoking behaviour involved five "clicks" or steps. That process was reduced to two clicks by designing a brief smoking status box that displayed beneath the patient's name (Appendix 5). In this way, primary care offices were simply required to pull-up the patient's page in P-PROMPT CDMS and click on one of three "current patient smoking status" options that were immediately displayed.

4.6. Smoking Status Identification Cards (SSICs)

SSICs were originally referred to as Smoker Identifying Cards (SICs), but were renamed later as Smoking Status Identification System (SSICs) to better reflect their function. The purpose of the SSIC was twofold: First, as already mentioned, the information obtained on them from patients was used to populate the smoking registries of the physicians in the intervention group. Second, SSICs provided an estimate for the weekly number of smoking patients who presented at the primary care practice. This estimate was important to obtain because, other than a tedious chart review that will likely not have all smokers documented, there is no way of knowing how many individuals on a physician's

patient roster are smokers. This otherwise missing number is of critical importance because it is the denominator needed to determine the proportion of smoking patients who presented at the primary care practice and who were treated with smoking cessation counselling during the study period. Patients were asked to drop the completed SSIC into the above-mentioned secure box that had a slit opening and a lock closure to ensure privacy of the health information provided. No further action was taken with the SSICs by control group primary care practices. However, in the intervention group physicians' offices, a staff member entered the information from the SSICs into the enhanced smoking cessation module of P-PROMPT CDMS on a daily basis.

The SSICs that were distributed for completion in physician's waiting rooms were 3.7" x 8.5" cards (Appendix 6) that asked for patient initials, health card number, smoking status (one of: (a) never smoked, (b) current smoker (number of years smoking, cigarettes smoked per day, any quit attempts, date of most recent quit attempt), or (c) previous smoker (how long since quitting)). On the reverse side, each SSIC was numbered and included the physician's name to help track how many SSICs went missing or were discarded during the study.

4.7. Characteristics of Physicians and Primary Care Practices

Participating physicians were asked to fill out both pre-study and post-study questionnaires. The pre-study questionnaire was administered to obtain information about their apparent delivery of smoking cessation counseling and

their billing practices. In addition, the physicians were asked about perceived barriers to the delivery of smoking cessation programs and current smoking cessation programs implemented at their practice site (Appendix 7). The post-study questionnaire collected information about the physicians' demographic information including practice description, personal smoking status, and the primary care practice in which they work (Appendix 8). The pre-study questionnaire was delivered to the physician at the site activation visit and was either filled out during the visit or completed a couple days later. The post-study questionnaire was faxed to the physicians' offices a week after study completion. They were completed by the physician and faxed back to the P-PROMPT CDMS office within two weeks.

4.8. Measurement Timepoints

Baseline data regarding each physician's use of the regular, existing smoking cessation management module in P-PROMPT CDMS was collected from the system's activity logs two weeks before the active intervention study period began. A summary of each physician's billings for health care services delivered to patients is compiled as a monthly remittance advice file by the MOHLTC. These files were analysed to determine how many times each physician billed for smoking cessation counselling. The data from the remittance advice files, P-PROMPT CDMS activity logs and SSICs was collected at the end

of the twelve-week study period. Data from the questionnaires was collected and compiled after each visit, as outlined above.

4.9. End-point for Early Withdrawal

Withdrawal from the study was planned to occur whenever a physician did not wish to continue to participate in the study. A second planned reason for withdrawal was the scenario where a physician who consented to the study but later denied the investigator access to the billing records that are needed to perform data analysis. The data collected from withdrawn physicians was planned to be kept and used in the analysis unless a request were made to be completely removed from the study, in which case all data from the physician was planned to be destroyed. The reasons for any withdrawals from the study were planned to be documented.

5.0 Study Timeline

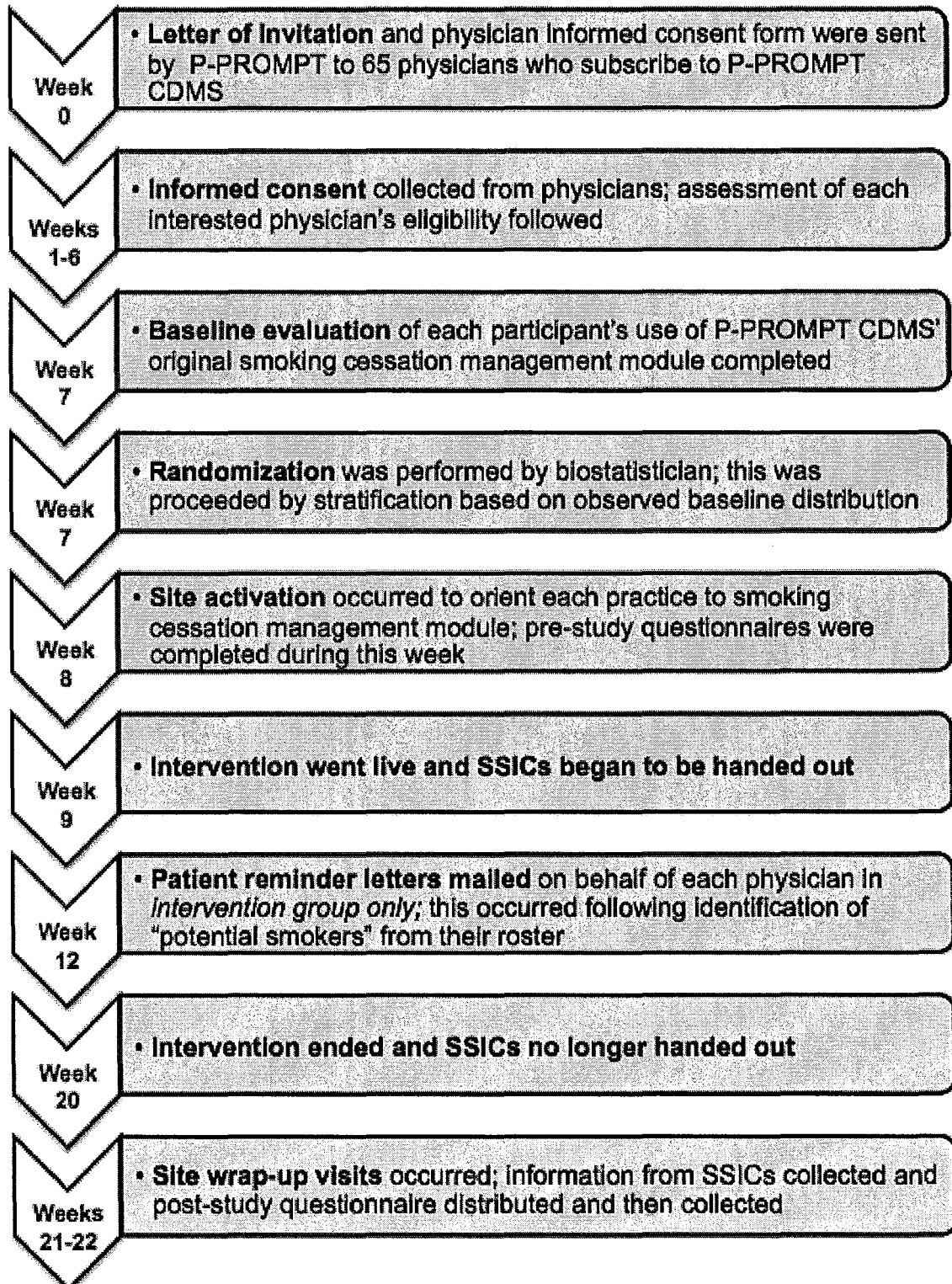
5.1. Phase I

This phase included two components: (a) physician enrollment in the study, which involved recruitment, informed consent and assessment of eligibility; and (b) a baseline evaluation of each physician's use of the standard smoking cessation management module. Figure 2 is a study timeline that illustrates when the elements of each study phase were rolled out.

5.1.1. Recruitment

The population of 65 P-PROMPT CDMS physicians was invited to participate in the study. The invitation was mailed by the service provider of P-PROMPT CDMS, Fig.P Software Incorporated, informing their subscribers of the proposed study as an opportunity to participate in research that the service provider believes may be of interest to its clients. The package contained an informative description of the study, a half-page flyer highlighting the benefits of study participation, as well as an informed consent fax-back form that interested physicians were requested to return within one week of receipt of the invitation. It was acknowledged that physicians can have very busy schedules that may cause them to overlook certain correspondences. Thus, at the one week mark, physicians who had not responded were followed up by telephone. As an option, the Principal Investigator, Natalie MacLeod, offered to schedule an appointment with interested physicians to present the study to them in person. This pilot trial was registered with clinicaltrials.gov prior to the start of study recruitment.

Figure 2: Study timeline



5.1.2. Informed Consent

For a physician to be enrolled in this study, written informed consent was obtained. Informed consent was not necessarily collected in-person by the Principal Investigator. If the physician was content with the study explanation and felt comfortable to participate in the study after reviewing the written information provided in the invitation package and asking any supplementary questions, then the physician signed the informed consent form and faxed it to the service provider. If the physician requested an in-person meeting to further review and discuss the details of the study, then such a meeting was arranged, and informed consent was collected at that time. Physicians were provided with the Principal Investigator's contact information in the package to address any questions or concerns they may have. All participants retained a copy of the signed and dated informed consent.

5.1.3. Assessment of Eligibility

Once informed consent was received, an effort was made to ensure that each physician's billing information would be electronically available to be scanned for the appropriate smoking cessation counselling billing codes. All consenting physicians' billing information met this criterion, either through P-PROMPT CDMS's automated daily data acquisition system called DataSynch or through an alternative, mutually agreeable method.

5.1.4. Baseline Evaluations

Baseline “smoking cessation counselling events” data sheets were faxed to each participating physician’s primary care practice at the start of January 2010. It became evident through telephone conversations that the sheets were not being as diligently completed as requested because they were not readily integrated with the physician’s workflow. Alternatively, data was obtained from each physician's P-PROMPT CDMS system about their use of the smoking cessation module prior to the intervention rather than their smoking cessation counselling rates.

This latter alternative was considered a reasonable factor by which to stratify because practices that demonstrate greater use of the module prior to the study will most likely show greater use post-intervention, as well. Since baseline use of the module is associated with the predictor variable and is a cause of the outcome variable, it must be dealt with to prevent bias and to rule out an alternative explanation to any cause-effect relationship observed in the study. Each sample will have individuals with varying levels of the potential confounding variable. Stratification ensures a balance of the confounding variable in each treatment arm so that similar levels of a potential confounding variable are ultimately compared. Thus, for the purposes of stratification, baseline data about the physician’s use of the clinical information system was considered. Use of the system was measured by the number of times each of the physician’s patients

had an activity or event recorded in the original smoking cessation module. An activity or event was defined as any one of:

- a) Registration of a patient into the smoking cessation module
- b) A change or addition made to a patient's smoking information once registered
- c) De-registration of a patient from the smoking cessation module

5.2. Phase II

This phase included three components: (a) randomization, which was preceded by stratification; (b) in-person orientation by the Principal Investigator of each participating primary care practice, which included administration of the pre-study questionnaire and (c) mailing of patient prompts, which was preceded by identification of potential smokers from each physician's rostered patients. Also, about 6 weeks after the new smoking cessation management module was made available to the intervention group, the Principal Investigator telephoned each of the primary care practices to inquire about how the study was going at their site and to answer any questions they had.

5.2.1. Stratification and Randomization

The observed baseline distribution was used to define groups of low and high frequency of baseline use of the P-PROMPT CDMS smoking cessation management module. To reduce variation in outcomes due to chance

disproportions in this important baseline variable, the study sample was stratified according to use of the smoking cessation management module. The baseline measurements of this variable were averaged for physicians who belonged to the same practice, and the related primary care practice was placed in the appropriate stratum.

5.2.2. Randomization Procedure

Since the trial was designed as a cluster design, randomization was done all at one time following the recruitment of all of the sites due to the stratification and to avoid the chance of allocation bias. Within each stratum (A or B), the practices to be randomized were given a sequential number. The Principal Investigator assigned the list of practices to be randomized to the appropriate strata and numbered the practices in each stratum. Randomization was then performed by a blinded biostatistician. The biostatistician used the program R¹⁴² to accomplish random number generation to assign practice numbers to groups. The practice allocation to intervention and control groups was then disclosed to the P-PROMPT CDMS system coordinator who matched up the group assignment to the each practice setting. Following a two-week lag period to permit on-site orientation sessions, the practice settings randomized to the intervention group were automatically provided access to the enhanced version of the P-PROMPT CDMS with the new (improved) smoking cessation management module.

5.2.3. On-Site Module Orientation Sessions and Study Kits

After randomization of the primary care practices into each arm of the study, the Principal Investigator arranged a meeting with each participating physician during the week before the multifaceted-intervention was set to be introduced. The in-person visit intended to deliver the study kits, review the allocated smoking cessation management modules in P-PROMPT CDMS on the computer with staff and physicians, and increase compliance with study protocol. A one-on-one brief training session for both the intervention and control groups about the allocated smoking cessation management module took place with each member of the team who is normally involved with any component of smoking cessation counselling. For the control group physicians and members of their team, the training served to re-introduce the previously existing smoking model and to respond to any questions regarding its use.

For both the intervention and control groups, information material regarding smoking cessation was provided to ensure equal access to reference material was available. As a part of this material, the following was provided: a standard sheet from the Centre for Addiction and Mental Health (CAMH) that depicted the “algorithm for tailoring pharmacotherapy in primary care settings” (Appendix 9), a page showing a table of “the 5Rs to enhance motivation to quit” adapted from the 2000 version of the CDC Guideline (Appendix 10), and a sheet describing the STOP study as a source for patients from which to receive free

smoking cessation pharmacotherapy and that provided the URL for the STOP Study's website,

Study materials delivered at this time to both the intervention and control groups consisted of a complete copy of the study protocol, 500 SSICs, a secure, plastic ballot/suggestion box was also delivered with built-in lock, a slit to deposit completed SSICs into the box, and a plastic sheet protector that housed a sign instructing patients to drop their completed SSICs into the box. A month after the study began in the primary care offices, an additional 1,000 SSICs were printed and mailed out to each site.

The pre-study physician questionnaire was completed either during the site visit or a few days after site activation but before the intervention was introduced and either faxed or mailed to the P-PROMPT CDMS office at Fig.P Software in Hamilton.

5.2.4. Patient Letter Prompts inviting to present for Smoking Cessation Counselling

Patient letter prompts were sent out to a group of identified potential smokers on behalf of the physician a month following randomization, as described in Section 4.4.5 above. The letter prompts were on physician letterhead and prepared at Fig.P Software Incorporated, the service provider of P-PROMPT CDMS that routinely prepares and mails similar letters for a number of preventive care services.

5.2.5. Smoking Status Identification Cards (SSICs)

Throughout the three-month study duration, patients 15 years of age and older who presented at each participating physician's primary care office were asked by the physician's administrative assistant to complete a SSIC. In cases where a patient visited the primary care office more than once over the twelve-week period, he/she was only asked to complete the SSIC once. Physicians in the intervention group were instructed to enter the information obtained from the SSICs into P-PROMPT CDMS as soon as it was obtained from the patient.

5.3. Phase III

This phase consisted of the site wrap-up visits, which included data collection and the administration of the post-study physician and primary care practice questionnaire.

5.3.1. Site Wrap-up Visits

The site wrap-up visits occurred during the first two weeks after the three-month study. At that time, the Principal Investigator visited each site, collected the data from the SSICs and provided the physician with the post-study questionnaire. The counting of the SSICs was done on the primary care practice's premises unless the physician requested otherwise. Since the SSICs were treated as the physician's property, it was left to the physician's discretion to decide what to do with them once they were counted for study purposes. Any

conditions or restrictions the physician imposed on the Principal Investigator about the use and disposal of the information was complied with.

6.0 Measurements

6.1. Outcome Measures

Details about what data was collected and how it was collected for each of the feasibility objectives follows.

- (1) To evaluate whether the SSICs that will collect the smoking status of at least 90% of unique patients 15 years of age or older who present at the primary care practice for the study duration.

The first feasibility objective was measured as the percentage of patients presenting at the primary care practice who completed and returned a SSIC to the practice's administrative assistant. Data that was gathered was the number of completed SSICs and the numbers of smokers, non-smokers and previous smokers identified by the SSICs. This data was recorded on a SSIC Data Documentation Sheet (Appendix 11).

The number of unique patients who presented at the primary care practices during the study was determined from each physician's remittance advice files, which were accessed through P-PROMPT CDMS. The data was exported into a Microsoft Excel file from which the number of unique health card numbers to whom physicians provided a health care service was determined.

- (2) To determine whether the smoking cessation management module is used for at least 30% of patients.

The second feasibility objective was primarily measured by analysing the physicians' P-PROMPT CDMS smoking registry and activity log to determine the percentage of unique patients 15 years of age or older who were registered into the smoking cessation management module during the study. The number of unique patients who presented at the primary care practices during the study was determined from each physician's remittance advice files, which were accessed through P-PROMPT CDMS. All data about use (activity log and smoking status registration) was electronically extracted by a P-PROMPT CDMS programmer and exported into an Excel file for analysis by the Principal Investigator.

To further evaluate the use of the module, the above data sources were used to examine the following items: (a) the percentage of registered smoking patients whose smoking-related information field(s) was changed or added through the Patient Status and Update Form; (b) the number of times the physician and staff logged into the smoking cessation management module; and (c) the frequency with which the audit-and-feedback for smoking cessation delivery was viewed by physician and staff.

- (3) To conduct a preliminary evaluation of the smoking cessation counselling events delivered by each primary care physician.

The third feasibility objective was calculated as the percentage of identified smokers for whom smoking cessation counselling was initiated and/or continued. The data regarding the number of smokers who presented was gathered from the SSICs, while the smoking cessation counselling events were measured by the appropriate physician service billing codes (E079A and/or K039A+Q042A) that appeared on MOHLTC remittance advice files uploaded to P-PROMPT CDMS. This data was electronically extracted by a P-PROMPT CDMS programmer and exported into a Microsoft Excel file for analysis by the Principal Investigator.

6.2. Statistical Methods

Percentages were used to analyze the first, second, and third feasibility objectives. To evaluate whether the SSICs collected the smoking status of at least 90% of unique patients 15 years of age or older who presented at the primary care practice for the study duration, a percentage was calculated and is represented by the following formula:

$$\text{Percentage of completed SSICs} = \frac{(\# \text{ of completed SSICs} \times 100)}{\# \text{ of unique patients 15 years of age or older who presented at the primary care practice}}$$

To determine whether the smoking cessation management module was used for at least 30% of patients who presented during the study, the following percentage was calculated:

$$\text{Percentage of basic module use} = \frac{(\# \text{ of patients registered in smoking cessation management module} \times 100)}{\# \text{ of unique patients 15 years of age or older who presented at the primary care practice}}$$

To further evaluate the use of the smoking cessation management module, a second percentage was calculated that represents more advanced use of the module for the management of smoking cessation counselling. This second percentage is represented by the following formula:

$$\text{Percentage of advanced module use} = \frac{(\# \text{ of registered smoking patients whose smoking related information was changed or added} \times 100)}{\# \text{ of smokers registered in P-PROMPT CDMS's smoking registry}}$$

To conduct a preliminary evaluation of the smoking cessation counselling events delivered by each primary care physician, a percentage was calculated and is represented by the following formula:

$$\text{Percentage of counselling events} = \frac{(\# \text{ of patients for whom E079A and/or K039A+Q042A billing codes submitted during the study} \times 100)}{\# \text{ of patients identified by SSICs as smokers}}$$

A Generalized Estimating Equation (GEE) was originally planned to be used to analyze the data. However, due to the lack of a cluster in the form of more than

one physician participant from the same primary care practice and the lack of sufficient data, this analysis was not performed. The results of this third objective concerning smoking cessation treatment delivery were compared to the results of the second objective, which concerns the use of the smoking cessation management module in P-PROMPT CDMS. This helped develop a sense of the relationship between P-PROMPT CDMS use and smoking cessation counselling rates.

7.0 Ethics

This study was conducted in compliance with the Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and the Personal Health Information Protection Act privacy legislation.

7.1. Research Ethics Board Review and Approval

The Principal Investigator submitted the study protocol and Participant Informed Consent Form to the Faculty of Health Sciences Research Ethics Board (REB) at McMaster University for review and, prior to the start of subject recruitment, received written signed and dated approval for both the study as a whole and for the written information to be provided to study subjects.

7.2. Subject Consent

The subjects who consented to participate in this pilot trial were physicians. As clients of the service provider, Fig.P Software Incorporated, the

initial contact with the physicians regarding this trial was made by the service provider who informed them of this study and invited them to participate. These subjects were mailed a comprehensive information package along with an informed consent form approved by the REB that was followed-up with a phone call and, in one case, a meeting. The physicians were provided in the package with the Principal Investigator's contact information to be able to address any questions or concerns.

7.3. Data Management and Confidentiality

Confidentiality of all collected data was of primary concern, and every effort was made to ensure that study data management respected the privacy and confidentiality of participants and their patients. The data collected about the physicians was not shared with anyone who was not directly related to the study as a member of the trial team. All personal identifiable information, such as the physician's name, address, phone number, was removed from the data and replaced with a number. A list linking the number with the physician's name was kept in a secure place, separate from the physician's file. The data, with identifying information removed, was securely stored in a locked office in the office of Fig.P Software Incorporated. The data for this research study will be retained for 10 years.

No records that identify the physician by name or initials were allowed to leave the office of Fig.P Software Incorporated. No information that discloses the

physicians' identities will be released or published without their specific consent to the disclosure.

7.3.1. Health Information Custodians and their Agents

The service provider of P-PROMPT CDMS has been contracted by the physician, who is a Health Information Custodian (HIC), to provide the HIC with both preventive care and chronic disease management services. As such, the service provider, Fig.P Software Incorporated, is considered an "agent" of the HIC, which is defined under Ontario privacy legislation (the Personal Health Information Protection Act 2004 (PHIPA)) as "a person that, with the authorization of the (health information) custodian, acts for or on behalf of the custodian in respect of personal health information for the purposes of the custodian, and not the agent's own purposes, whether or not the agent has the authority to bind the custodian, whether or not the agent is employed by the custodian and whether or not the agent is being remunerated."¹⁴³

7.3.2. Collection of Personal Health Information

The SSICs served as the method to collect patient personal health information. The personal health information was collected by the HIC (physician) and was in the custody/control of the HIC at all times. While the collection of personal health information generally requires consent, "the consent

is usually implied from the fact that the individual is providing the information.”¹⁴⁴

Significantly, a patient is free to decline to complete the SSIC.

No personal identifiable patient information was used for study purposes. Thus, patient initials and health card number were only necessary to ensure that the administrative assistant of the physician could accurately enter the appropriate patient information into their P-PROMPT CDMS. The only information of importance to the study that was obtained from the SSICs included the number of SSICs that were completed and the number of current, previous and non-smokers that were documented. The patient’s initials and health card number were not collected by the study.

7.3.3. Disclosure for Research

As described in section 7.3.1, health care practitioners are Health Information Custodians (HICs) under PHIPA. They may disclose personal health information about an individual to a researcher if the researcher submits a written application, a research plan that meets specified requirements, and REB approval of the research plan to the HIC.¹⁴³ As well, the researcher must enter an agreement with the HIC respecting disclosure (Appendix 12). The Principal Investigator of this study complied with conditions and restrictions set forth by PHIPA and imposed by the HIC regarding any personal health information of an individual.

8.0 Results

8.1. Physician Interviews to Guide Development of the New (Improved) Smoking Cessation Management Module in P-PROMPT CDMS

The semi-structured interviews were conducted with seven physicians and/or their staff belonging to five primary care practices located in either Hamilton or Toronto. Four of the physicians were part of a FHT, while three had solo practices. The pattern that emerged from the interviews of various physicians and staff within the primary care practices was that P-PROMPT CDMS was most closely associated with the idea of keeping track of patient's care goals and the provider's healthcare deliverables. Physician use of P-PROMPT CDMS varied greatly and included sporadic, bi-weekly, weekly or daily use, whereas staff use of P-PROMPT CDMS was more frequent and occurred at least once per week. While some physicians used it for a portion of their chronic disease management, the majority reported using it for preventive care services. The main reason cited for this was their use of an electronic medical record to deal with chronic diseases. While EMRs do not track and help manage chronic diseases nor physician's registries of patients with them, the offices use them to input and record data about a patient's disease. To subsequently input this data again into P-PROMPT CDMS was reported as increasing workload and was perceived as redundant, demonstrating a lack of knowledge by the clinicians about how to use the CDMS in the manner that avoids the need for duplicate

data entry. Despite these issues, all physicians acknowledged the potential of P-PROMPT CDMS to help them provide improved chronic disease management. When asked about which features they liked the most in P-PROMPT CDMS, doctors and staff listed the way the data is organized, the registry and roster views, the reports on care goals, colour coding of patients, and patient reminder letters. Disliked aspects of the tool included too many steps to get to or find certain pages and the “check and submit” feature associated with data entry. These results helped shape the design of the new intervention module that was implemented in the intervention group of physicians’ offices. This process informed three changes that were deemed required to be made to P-PROMPT CDMS to enhance utilization and functionality related to smoking cessation counselling. Two of the changes were made to the Smoking Cessation Management Module and one was made to P-PROMPT CDMS itself through the incorporation of the physician cues for delivery of smoking cessation counselling.

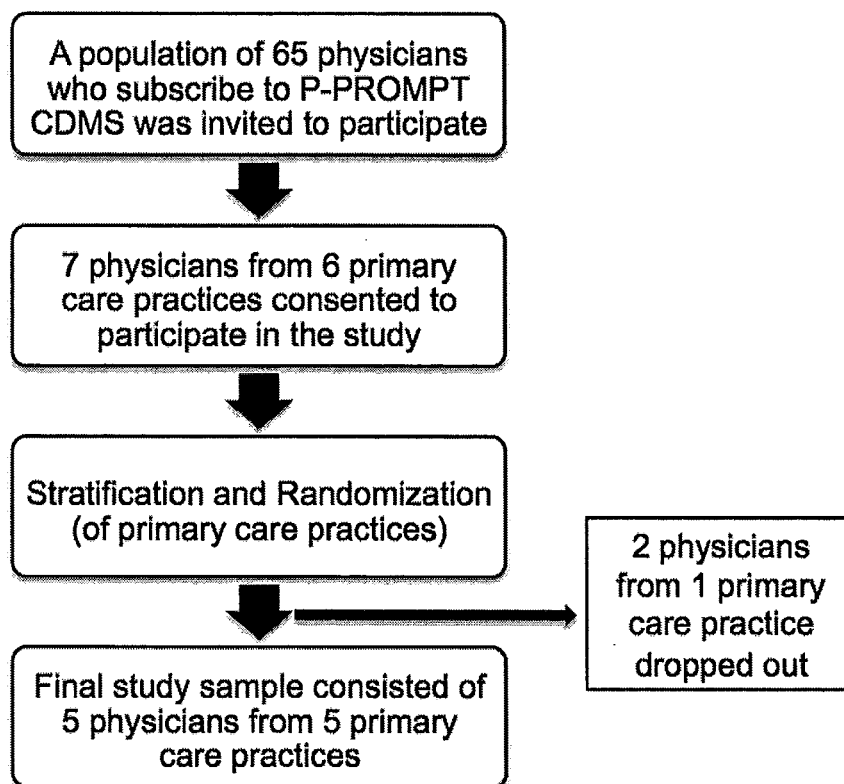
8.2. Study Outcomes

During a 6 week period starting in November 2009, 6 eligible primary care practices with a total of 7 primary care physicians were recruited into the pilot study. Figure 3 presents the consort statement (flowchart) for physician recruitment. Of the 65 eligible primary care physicians who were P-PROMPT CDMS subscribers, 10 physicians expressed interest in participation but only 7 were able to commit by the study’s recruitment deadline. The six primary care

practices that consented to participate in the pilot trial were randomized into two strata such that there were three practices in each stratum. Following randomization, one primary care practice with two consenting physicians dropped out of the study due to an unforeseen loss in staff and heavy workload. As a result of the odd number in each stratum, a perfect balance could not be obtained. The final five participating primary care practices were located in Hamilton (2 practices), Windsor and 2 rural towns, all in Ontario.

The physicians who participated in the study were on average 50 years of age (range 41 to 69). Two were female while three were male. One physician had received their medical training abroad while four were trained in Canada, including three trained in Ontario. The physicians were in practice for an average of 23 years (range 12 to 44). Four of the physicians reported never being a smoker, while one was a previous smoker.

Figure 3: Physician recruitment flow chart



The physicians' roster sizes ranged from 680 to 2,076 patients (mean 1,455). Two physicians had a solo practice, while three were part of a family health team (FHT). Of those who worked as part of an FHT, the average number of physicians per FHT was five. These FHTs averaged about 9 support staff that included administrative assistants, registered nurses and nurse practitioners. The two solo practices averaged about 2 support staff who were administrative assistants. Table 4 presents a profile of each participating physician and primary care practice.

Table 4: Participating physicians' and primary care practices' characteristics

Physician (P)	Sex	Age	Smoking status	Location of medical training	Years in practice	Roster size	Type of practice	# of P's	# of RN's	# of NP's	# of admin	P-PROMPT subscriber since
Intervention Group												
P1	M	48	Never smoker	Ontario	23	2,076	FHT	5	4	0	6	July 2007
P2	F	47	Never smoker	British Columbia	22	920	FHT	4	0	3	4	October 2009
Control Group												
P3	M	41	Never smoker	Ontario	13	1,450	FHT	7	5	2	3	November 2008
P4	M	69	Previous smoker	United Kingdom	44	2,150	Solo practice	1	0	0	3	September 2004
P5	F	45	Never smoker	Ontario	12	680	Solo practice	1	0	0	1	May 2008

8.2.1. Baseline Use of the Smoking Cessation Management Module

The P-PROMPT CDMS activity log for the smoking disease registry was queried for each participating primary care physician. Data regarding module use from February 1st to April 30th, 2009, was also collected to compare with results collected from February 1st to April 30th, 2010, the active intervention study period. The query looked for the number of times the physician's patients experienced an activity or event (registration, de-registration, change to smoking information field) in the regular, already existing smoking cessation management module (Table 5). For the purpose of stratification, total events in the smoking cessation management module up to January 22nd, 2010, were used to place each primary care practice in either the high or low module use stratum.

Table 5: Baseline use of the original smoking cessation management module

	Patients <i>manually</i> registered in smoking registry Feb.1-Apr.30, 2009	Smoking related information field changes Feb.1-Apr.30, 2009	Total patients registered in smoking registry up to Jan. 2010	Total events in smoking cessation management module up to Jan. 2010 (used for stratification)
Intervention Group				
Physician 1	29	31 (all billings)	162 (all manual)	362
Physician 2	0	0	14 (all import)	48
Physician 6 (dropped out)	10	1	4 (all manual)	6
Physician 7 (dropped out)	0	0	1 (manual)	2
Control Group				
Physician 3	0	0	6 (1 import/ 5 manual)	9
Physician 4	1	1	4 (1 import/ 3 manual)	6
Physician 5	0	30 (all billings)	46 (all import)	77

8.2.2. Pre-Study Questionnaire

The pre-study questionnaire investigated the physicians' frequency of delivery of smoking cessation counselling, subsequent billing patterns, and perceived barriers to delivery. The pre-study questionnaire was completed by two of the physicians during the site visit and by the remaining three after site activation but before the intervention was introduced. It was either faxed or mailed to the P-PROMPT CDMS office in Hamilton.

The questionnaire demonstrated that none of the participating physicians had a formal, pro-active smoking cessation treatment program established in their practice. Further, it revealed considerable variation in the physicians' baseline frequency of delivery of smoking cessation counselling and associated billings. Table 6 presents each physician's responses to this questionnaire.

Table 6: Summary of Pre-Study Questionnaire Responses by Physicians (P1 to P5)

Questionnaire Items	INTERVENTION Group		CONTROL Group		
	P1	P2	P3	P4	P5
How often do you ask patients about their smoking status?	30% of visits	95% “of patients whose smoking status I don’t know”	5% – 10% of visits	75% of visits	85% of visits
How often do you provide complete smoking cessation treatment according to the 5A’s?	50% of applicable times	60% of applicable times	2.5% of applicable times	25% of applicable times	85% of applicable times
What do you consider a barrier(s) to providing smoking cessation counselling?	“Time to deal with in busy practice”	“Time and patients’ attitude – oh no, the doctor’s naggin me again”	“Patient is not at stage to welcome treatment”	“None”	“Billing restricted to dedicated session; patients often reluctant to return must catch them when present for a health concern”

Table 6 continued: Summary of Pre-Study Questionnaire Responses by Physicians (P1 to P5)

Questionnaire Items	INTERVENTION Group		CONTROL Group		
	P1	P2	P3	P4	P5
How often do you bill for the smoking cessation counselling you provide?	75%	80%	0%	10%	100% of E079 10% of K039/Q042 because usually provide service as part of visit for other health concern therefore provide service but can't bill for
Do you have a smoking cessation program in place?	"No"	No	"No formal program"	"Just about"	No
What resources do you feel you need in order to provide consistent smoking cessation counselling?	Nurse practitioner	-	Computer stamp and assistance and funds	None	Flow sheet for follow-up even those resistant/refusing treatment so can track change in reasons/motivation

8.2.3. Utilization of the SSICs

During the 12 week study intervention period from February 1st to April 30th, 2010, a total of 4,718 patient visits of 2,906 individual patients occurred across the 5 practice sites (Table 7). To evaluate the use of SSICs in the primary care practices the outcome of interest was the percentage of unique individuals 15 years of age or older who complete a SSIC. The *a priori* threshold criterion to claim success was set at a 90% rate of completion. The completion of the SSICs varied widely among the physician practices, from as many as 865 (94.6% completion rate) in one primary care practice to as few as 37 (10.9% completion rate) in another (Table 7). A summation of each of the physicians' number of unique patients 15 years of age or older who were seen during the active study period shows the number of SSICs that potentially could have been completed. Taking the total number of SSICs actually completed during the study as a percentage of the number of SSICs that could have been completed reveals an overall SSIC completion rate across all practices of 58.6%.

The smoking status of the patients who completed a SSIC is outlined, by physician, in Table 8. Of the total SSICs distributed to patients for their completion, 92.7% were completed across all practices. Smoking prevalence was calculated as the percentage of patients who self-identified themselves as current smokers on the SSICs. The completed SSICs from all 5 participant physicians revealed an average smoking prevalence of 19.0% and individual prevalences as follows: Physician 1=27.3%; Physician 2=17.6%; Physician

3=20.5%; Physician 4=18.9%; Physician 5=10.8%. Among the two primary care practices with the highest SSIC completion percentages, the average smoking prevalence was 23.1%. As well, the prevalence of previous smokers was calculated across all practices to be about 31.1% of all patients who completed a SSIC. Finally, the burden of the chronic disease of tobacco use in each primary care practice was determined by calculating the percentage of completed SSICs that were the sum of current and previous smokers. In each primary care practice, this burden of disease presented as follows: Physician 1=57.8%; Physician 2=51.8%; Physician 3=60.3%; Physician 4=48.1%; Physician 5=43.2%. Across all practices this burden of disease was reflected in 54.5% of all patients who completed a SSIC.

Table 7: SSIC completion and patient attendance over the 3-month active study period

	Patient Visits (N)	Unique individuals	Unique patients 15+ (P)	SSICs completed (S)	Percentage completed* (S)x100/(P)
Intervention Group					
Physician 1	1,899	1,011	914	865	94.6%
Physician 2	575	353	325	170	52.3%
Control Group					
Physician 3	1,068	673	609	78	12.8%
Physician 4	560	471	416	376	90.4%
Physician 5	679	398	341	37	10.9%
TOTALS	4,781	2,906	2,605	1,526	

**a priori* threshold criterion = 90% SSIC completion

Table 8: Summary of data collected from SSICs

	Current Smokers	Previous Smokers	Never Smokers	Total SSICs Completed	Missing SSICs	Total SSICs Disseminated	Completed SSICs of those disseminated (%)
Intervention Group							
Physician 1	236 (27.3%)	264	365	865 (94.6%)	45	910	95.1%
Physician 2	30 (17.6%)	58	82	170 (52.3%)	30	200	85.0%
Control Group							
Physician 3	16 (20.5%)	31	31	78 (12.8%)	22	100	78%
Physician 4	71 (18.9%)	110	195	376 (90.4%)	23	399	94.2%
Physician 5	4 (10.8%)	12	21	37 (10.9%)	0	37	100%
TOTALS	357	475	694	1,526	99	1,646	

8.2.4. P-PROMPT CDMS Access and Utilization

The use of P-PROMPT CDMS to help in the delivery of smoking cessation counselling was determined by considering each primary care office's access to the smoking cessation management module in P-PROMPT CDMS. Access was considered and quantified on two levels: (a) patient registration into the smoking status registry of the smoking cessation management module, and (b) changes and additions to any of the smoking-related data fields on the patient tab of P-PROMPT CDMS. Either the physician or the staff at the primary care practice could potentially access the system, as long as a password had been assigned to the individual. The activity and audit logs produced by P-PROMPT CDMS allowed for the history of data changes in the system to be tracked and the individual who made each change to be identified by user name at log-in. The amount of different types of activity of the physicians and their respective staff at each site is presented in Table 9.

To evaluate the use of the smoking cessation management module, the primary outcome of interest was the percentage of unique individuals 15 years of age or older who were registered into the module. The *a priori* threshold criterion to claim success was set at 30%. Results in Table 9 show that the outcome of interest occurred at percentages consistently below the threshold criterion, with the two highest values observed in the intervention group physicians at 21.9% and 19.0% of patients registered.

Although each primary care practice in the intervention group was instructed to input the smoking status of all patients (current smokers, previous smokers and never smokers), Table 8 shows that the registration probability of patients differed among current smokers, previous smokers and never smokers. The vast majority of registrations into the smoking registry of Physician 1 were those of smokers, while Physician 2 registered patients' smoking status with less bias.

The existing smoking cessation management module that control group physicians were exposed to only allowed registrations of smokers, which is why the minimal patient registrations, if at all, observed in the control group were only of smokers. A comparison of "current smoker" patients registered in the smoking cessation management module reveals that the majority of the activity is associated with the intervention group. Of the total current smokers identified by the SSICs, the intervention group entered 84.7% (Physician 1) and 86.7% (Physician 2). In the control group, the primary care practice of Physician 3 did not register any patients into the smoking registry, while Physician 4 and Physician 5 registered 18.0% (13 smokers of the 71 identified) and 25% (1 smoker of the 4 identified), respectively.

Table 9: Registrations and changes to smoking information fields over the 3-month active study period

	(R)	(S)	(D)	(P)	Percentage basic module use* (R)x100/(P)	Percentage advanced module use* (D)x100/(S)
Intervention Group						
Physician 1	200	193	184	914	21.9%	95.3%
Physician 2	63	26	0	325	19.0%	0
Control Group						
Physician 3	0	0	0	609	0	0
Physician 4	13	13	1	416	3.1%	7.7%
Physician 5	1	1	0	341	0.30%	0
TOTALS	277	233	185	2,605		

**a priori* threshold criterion = 30% use of smoking cessation management module

R = Patients registered in the smoking cessation management module

S = Smokers registered in the smoking cessation management module

D = Patients whose smoking related data was added/changed

P = Unique patients 15 years of age or older

To further evaluate the use of the smoking cessation management module, a second outcome of interest was considered, which was the percentage of smokers registered in the smoking cessation management module who had smoking-related information added or changed during the study. The same *a priori* threshold criterion of 30% was applied to this outcome but was considered separate from the above outcome. Table 9 shows that only Physician 1 reached and greatly surpassed this threshold criterion with 95% advanced module use.

The primary care practices' global use of P-PROMPT CDMS was also evaluated by considering physician and staff log-ins and viewings of audit-and-feedback displays. A summary of this data is provided in Table 10 and illustrates that P-PROMPT CDMS use varied greatly across the participating primary care practices. The proportion of total log-ins by physicians 1 through 5 at each site was 44.4%, 0, 0, 0, and 100%, while the proportion of log-ins by their staff was 55.5%, 100%, 100%, 100%, and 0, respectively.

Table 10: Physician and staff use of P-PROMPT CDMS over the 3-month active study period

	# of P-PROMPT passwords assigned	Physician log-ins	Staff log-ins	Audit-and-feedback viewings
Intervention Group				
Physician 1	2	40	50	3
Physician 2	13	0	74	12
Control Group				
Physician 3	26	0	80	0
Physician 4	2	0	49	0
Physician 5	1	109	0	1

Three of the physicians did not log-in to P-PROMPT CDMS at any time during the study, while their staff logged in from 49 to 74 times over the twelve week period. To further gauge use of P-PROMPT CDMS, information about how many individuals in each primary care practice have passwords was examined. The number of assigned passwords ranged from 1 to 26. In each case, one of the passwords belonged to the physician and the rest belonged to staff. Physicians 2 and 3 belonged to larger FHTs that had more than one physician subscribed to P-PROMPT CDMS. The number of passwords assigned reflects the number of passwords at the particular site (primary care practice) and includes all physicians and staff. Thus, the 13 and 26 passwords cited in the case of Physicians 2 and 3 respectively are not representative of the individuals

who have contact with the participating physician's patients and who could potentially log-in to alter or add information to any of the participating physician's rostered patients. A review of the activity logs to determine the number of staff who logged in during the study shows the following diversity: 1 staff member for Physician 1 logged in 50 times; 6 staff members for Physician 2 logged in 3, 1, 9, 1, 57 or 3 times; 3 staff members for Physician 3 logged in 72, 1 or 7 times; 1 staff member for Physician 4 logged in 49 times. Data about the number of times the audit-and-feedback page of the smoking cessation management module was viewed by the primary care practices is also presented in Table 10.

8.2.5. Delivery of Smoking Cessation Counselling

To conduct a preliminary evaluation of the smoking cessation counselling events delivered by each primary care physician, the outcome of interest was the percentage of smokers who received smoking cessation counselling as indicated by the appropriate physician service billing codes. Since this pilot study was not powered to detect any significant difference, no threshold criterion to claim success was set. All physician billing codes submitted for providing smoking cessation counselling were for unique patients, which means the physician did not provide smoking cessation counselling more than once to any of the patients over the three month active study duration. As Table 11 shows, the percentage of counselling events counted from this data ranged from 0% to 67%. Adjusted percentages were also calculated to account for the different SSIC completion

rates observed in each primary care practice. This adjustment divided the number of identified smokers by the percentage of completed SSICs to determine the total number of smokers that may have presented and assumes that the portion of the patient population that did not fill out a SSIC had as many smokers as were observed in the portion that did complete a SSIC. The adjustment shows that higher smoking cessation counselling rates were clearly observed among the physicians in the intervention group, as seen in Table 11.

The pre-study questionnaire collected physicians' self-reported percentage of billing for smoking cessation counselling delivery. Taking these percentages to adjust the observed values increases the number of potential billings that indicate counselling events. In turn, this increases the percentage of counselling events by Physicians 1, 2 and 4, who indicated less than 100% billing. The adjusted percentages of counselling events for these physicians are 22%, 44% and 9%, respectively.

Table 11: Rates of delivery of smoking cessation counselling over 3-month active study period

	E079A billings	K039A/ Q042A billings	Total billings (C)	Smokers (as identified by SSICs) (X)	Smokers (adjusted by SSIC completion %)	Percentage counselling events (C)x100/(X)	Adjusted percentage counselling events
Intervention Group							
Physician 1	37	5	42	236	249	18%	17%
Physician 2	18	2	20	30	57	67%	35%
Control Group							
Physician 3	0	0	0	16	125	0	0
Physician 4	5	0	5	71	79	7%	6%
Physician 5	1	0	1	4	37	25%	3%

8.2.6. Post-Study Informal Staff Interviews

During the site wrap-up visits, the staff who participated in the study by either handing out and collecting the SSICs or inputting data were briefly asked about their experience with the study. All staff felt the process was unintrusive and did not impede their work flow. They were asked to describe how they implemented the study procedures to confirm adherence to the protocol. While the offices of Physicians 1 and 4 reported executing procedures as described in the protocol, three of the offices did not. Of these three, the offices of Physicians 3 and 5 reported placing the secure box where the SSICs were to be stored on a table amongst magazines in the waiting room of the primary care practice. The office of Physician 2 placed the box in the office of the registered nurse, who generally acts as a triage nurse in the FHT. She handed out and collected the SSICs from applicable patients. In the two primary care offices that had the secure box placed in the waiting room, the staff member would hand-out the SSICs, however, their collection relied on the patient's adherence to the instructions to place it in the box, as opposed to returning it to the administrative assistant. Three of the four primary care practices that had missing SSICs reported that this was mainly due to a tendency of patients to use them to write on or take note of something. One primary care practice could not explain what may have happened to the SSICs that were missing from their collection. When asked, none of the staff had recommendations for improving the process of SSIC collection as they felt it was already concordant with the practice's activities. With

regard to data input, the staff of Physician 2's office acknowledged the difficulty of consistently inputting data as it is received from the patients due to time constraints, since that particular staff member was responsible for the patients of more than one doctor in the primary care office. However, both practices in the intervention group felt that the improvements to P-PROMPT CDMS in the new enhanced smoking cessation management module greatly increased workflow efficiency. In particular, they stated that the changes to the module greatly increased their ability to update the patient's smoking status, which was nearly impossible with the previous smoking cessation module.

8.2.7. Post-Study Physician Questionnaire

This questionnaire collected information about characteristics of both the physician and primary care practice (Table 4). It also considered the physician's opinions about using P-PROMPT CDMS to help deliver smoking cessation counselling and what, if anything, may limit their use of it. In alignment with data obtained from the access logs, none of the physicians reported frequent or consistent use of P-PROMPT CDMS to help deliver smoking cessation counselling. Explanations for this underuse included use of paper tracking forms, better familiarity with the electronic medical records that they use, lack of time, and lack of access due to lack of a computer in the patient examination room. Physicians 1 and 5 reported using P-PROMPT CDMS and stated that they liked

the audit-and feedback feature of the system and the ability to deliver better patient care by using P-PROMPT CDMS.

9.0 Discussion

This pilot study was developed to assess the feasibility of conducting a larger clinical study, and therefore all effort was made to replicate the design of the future trial as closely as possible. Three primary objectives were examined to assess the feasibility of conducting a larger cluster randomized controlled trial in primary care practices. The motivation for choosing the specific set of objectives were the thoughts that (a) the SSICs would help primary care physicians collect the smoking status of the majority of their patients who presented at the practice during the study, (b) the new smoking cessation management module in P-PROMPT CDMS would be used more often than currently by members of the primary care practice, and (c) the use of the multi-faceted intervention would lead to increased delivery of smoking cessation counselling by primary care physicians.

The first goal of this pilot study was to evaluate the use of the SSICs as a means of prospectively and progressively ascertaining and documenting patient smoking status in order to create the Smoking Registry from each physician's rostered patients. The completion of the SSICs reached and surpassed the *a priori* threshold success criterion of 90% completion in 2 of the 5 primary care practices: in one solo practice and one FHT. Notably, these two practices also had the largest patient rosters, which may be an indication that practices with larger rosters may inherently be more experienced in, or naturally inclined towards, implementing protocols systematically. The FHT that had the highest

SSIC completion rate only had 2 support staff, while the solo practice that had the second highest SSIC completion rate had 3 support staff. Two of the offices with low SSIC completion rates (Physicians 2 and 3), however, had the most support staff working with the patients of these physicians (7 and 10 support staff, respectively), while Physician 5 had 1 support staff. These data may indicate that more staff are not required to successfully implement this method. The success in the use of SSICs in 2 primary care practices demonstrates that their distribution and collection can be feasible in a primary care practice setting. However, the SSIC completion percentages of 52%, 13% and 11% in the other three primary care practices indicate that either the method itself or the implementation of the method should be modified if it is to be used in a future trial.

Two measures of successful SSIC completion in a primary care office are (a) whether the patients completed and returned their SSICs; and (b) whether the practices were able to distribute and collect back the completed SSICs. The overall completion of SSICs by patients reached 92.7% of all SSICs disseminated across the 5 primary care practices. In the primary care offices of Physicians 1 and 4, where 99.6% and 95.9% of eligible patients were given a SSIC by staff, SSIC completion by patients reached 95.1% and 94.2%, respectively. The data also shows that the primary care offices of Physicians 2, 3 and 5 only disseminated the SSICs to 61.5%, 16.4% and 10.9% of eligible patients. Thus, the three primary care offices that did not reach the threshold criterion of success

either stopped or did not consistently hand out the SSICs to patients for completion. Accordingly, it can be concluded that the low SSIC completion percentages calculated for the first feasibility objective were a result of the incomplete or inconsistent implementation of the protocol procedure. Qualitative data collected in the form of informal interviews with staff at each primary care office demonstrated that the staff did not consider the process of handing out and collecting the SSICs burdensome. Indeed, the two primary care practices where high staff compliance was observed demonstrate that the process can be implemented and managed. These two practices were able to follow protocol procedures by placing the secure box near the administrative assistant and asking patients to return the SSICs to the administrative assistant. Among the primary care practices with low completion rates, two (Physicians 3 and 5) deviated from protocol procedures by placing the secure box away from the administrative assistant in the patient waiting room. It is possible that since the secure box was not near the administrative assistant, he/she could have forgotten to hand out the SSICs. The primary care practice of Physician 2 elected to place the box and SSICs in the office of the nurses that complete a preliminary assessment of the patients for a number of physicians in the FHT. These nurses generally have heavy workloads and the process of disseminating and collecting the completed SSICs from every patient rostered to the one participating physician may have been too onerous in this setting. Physician 3 also shared staff with other non-participating physicians in the FHT. The administrative

assistants at this site rotated and served the patients of 3 other physicians' rosters. Perhaps the inconsistent distribution of SSICs that occurred in these practices was a result of not consistently informing, educating or encouraging each staff member about the study and its procedures. Also, it seems that the observed non-compliance may be because the stipulated protocol procedures were less conducive to integration with existing workflows in the three primary care offices that did not reach the threshold criterion for SSIC completion.

It appears, then, that adherence to protocol procedures was associated with greater rates of SSIC completion. The stipulated protocol procedure was slightly different for practices in the intervention group than for those in the control group, in that the intervention group was asked to input a minimal amount of the information on the SSICs into P-PROMPT CDMS to create the Smoking Registry as one component of the multi-faceted intervention tested in this pilot study. Since this difference in protocol procedures was part of the multi-faceted intervention under study, it was not a co-intervention. SSIC data entry into P-PROMPT CDMS was not stipulated to be done in the control group protocol because doing so would have deviated from standard, control conditions. Nevertheless, this difference in protocols between the groups, by failing to control for data entry, prevents drawing a complete comparison on ease of use between the new and standard smoking cessation management modules. To resolve this problem, a future study might also ask the primary care practices in the control group to input the data into their regular smoking cessation management module

in P-PROMPT CDMS. The data could be stored, but unavailable, in P-PROMPT CDMS until the end of the study, at which point the information entered could be imported into the Smoking Registry of the physicians in the control group. This difference in procedures between the control and intervention groups may also have had an effect on compliance with the distribution of SSICs to patients. In an attempt to mitigate the effects of the protocol difference, the Principal Investigator agreed to input the data collected from the SSICs in the control group into the Smoking Registry of physicians' P-PROMPT CDMS after completion of the study. Although the provision of this information is ultimately potentially helpful to the control group practices, it still provides the intervention group with immediate access to the “reward” of SSIC completion, which may incline those practices to better comply with the procedure than those in the control group, whose “reward” from the SSICs would be delayed until a later time.

Among the two primary care practices with the highest SSIC completion percentages, the average smoking prevalence was 23.1%. Although higher than the Ontario provincial smoking prevalence of 20%, according to a 2007/2008 Canadian Community Health Survey, this prevalence is similar to the 23% smoking prevalence in the City of Hamilton,⁶⁸ where these two practices are located. It should be noted that the survey considered individuals 12 years of age or older, while the SSICs in this pilot study were collected from patients 15 years of age or older. This observed prevalence suggests that SSICs are a

potentially useful method for determining the smoking status of patients who present at a primary care practice and who complete and return the SSICs.

The SSICs provide an advantage that is currently unavailable in the traditional form of smoking status identification by primary care practice staff or physicians. Whenever providers or staff are unable to identify the smoking status of the patient during the patient's visit, smoking status information would remain unknown until, at the earliest, the next time he/she presents at the primary care office. This study piloted SSICs that require each patient to personally fill out a card regarding his/her smoking status. Although ideally a staff member would have entered the data into P-PROMPT CDMS during the patient visit, this form of smoking status identification gave the primary care office the added flexibility to input smoking status data at a more convenient time for future use. This feature of the smoking status identification system was used in the pilot study because, even if the practice was unable to input the data into P-PROMPT CDMS, the critical information of smoking status was still collected for the purposes of the study, making available the number of smokers who presented to the practice. In the long-term, this tool would capture the smoking status of a physician's entire roster and the dataset would be complete. This feature of the SSICs, as well as the high SSIC completion rate in two of the primary care offices and the accurate regional smoking prevalence that they yielded, lead to the conclusion that this method of collecting patient smoking status can be adopted in a future study.

The second objective of this pilot trial was to evaluate the percentage of use of the smoking cessation management module in P-PROMPT CDMS. This was assessed at two levels, namely: (a) basic data entry and (b) advanced module use. As part of the protocol, primary care practices in the intervention group were asked to input the smoking status collected on the SSICs into the improved smoking cessation management module. Successful input of smoking status data into the module was considered “minimal or basic module access” and is reflected in the results of 21.9% and 19.0% for the basic module access in the 2 physicians in the intervention group, compared to only 0% to 3.1% in the 3 control group physicians. The utilization patterns by the two physicians in the intervention group show that the primary care practice of Physician 1 elected to enter only the smoking status of current smokers into the smoking cessation management module (except for 7 “previous smoker”s), while the practice of Physician 2 averaged about 3 patient registrations per day (regardless of smoking status), on the days it elected to input data. The intent in the study was to enter the smoking status (never smoker, previous smoker, current smoker) of every patient who completes a SSIC into P-PROMPT CDMS. The intervention group percentages did not reach the *a priori* threshold criterion for the second objective, however they are higher than the observed basic data entry percentages 0%, 0.3% and 3.1% in the control group. Since the control group was not asked to enter data from the SSICs into P-PROMPT CDMS, these low percentages in the control group indicate that the physicians infrequently use the

current, regular smoking cessation management module in their daily practice. This difference in basic module use is also due to the control group's ability to only register "current smoker" patients using the existing smoking cessation management module. Thus, a more relevant comparison is of "current smoker" registrations in the intervention group versus the control group. Of the total current smokers identified by the SSICs, the intervention group entered 84.7% (Physician 1) and 86.7% (Physician 2). In the control group, the primary care practice of Physician 3 did not register any patients into the smoking registry, while Physician 4 and Physician 5 registered 18.0% (13 smokers of the 71 identified) and 25% (1 smoker of the 4 identified), respectively. Since the denominators of these calculations do not accurately represent the total number of smokers who presented at the primary care practice and are likely underestimates of the true values, these percentages over-estimate the true use of the modules for basic "current smoker" data entry. A comparison of the same 3 month time period (February 1st to April 30th) in the years 2009 and 2010 reveals that manual smoker registrations in each of the primary care practices generally increased (at least slightly) or remained constant (no use) in one case. From 0, 1, 0 and 29 registrations in 2009, Physicians 5, 4, 2 and 1 increased basic data entry to 1, 13, 26 and 193 smoker registrations, respectively, in 2010. However, due to the unavailability of the number of smokers who presented during this time period in the year 2009 (denominator), an accurate comparison cannot be drawn. Qualitative data obtained through informal staff interviews

revealed that staff felt comfortable with the workload associated with protocol procedures and did not feel that they interfered with daily workflow. Perhaps the observed percentages of registered patients may be interpreted as the rate of access a primary care practice can engage in without disruption to or imposition on regular, daily office duties. It appears that a primary care practice may not be able to persistently access P-PROMPT CDMS on a daily, per-patient basis if doing so for the sole purpose of inputting or updating the smoking status for every individual who presents at the primary care practice, despite the more accessible manual input process piloted in this study.

In the primary care practices of Physicians 2 (intervention group), 3 and 5 (control group), there was no advanced use of the smoking cessation counselling module to record other smoking related information, while advanced use was about 8% in the practice of Physician 4 (control group) and 95.3% in the practice of Physician 1 (intervention group). The higher percentage of advanced use observed with Physician 1 is a result of his daily paper documentation and later data input by either himself or his staff member on a nearly equally shared basis. Physician 1's consistent documentation and data input about care provided to smokers builds a relatively complete patient smoking profile and allows for greater tracking of care goals and more physician prompts. This form of activity may well be of great value to this physician's management of his smoking cessation counselling on a practice level. On the other hand, it does not include the aspect of in-practice daily use to manage patient care for smoking cessation.

It appears that none of the physicians incorporated the use of P-PROMPT CDMS into their daily practice at the point and time of care. The primary utilization of P-PROMPT CDMS system was by allied health professionals and staff at the primary care practices, which indicates that measuring only the physician's utilization behaviour as a part of the study is not sufficient to examine the overall actual or potential use of P-PROMPT CDMS in a primary care practice. In the current pilot study that primarily considered physician delivery of smoking cessation counselling, it is concluded that utilization of the smoking cessation management module was low and did not reach the threshold criterion of 30% by any of the participating practices.

The third goal of this pilot trial was to perform a preliminary evaluation of the smoking cessation counselling that occurred during the study. After adjusting for the different rates of SSIC completion, the greatest rates of smoking cessation counselling were observed among the intervention group physicians (17% and 35% assuming that the portion of the patient population that did not fill out a SSIC had as many smokers as were observed in the portion that did complete a SSIC). These rates were achieved despite the potentially heavy burden of tobacco use in these primary care practices, as estimated by the SSIC data of the 57.8% and 51.8%, respectively, of presenting patients who completed a SSIC in these practices. These counselling rates were higher among physicians who demonstrated greater use of the smoking cessation management module. However, baseline data about smoking cessation counselling was not collected,

which prevents accurate interpretation of this data. This informal observation must be interpreted with much caution as it is not validated by tests of statistical significance, nor was the pilot study powered to detect such a difference. As well, the number of practice days of each physician during the study period was not collected adding uncertainty to estimates of the daily patient load that each physician experienced and preventing precise discussion of how feasible the provision of smoking cessation counselling to every eligible patient who presented would have been. A future trial should collect each physician's number of practice days during the active study period and should also incorporate a baseline period to measure the rate of delivery of smoking cessation counselling and the total number of smokers who present over the same period.

Physician service billing codes were used to represent and measure the number of smoking cessation counselling events that occurred. For research purposes, the use of each physician's electronic billing information to determine the smoking cessation counselling events in each primary care practice is practical and minimally intrusive to the physician. However, electronic billing information does not seem to be a true representation of smoking cessation counselling events delivered by a primary care physician and other members of their team, for the following reasons. During the study's baseline data collection, each physician was provided with a one-page sheet to facilitate documentation of the counselling they provide for smoking cessation. Although the physicians

verbally indicated they had counselled on a few occasions, the page remained nearly empty in almost all cases. Later, physicians verified this observation with their responses to the pre-study questionnaire item that asked them what percentage of smoking cessation counselling they bill for. It became clear that physicians would not regularly bill for or report much of the smoking cessation counselling they provide. One explanation for this discrepancy is found in a comment made by one of the participating physicians who indicated the “nickel and dime” billing incentives that are in place “are not worth the hassle”. Another explanation might be that other allied health professionals within a FHT may be providing the smoking cessation counselling. When these other primary health care professionals provide smoking cessation counseling, the service cannot be compensated by the billing codes used by physicians, since the codes only apply to physicians who provide the counselling. Tracking smoking cessation counselling using only physician billing information in a future study will not represent the complete activities of the FHT because allied health professionals working in a FHT are generally compensated by a salary or sessional funding and, unlike physicians, are not eligible for chronic disease management and prevention incentives. Thus, in a future study, an alternative method, such as a patient exit survey, could be used to determine how many eligible patients received smoking cessation counselling and by which health care professional.

This identified discrepancy between counselling events and billing information will, if uncorrected, result in an underestimate of the care provided.

The underbilling could also have affected the development of the patient smoking registry in the intervention group since billing codes were used to help identify a group of potential smokers. However, this shortcoming in the use of billing files was somewhat compensated for by using an additional electronic algorithm which identified an age bracket with epidemiologically one of the highest average smoking prevalence as potential smokers. Along with the patients who were previously billed for smoking cessation counselling, these patients received a patient letter to prompt them to visit the physician to talk about their smoking.

Beyond the evaluation of the objectives of this pilot study, observations of importance to the feasibility of the larger trial have also been obtained on the subject of physician recruitment. Of 65 physicians who were invited to participate in the study, 20 expressed interest to participate at a later date, 10 expressed interest to participate in the current pilot trial, but only 7 physicians actually enrolled by the time of the recruitment deadline, and two of these later dropped out. The major barrier to enrolling to participate in the study cited by most physicians was a lack of time to participate. This was despite the minimal added activities stipulated in the study protocol. A potential contributing factor to this low rate of recruitment was that the letter of invitation was sent out during the seasonal influenza vaccination period. Moreover, unlike in other years, vaccines for both H1N1 (swine) influenza and regular seasonal influenza were being provided by primary care physicians, which increased workload to an unusual degree. In this context, physicians may have been less inclined to commit to a

study protocol. Although the study itself was to begin in February, 2010, once the vaccination period was over, physicians expressed a need for a break. Thus, study recruitment may be more readily feasible during a “slower” season.

It is informative to examine the primary findings of this pilot trial in relation to prior research reported in the literature. While the use of SSICs showed promise in this study, SSICs failed to meet the threshold criterion to claim their success and to confidently justify their use as a measurement tool in the larger trial. Yet two practices where implementation was done as described in the protocol demonstrated that this method for the identification of patient smoking status can collect the smoking status of at least 90% of patients who present and therefore can be workable. Previous studies that have implemented smoker identification systems in clinical practice have relied on the provider or a staff member to document a patient’s smoking status information.^{48,51,118,145} In a prospective before-after study, Fiore and colleagues assessed the effect of expanding the vital signs to include smoking status. The intervention involved adding smoking status to the staff’s regularly used progress notepaper and increased smoking status identification to 81% from 58% at baseline. Robinson and colleagues evaluated the effect of including smoking status as a vital sign on the frequency of physician discussions with patients about smoking and physician advice to quit. In their prospective before-after trial set in a metropolitan ambulatory family practice residency program, members of the nursing staff asked patients about their smoking status each time they took vital signs and

recorded it on the vital sign stamp of the patient's chart (by circling the appropriate smoking status). This procedure increased identification of smoking status to 86% from 47% at baseline. Ahluwalia and colleagues also evaluated the effect of including smoking status as a vital sign to see if it would increase physician delivery of the 5A's for smoking cessation treatment. During the intervention period of this post-test only assessment, a research assistant imprinted a "smoking status stamp" on each chart before the patient saw the physician. The physician received brief instructions to circle one of the three options that correctly identified each patient's smoking status and to intervene accordingly, which resulted in 78.4% of patients' smoking status identification compared to 45.6% of patients during the control period. Fisher and colleagues investigated a multi-faceted intervention that involved a number of system changes, one of which included documenting smoking status on a routinely used "patient encounter form" that also routinely documents physician service billing codes. Although smoking status previously existed on this form, as part of the system change, forms that did not identify the patient's smoking status were returned to the appropriate physician for completion. This change resulted in an increase from 2% smoking status identification at baseline to 94.3% during the last 3 months of the two-year program. Thus, physician compliance with patient smoking status identification was, in a sense, routinely insisted upon. While the 94.3% identification percentage is successful, it took over a year to attain that percentage and the patient smoking status indicated may be subject to physician

recall bias to varying degrees, in the case that the form is sent back for completion. While all of these studies saw statistically significant increases in smoking status identification, only one of them surpassed 90% documentation of patient smoking status. These successful smoking status identification systems all involved the patient chart. None of them used the approach of patient reporting through SSICs as used in the present study. Patient completion of a SSIC is a form of smoking status self-report. Generally, self reports of smoking may be in the form of in-person interviews with subjects, which have been found to be the most accurate, or in the form of a self-report questionnaire.¹⁴⁶ This self-report measurement tool was developed and adopted in this study because it is less invasive, time-consuming and expensive than the use of imperfect biochemical markers.¹⁴⁶ Mixed evidence exists in specific populations such as youth and individuals with smoking-related diseases who may have a greater tendency to underreport current smoking.¹⁴⁷⁻¹⁵² However, a review and meta-analysis of studies that validated self-reported smoking with biochemical measures demonstrated that in the general population self-reports of smoking are reasonably accurate.¹⁴⁶ In this meta-analysis of 26 published reports that included 51 comparisons between self-reported behavior and biochemical measures, the sensitivity of self-report was 87% while the specificity was 89%.¹⁴⁶ Thus, the use of the self-report smoking status identification system used in this pilot study amongst a general population of patients rostered to a primary care

physician is an interesting advance that could be acceptable for use in a future study.

The pilot study results demonstrated that the smoking cessation management module and even P-PROMPT CDMS itself was used infrequently or not at all by physicians and staff in the primary care practices. This is in-line with prior studies that have demonstrated the implementation of information technology in a medical setting can be challenging.¹⁵³ Leatt and colleagues conducted a literature review that aimed to determine the organizational factors that facilitate or inhibit successful implementation of information systems and technology in healthcare organizations.¹⁵⁴ Their review found that management support, financial resource availability, implementation climate and implementation policies and practices were key elements to the implementation of various medical information technology. As well, health care providers have identified a number of barriers to and facilitators of the adoption of technology in a medical setting.¹⁵⁵ Barriers include time, training required and computer literacy, while an in-house problem solver has been identified as a facilitator of medical informatics adoption.¹⁵⁵ Although this pilot trial did not have the resources to implement the full spectrum of implementation strategies identified in prior research, it did include in-person training visits to physicians in the intervention group, who were oriented to the new smoking cessation management module, and physicians in the control group who were oriented to the existing smoking cessation management module. Although the physicians in

this pilot trial were current, out-of-pocket subscribers to P-PROMPT CDMS who presumably would have already adopted a change of practice that integrated P-PROMPT CDMS into their daily practice, the study demonstrated that the adoption was inconsistent with respect to its smoking cessation counselling module.

Smoking cessation counselling events delivered by physicians during the present study were below the physician's self-reported delivery of smoking cessation counselling. The tendency to overestimate health care delivery has been documented in past studies^{38,72} that compared physician self-reports of counselling events to patient self-reports of counselling received. It is believed that physicians tend to overestimate the care that they provide, while patients tend to underestimate the care that they receive.³⁸ Although not powered to detect treatment effect, a simple tabulation of results without statistical significance testing in the present study suggested that greater use of the smoking cessation management module may be associated with increased percentages of smoking cessation counselling. It is interesting to note that higher counselling percentages were not necessarily associated with greater adoption of the smoking status identification system used in this study. This finding may be supported by evidence provided by Boyle and Solberg and Piper and colleagues.^{40,113} Boyle and Solberg evaluated the impact of introducing routine use of smoking status as a vital sign on clinician cessation support in a primary care setting.¹¹² The results of a telephone administered 28-item questionnaire in

a cohort of smoking patients were compared before and after smoking status was used as a vital sign. Their study showed that patient self-report of receiving advice about smoking in the past year remained at about 66% even after implementation of smoking status as a vital sign.¹¹² Similarly, Piper and colleagues examined the ability of a simple system-wide screening assessment tool to increase physician advice to quit smoking and provide assistance.¹¹³ In this pretest-posttest designed study, 5 primary care clinics were randomly assigned to receive the intervention of a vital sign stamp for smoking status or the control condition. At each of the 5 clinics patients were surveyed using an exit interview before and after the vital sign intervention was introduced. Further follow-up about physician smoking cessation counselling delivery was conducted over the phone with smokers 1 year after their initial visit at the primary care practice during the study. Results of this study demonstrated that the implementation of the smoking status identification system did not increase physician delivery of smoking cessation counselling (rates stayed constant or decreased).¹¹³ These papers also concluded that, while a smoking status identification system is very important, it is not sufficient to increase provider delivery of evidence-based health care, rather, greater environmental changes are required.^{40,113} The present pilot study also seems to suggest that greater environmental changes are required to change provider behaviour.

Few studies have been published that specifically investigate the use of a clinical information system to affect physician delivery of smoking cessation

counselling. Fisher and colleagues investigated increasing smoking cessation services within federally qualified health centres in the U.S. by implementing systems changes that included documenting smoking status as a vital sign, an electronic information system, stage-based information system and print materials, training of provider teams, feedback to provider teams, reimbursement for medications and neighborhood resources and supports for smoking cessation.¹⁴⁵ However, this study took place in only two health centres and did not guard against contamination by clustering as the pilot trial presented above did. Although the study showed improvements in smoking cessation services and neighborhood support for smoking cessation, they were not consistent or statistically significant.¹⁴⁵ Their research investigated a multi-faceted intervention, similar in scope to that tested in this pilot trial, that suggested potential effectiveness. Fisher and colleagues used an exit survey to quantify smoking cessation counselling provided by the primary care physician, instead of the physician service billing codes used in this pilot trial. Despite the 24-month duration of their study, it was not rigorous enough to draw meaningful conclusions. More recently Linder and colleagues investigated the use of an electronic health record-based intervention to improve tobacco treatment in primary care.¹⁵⁶ This study specifically aimed to improve the documentation and treatment of smokers in primary care. They developed and implemented a 3-part electronic health record enhancement that included smoking status icons, tobacco treatment reminders, and a Tobacco Smart Form that facilitated the

ordering of medication and fax and e-mail counselling referrals. The study's results demonstrated that in the intervention group access to the electronic health record-based intervention increased the documentation of smoking status and increased the percentage of patients who made contact with a cessation counsellor (physicians were not obliged to provide the smoking cessation counselling).¹⁵⁶ Although not entirely comparable, preliminary results of the present pilot trial also demonstrate that increased use of a clinical information system is associated with increased smoking cessation counselling delivery.

Apart from the use of clinical information systems to manage tobacco dependence in patients, they have been widely applied in diabetes management at the primary care level. A Cochrane systematic review of interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings concluded that multi-faceted professional interventions can enhance health professionals' management of diabetes care.¹⁵⁷ As well, organizational interventions such as central computerized tracking systems showed improvement to diabetes management.¹⁵⁷ Weber and colleagues implemented a multi-faceted intervention and employed an electronic health record to improve compliance with recommended diabetes performance measures.¹⁵⁸ The multi-faceted intervention included an electronic registry with audit-and-feedback, computerized physician reminders and financial incentives. The study showed significant increases in all measures of diabetes care of the 12-month study period.¹⁵⁸

The present pilot trial tested the use of a clinical information system to increase the delivery of the chronic disease of tobacco dependence in primary care. The literature suggests that clinical information systems are an essential component of effective patient care management.^{108,159,160} Like part of the multifaceted intervention tested in this pilot trial, clinical information systems generally include disease registries and some form of an electronic medical record.¹⁶¹⁻¹⁶³ In a multilevel analysis of the chronic care model and the 5A's for treating tobacco use in urban primary care clinics, Hung and colleagues considered cross-sectional survey results from 497 health care providers in 60 primary care clinics in New York City.¹²⁷ They found that adjusting for all other CCM elements revealed that the strongest correlate for 5A's smoking cessation delivery was the use of clinical information systems.¹²⁷ Thus, the use of clinical information systems has shown potential and may have a role in the management of chronic diseases like tobacco dependence.

The present pilot study has both strengths and weaknesses. The most successful method developed in this pilot study was the SSICs used to identify patient smoking status. The smoking status identification tool demonstrated utility in producing an average smoking prevalence similar to the province-wide prevalence of smoking in a few practices. As well, it demonstrated that it was potentially implementable in a busy primary care practice setting and that, when adopted by the practice, it provided the much-needed "denominator" for the

Smoking Registry in the calculation of physician smoking cessation counselling percentages, which will be the primary outcome in the larger trial.

Several factors that will influence the ability to use the results of this pilot study as a final step towards developing a larger trial include: (a) the lack of participation of more than one physician from any primary care practice, which means the protocol was not tested in the intended manner of a cluster; (b) the sample size of 5 physicians was slightly less than the minimum 10% pilot study sample size requirement, which limited the amount of data available for analysis; and (c) the short pilot study duration of 3 months did not allow adequate data collection to document a full one-year cycle of smoking cessation counselling as reasonably and realistically allowed by the MOHLTC physician service billing codes.

In conclusion, this pilot trial demonstrated mixed adoption of the protocol and mixed utilization of the smoking cessation management module. As this study was a pilot trial, it was not powered to detect significant differences in outcomes, which means it does not provide evidence to change practice. It is concluded that a randomized clinical trial comparing the use of the new enhanced smoking cessation management module to the standard one is not feasible with the current study design. This conclusion is primarily drawn from the fact that the threshold criteria set for the feasibility objectives were not met. Nevertheless, many lessons were learned throughout the execution of this pilot trial.

10.0 Future Directions

In light of the study's results, strength and limitations, significant modifications should be made to the present study design that could be tested before progressing to a larger trial. The following seven items are presented as a summary of the major changes that will be proposed in this section.

- (1) Acknowledge the nature of one of the newer models of primary health care delivery in Ontario, the FHT and consider alternate recruitment strategies, by (a) expanding the inclusion criteria to recruit at least nurse practitioners and may be pharmacists, alongside physicians, as potential providers of smoking cessation counselling and users of the web-based P-PROMPT CDMS, and by (b) recruiting an entire FHT as opposed to some of the physicians;
- (2) recruit primary care practices that are not P-PROMPT CDMS subscribers;
- (3) introduce an adaptable SSIC dissemination and collection methodology with a test period that requires at least 90% SSIC completion as an inclusion criteria for the larger trial;
- (4) stipulate similar SSIC information data entry in both the intervention and control group with the information only populating the respective Smoking Registry of each physician in the intervention group;
- (5) introduce an accessible, portable tablet computer to replace the patient chart during each patient visit;

(6) implement patient exit surveys to determine the amount of counselling that occurs in each primary care practice and to identify the health care provider of this service; and

(7) use rigorous evidence-based implementation strategies to ensure adoption of study methods.

To address the inconsistent adoption of SSIC distribution methods among primary care practices, a number of changes to the study methods and implementation would be necessary if a larger study was to be conducted. For example, all staff who will be involved in the study could be requested to be present at the site activation visit to receive in-person instructions or should be contacted by phone to discuss the protocol procedures. The study purpose, instructions and the Principal Investigator's contact information could be printed on a card and taped to the back of the secure box that would face the administrative assistant as a reminder of the procedures to be followed. The location of the secure box where the SSICs are to be stored could be consistent and the pilot study experience could be recounted with staff, so that they understand the importance of box positioning. A one-month test period for SSIC distribution should be incorporated into the study design, including a process of early and potentially repeated follow-ups with each participating site to perform interim progress reviews and process assessments that inform a potentially individualized process of SSIC distribution that is mindful of each practice's unique dynamics, including patient and work flows. This SSIC distribution test

period could begin with the routine adoption of the methods specified in the protocol but then be allowed to be modified on a per case basis, as may be seen fit by both the staff and Principal Investigator. For example, perhaps the SSIC method and utilization could be modified based on findings in the literature presented above such that a SSIC could be attached to the front of every patient's chart that was rostered to the physician. The SSIC could then be removed from the chart and handed to the patient for completion either by the administrative assistant prior to the physician-patient encounter or by the physician at the end of the physician-patient encounter. This would preserve the patient completion of smoking status identification in this pilot study, which is believed to have led to the high smoking status identification percentages observed in two primary care practices. As the creation of the Smoking Registry is essential to study measurements, the adherence to this component of the protocol and SSIC compliance during the test period could be an inclusion criteria for study participation.

The infrequent use of the smoking cessation management module in P-PROMPT CDMS also requires that its implementation be revised. This pilot trial shows that a broader spectrum of implementation strategies should be used even among physicians who have a subscription to P-PROMPT CDMS prior to the study. A future study could incorporate a run-in period for training to ensure that expected users of the system are able to use the base module and demonstrate comparable utilization.

Ideally a physician should have P-PROMPT CDMS open during each patient visit and use it to guide the delivery of the individualized treatment each patient requires. According to qualitative data collected, a contributing factor to the underuse of P-PROMPT CDMS is the lack of its portability. Since P-PROMPT CDMS is web-based, a computer is required to access it. Both those physicians who were interviewed for the purpose of intervention development and those who participated in the pilot study reported not always having a computer in each examination room. When they do, they expressed concern about facing the computer as opposed to the patient. A potential solution to this identified access barrier may come in the form of the newest technology trend of tablet computers that resemble a thin textbook or look like a thicker digital piece of paper, as opposed to a desk-top computer. In this manner, the tablet computer may in the future provide the needed portability and unobtrusive, convenient access to the web-based P-PROMPT CDMS that may facilitate its intended use by physicians. A specific example of this may be the Apple® iPad® that uses the popular iPhone® interface, which millions of people around the world already own, many of them presumably primary care physicians. The familiarity and user-friendliness of this device for portably viewing web pages makes it a viable option that can potentially be implemented to increase physician access to and use of P-PROMPT CDMS. It should be noted that this potential solution to the underuse of P-PROMPT CDMS is proposed based on one identified access barrier. A more detailed qualitative investigation of physicians' practice patterns,

technical/computer knowledge and general opinions and understanding of P-PROMPT CDMS could be undertaken to identify all barriers prior to such a substantial change in the study design. As a potential solution to the underuse of P-PROMPT CDMS, the use of a tablet would require feasibility testing prior to its implementation in a larger trial and should be made available to both the intervention and control group so that it is not a co-intervention.

Although physicians did not consistently use P-PROMPT CDMS, study results showed that staff generally used P-PROMPT CDMS more often than the physician. In light of this finding, the participants, training and data capture should be changed in a larger study. Since smoking cessation counselling can be provided by other primary health care professionals such as nurse practitioners, nurses and pharmacists, these individuals could also be enrolled in a future study to better understand who is accessing the CDMS and how it is incorporated into patient care.

Based on the limited recruitment of physicians observed in this pilot trial, an important additional consideration for designing the future trial is the recruitment of physicians who are not subscribers to P-PROMPT CDMS. Considering the low recruitment that was observed among subscribers to P-PROMPT CDMS (7.7% of invited physicians enrolled and completed the study), the feasibility of recruiting physicians who would have to implement a change of practice to use P-PROMPT CDMS as part of a study may prove to be difficult. Yet the generalizability of this pilot trial and future trial may be limited if the

intervention is tested only in existing subscribers to P-PROMPT CDMS who pay for the subscription out-of-pocket. These physicians have made the choice to invest time to acquire and implement the program, which may indicate an above-average commitment to preventive care delivery and chronic disease management but that also encourages use of the system to get “one’s money’s worth.” In the current pilot study, time and financial constraints prevented non-subscribers to be recruited and oriented to the use and integration of the chronic disease management system. Consenting physicians in a future study can still be expected to have a stronger commitment to and belief in the importance of chronic disease management than their peers. However, it may be easier to generalize their results to the general population of primary care physicians since P-PROMPT CDMS could be supplied for free to these participating physicians. Recruitment could also be revised to better consider the FHT environment. Since an FHT is a team of interdisciplinary health care providers who work collaboratively to manage each patient’s care, it is important to consider which primary health care professionals from the team should be enrolled in a future study. In the case of smoking cessation counselling, physicians, nurse practitioners and pharmacists can provide this health care service to varying degrees. This pilot trial observed that the smoking cessation management module in P-PROMPT CDMS was used by staff at the majority of primary care practices, as opposed to the physician participant. Thus, to successfully study the multi-faceted intervention in this pilot trial, a future study may look at

recruiting an entire FHT with potentially multiple participants of varying health care roles at each site. Enrollment of an entire FHT as opposed to just one or just a few physicians in the team will also fit the culture of a FHT better since the FHT is meant to function as a cohesive unit. Indeed, enrollment of an entire FHT will better reflect the functioning of this primary health care delivery unit and may help realize the true potential of the multi-faceted intervention in this setting, which may otherwise be masked. In the current pilot study the lack of physician clusters prevented the assessment of the protocol methods in a cluster or primary care practice with more than one physician participant. The feasibility of implementing the study methods amongst a team should be tested prior to a larger trial so that any adjustments to make the protocol conducive to a group practice can be made.

The original sample size calculation was based on the assumption that physicians would have P-PROMPT CDMS open in front of them while seeing patients, which is the manner in which it is expected to assist the physicians' daily practice. Seeing that this key premise of physician usage at the point and time of care did not occur in this pilot trial, a redesign of objectives, design methods, and subsequent re-calculation of sample sizes is in order.

The original sample size calculation assumed the control group would provide smoking cessation counselling to 48% of its patient roster, based on a 2006 provincial estimate of smokers aged 15 and over who had visited a doctor in the past 12 months and were advised by their doctor to quit smoking.³⁹

Although this estimate may seem like an overestimate, since it only accounts for physician advice to quit smoking as opposed to full smoking cessation treatment, it is somewhat compensated for by the general tendency of patients to underestimate the health care they receive.⁶⁸ An update to the research based on data collected from February to December 2008 reveals that this proportion has decreased to 47.0%.⁶⁸ The proportion of patients counselled in the pilot study was much lower however, it is possible that the small sample size contributed to this observation. It is also possible that the value documented for smoking cessation counselling in the study is an underestimate since it was measured with a surrogate outcome of physician service provider billing codes for smoking cessation counselling, which proved to be unrepresentative of the actual physicians' activities. Initial baseline measurement and later pre-study questionnaire results revealed that physician service billing data is not necessarily an accurate representation of counselling since physicians do not always bill for the smoking cessation counselling they provide. Finally, the study's short duration may have contributed to the low counselling percentages observed. The future trial could provide a longer duration of follow-up to at least one year in length, to increase the likelihood of capturing the physician "Asking" about the patient's smoking status at least once in that timeframe. In light of the above considerations and since there is no reason to believe that physicians who subscribe to P-PROMPT CDMS would provide less counselling than the average primary care physician in Ontario, the new sample size calculation will continue to

assume that the percentage of counselling expected to be observed in the control group will be equal to the provincial estimate of about 47%.

The next component of the sample size calculation involves identifying a range of probabilities of access that is expected during the study in the intervention group. Based on the iPad improvement described above, the range of probability of use is expected to become more narrow than the original range. A 60% to 100% range is more feasible since the intervention will be put in the hands of participating physicians and the implementation strategy will be more rigorous with a minimum 70% compliance required for inclusion in the larger trial. Based on this range of probabilities of access a range of rates of counselling is calculated. Taking +/- 2 standard deviation units of this range yields a standard deviation estimate of 12.5. This is used to calculate sample size and then an adjusted sample size for the clusters using the same procedure described in section 4.2.1.2 above. Based on these calculations, the lowest expected probability of P-PROMPT CDMS use of 60% would require a sample size of 15 physicians per arm for a total sample size of 30 physicians. This is a feasible number that could be realized from the current sample of P-PROMPT CDMS subscribers or a future sample of non-subscribed primary care physicians.

This pilot study identified a critical gap in the physician's ability to use part of the multi-faceted intervention and demonstrated allied health professionals' potential role as users of P-PROMPT CDMS. It is evident that the clinical information system tested in this pilot trial must be better implemented and

integrated into the primary care practice environment to genuinely aid daily practice workflow and delivery of preventive care and chronic disease management. A CDMS, by its very nature of holding multiple overlapping patient disease registries (in addition to a smoking registry), is already a tool that can be expected to be applicable and useful in part of the management of a large majority of all patients in a physician's roster, since almost all either have a chronic disease or are eligible for at least one preventive care service or screening.

The future direction of quality improvement research in smoking cessation treatment is not clear. Further methodologically rigorous trials are required to identify either single- or multi-faceted interventions that will help busy primary care physicians provide this evidence-based health care intervention. Since physicians have considerable influence on their patient's health-related activities, their relative disinclination to provide smoking cessation treatment is a critical impediment to tobacco control. There is no doubt that an effective smoking cessation system must be comprehensive and, accordingly, necessitates actively engaging primary care physicians.

References

1. U.S. Department of Health and Human Services. Report on Reducing the Health Consequences of Smoking: 25 Years of Progress. 1989.
2. Makomaski Illing EM, Kaiserman MJ. Mortality attributable to tobacco use in Canada and its regions, 1998. *Canadian Journal of Public Health. Revue Canadienne de Sante Publique*. 2004;95(1):38-44.
3. WHO Report on the Global Tobacco Epidemic, 2008: The MPOWER Package. Geneva: World Health Organization; 2008.
4. Fiore MC, Baker TB. Smoking cessation treatment and the good doctor club. *Am J Public Health*. 1995;85(2):161-163.
5. Batra V, Patkar AA, Weibel S, Leone FT. Tobacco smoking as a chronic disease: notes on prevention and treatment. *Primary Care; Clinics in Office Practice*. 2002;29(3):629-648.
6. Fiore MC, Jaen CR, Baker TB, et al. Treating Tobacco Use and Dependence: 2008 Update. 2008.
7. Meredith LS, Yano EM, Hickey SC, Sherman SE. Primary care provider attitudes are associated with smoking cessation counseling and referral. *Med Care*. 2005;43(9):929-934.

8. Stead LF, Bergson G, Lancaster T. Physician advice for smoking cessation.[update of Cochrane Database Syst Rev. 2004;(4):CD000165; PMID: 15494989]. *Cochrane Database Syst Rev.* 2008(2):000165.
9. Lohr KN. Medicare: a strategy for quality assurance. *Journal of Quality Assurance.* 1991;13(1):10-13.
10. Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet.* 1993;342(8883):1317-1322.
11. Oxman AD, Thomson MA, Davis DA, Haynes RB. No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. *CMAJ Canadian Medical Association Journal.* 1995;153(10):1423-1431.
12. Grimshaw JM, Shirran L, Thomas R, et al. Changing provider behavior: an overview of systematic reviews of interventions. *Med Care.* 2001;39(8 Suppl 2):2-45.
13. Krumholz HM, Currie PM, Riegel B, et al. A taxonomy for disease management: a scientific statement from the American Heart Association Disease Management Taxonomy Writing Group. *Circulation.* 2006;114(13):1432-1445.

14. Weingarten SR, Henning JM, Badamgarav E, et al. Interventions used in disease management programmes for patients with chronic illness-which ones work? Meta-analysis of published reports. *BMJ*. 2002;325(7370):925.
15. Improving Chronic Illness Care. Clinical Information Systems.
http://www.improvingchroniccare.org/index.php?p=Clinical_Information_Systems&s=25. Updated 2010. Accessed December 4, 2008.
16. World Health Organization. WHO Report on the Global Tobacco Epidemic, 2009: Implementing smoke-free environments. 2009.
17. US Centers for Disease Control and Prevention. About Chronic Disease: Definition, Overall Burden, and Cost Effectiveness of Prevention. 2004.
www.cdc.gov/nccdphp/about.htm. Accessed January 30, 2010.
18. Henningfield JE, Fant RV. Tobacco use as drug addiction: the scientific foundation. *Nicotine Tobacco Res*. 1999;1(Suppl 2):S31-5.
19. Benowitz NL. Pharmacology of nicotine: addiction, smoking-induced disease, and therapeutics. *Annual Review of Pharmacology & Toxicology*. 2009;49:57-71.
20. van den Brink W, van Ree JM. Pharmacological treatments for heroin and cocaine addiction. *European Neuropsychopharmacology*. 2003;13(6):476-487.
21. U.S. Department of Health and Human Services. The Health Consequences of Smoking - Nicotine Addiction: A report of the Surgeon General 1988. 1988.

22. Guindon GE, Boisclair D. Past, Current and Future Trends in Tobacco Use. 2003.
23. Centers for Disease Control and Prevention (CDC). Cigarette smoking among adults and trends in smoking cessation - United States, 2008. *MMWR - Morbidity & Mortality Weekly Report*. 2009;58(44):1227-1232.
24. Statistics Canada. Healthy People, Healthy Places. 2010.
<http://www.statcan.gc.ca/pub/82-229-x/2009001/deter/cos-eng.htm>. Updated 2010. Accessed May 30, 2010.
25. World Health Organization. WHO Report on the Global Tobacco Epidemic, 2009: Implementing smoke-free environments. 2009.
26. WHO Atlas maps global tobacco epidemic. *Cent Eur J Public Health*. 2003;11(2):106.
27. Kamholz SL. Pulmonary and cardiovascular consequences of smoking. *Clinics in Occupational & Environmental Medicine*. 2006;5(1):157-171.
28. The Health Consequences of Smoking: A Report of the Surgeon General. 2004.
29. Strandberg AY, Strandberg TE, Pitkala K, Salomaa VV, Tilvis RS, Miettinen TA. The effect of smoking in midlife on health-related quality of life in old age: a 26-year prospective study. *Arch Intern Med*. 2008;168(18):1968-1974.

30. Peto R, Lopez AD, Boreham J, Thun M, Heath C, Jr, Doll R. Mortality from smoking worldwide. *Br Med Bull.* 1996;52(1):12-21.

31. Shafey O, Eriksen M, Ross H, Mackay J. The Tobacco Atlas 3rd Edition. 2009.

32. Murray CJ, Lopez AD. Alternative projections of mortality and disability by cause 1990-2020: Global Burden of Disease Study. *Lancet.* 1997;349(9064):1498-1504.

33. Mathers CD, Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. *PLoS Medicine / Public Library of Science.* 2006;3(11):e442.

34. Rehm J, Gnam W, Popova S, et al. The costs of alcohol, illegal drugs, and tobacco in Canada, 2002. *Journal of Studies on Alcohol & Drugs.* 2007;68(6):886-895.

35. Rehm J, Baliunas D, Brochu S, et al. The Costs of Substance Abuse in Canada 2002: Highlights. March 2006:1-14.

36. Baliunas D, Patra J, Rehm J, Popova S, Taylor B. Smoking-attributable morbidity: acute care hospital diagnoses and days of treatment in Canada, 2002. *BMC Public Health.* 2007;7:247.

37. U.S. Department of Health and Human Services. The Health Benefits of Smoking Cessation: A report of the Surgeon General, 1990. 1990.

38. Thorndike AN, Rigotti NA, Stafford RS, Singer DE. National patterns in the treatment of smokers by physicians. *JAMA*. 1998;279(8):604-608.
39. Ontario Tobacco Research Unit. Indicators of Smoke-Free Ontario Progress. 2008;13(2).
40. Solberg LI, Maciosek MV, Edwards NM, Khanchandani HS, Goodman MJ. Repeated tobacco-use screening and intervention in clinical practice: health impact and cost effectiveness. *Am J Prev Med*. 2006;31(1):62-71.
41. Maciosek MV, Coffield AB, Edwards NM, Flottemesch TJ, Goodman MJ, Solberg LI. Priorities among effective clinical preventive services: results of a systematic review and analysis.[see comment]. *Am J Prev Med*. 2006;31(1):52-61.
42. De Berardis G, Sacco M, Strippoli GF, et al. Aspirin for primary prevention of cardiovascular events in people with diabetes: meta-analysis of randomised controlled trials. *BMJ*. 2009;339:b4531.
43. Saitz R. Screening and brief intervention enter their 5th decade. *Substance Abuse*. 2007;28(3):3-6.
44. Babor TF, McRee BG, Kassebaum PA, Grimaldi PL, Ahmed K, Bray J. Screening, Brief Intervention, and Referral to Treatment (SBIRT): toward a public

health approach to the management of substance abuse. *Substance Abuse*. 2007;28(3):7-30.

45. Henry-Edwards S, Humeniuk R, Ali R, Monteiro M, Poznyak V. Brief Intervention for Substance Use: A Manual for Use in Primary Care. (Draft Version 1.1 for Field Testing). 2003.

46. Hahn DL, Berger MG. Implementation of a systematic health maintenance protocol in a private practice.[see comment]. *J Fam Pract*. 1990;31(5):492-502.

47. Kottke TE, Solberg LI, Brekke ML, Conn SA, Maxwell P, Brekke MJ. A controlled trial to integrate smoking cessation advice into primary care practice: Doctors Helping Smokers, Round III. *J Fam Pract*. 1992;34(6):701-708.

48. Fiore MC, Jorenby DE, Schensky AE, Smith SS, Bauer RR, Baker TB. Smoking status as the new vital sign: effect on assessment and intervention in patients who smoke. *Mayo Clin Proc*. 1995;70(3):209-213.

49. Rothemich SF, Woolf SH, Johnson RE, et al. Effect on cessation counseling of documenting smoking status as a routine vital sign: an ACORN study. *Annals of Family Medicine*. 2008;6(1):60-68.

50. Fiore MC, Jorenby DE, Schensky AE, Smith SS, Bauer RR, Baker TB. Smoking status as the new vital sign: effect on assessment and intervention in patients who smoke. *Mayo Clin Proc*. 1995;70(3):209-213.

51. Robinson MD, Laurent SL, Little JM, Jr. Including smoking status as a new vital sign: it works!. *J Fam Pract.* 1995;40(6):556-561.
52. Russell MA, Stapleton JA, Hajek P, Jackson PH, Belcher M. District programme to reduce smoking: can sustained intervention by general practitioners affect prevalence?. *Journal of Epidemiology & Community Health.* 1988;42(2):111-115.
53. U.S. Preventive Services Task Force. Counseling and interventions to prevent tobacco use and tobacco-caused disease in adults and pregnant women: U.S. Preventive Services Task Force reaffirmation recommendation statement. *Ann Intern Med.* 2009;150(8):551-555.
54. Anderson CM, Zhu SH. Tobacco quitlines: looking back and looking ahead. *Tob Control.* 2007;16(Suppl 1):81-86.
55. Curry SJ, McBride C, Grothaus LC, Louie D, Wagner EH. A randomized trial of self-help materials, personalized feedback, and telephone counseling with nonvolunteer smokers. *Journal of Consulting & Clinical Psychology.* 1995;63(6):1005-1014.
56. Bronson DL, Flynn BS, Solomon LJ, Vacek P, Secker-Walker RH. Smoking cessation counseling during periodic health examinations. *Arch Intern Med.* 1989;149(7):1653-1656.

57. Slama K, Redman S, Perkins J, Reid AL, Sanson-Fisher RW. The effectiveness of two smoking cessation programmes for use in general practice: a randomised clinical trial. *BMJ*. 1990;300(6741):1707-1709.
58. Zhu SH, Stretch V, Balabanis M, Rosbrook B, Sadler G, Pierce JP. Telephone counseling for smoking cessation: effects of single-session and multiple-session interventions. *Journal of Consulting & Clinical Psychology*. 1996;64(1):202-211.
59. Ockene JK, Kristeller J, Goldberg R, et al. Increasing the efficacy of physician-delivered smoking interventions: a randomized clinical trial. *Journal of General Internal Medicine*. 1991;6(1):1-8.
60. Gilbert JR, Wilson DM, Singer J, et al. A family physician smoking cessation program: an evaluation of the role of follow-up visits. *Am J Prev Med*. 1992;8(2):91-95.
61. Yarnall KS, Pollak KI, Ostbye T, Krause KM, Michener JL. Primary care: is there enough time for prevention?. *Am J Public Health*. 2003;93(4):635-641.
62. Bader P, McDonald P, Selby P. An algorithm for tailoring pharmacotherapy for smoking cessation: results from a Delphi panel of international experts. *Tob Control*. 2009;18(1):34-42.

63. Ebbert JO, Croghan IT, Sood A, Schroeder DR, Hays JT, Hurt RD. Varenicline and bupropion sustained-release combination therapy for smoking cessation. *Nicotine Tobacco Res.* 2009;11(3):234-239.
64. Nides M, Glover ED, Reus VI, et al. Varenicline versus bupropion SR or placebo for smoking cessation: a pooled analysis. *Am J Health Behav.* 2008;32(6):664-675.
65. The Smoking Treatment for Ontario Patients Study. <http://www.stopstudy.ca>. Updated 2009. Accessed October 4, 2009.
66. Raw M, Regan S, Rigotti NA, McNeill A. A survey of tobacco dependence treatment services in 36 countries. *Addiction.* 2009;104(2):279-287.
67. Brewster JM, Victor JC, Ashley MJ. Views of Ontarians about health professionals' smoking cessation advice. *Canadian Journal of Public Health. Revue Canadienne de Sante Publique.* 2007;98(5):395-399.
68. Ontario Tobacco Research Unit. Indicators of Smoke-Free Ontario Progress. 2010;2.
69. Williams GC, Levesque C, Zeldman A, Wright S, Deci EL. Health care practitioners' motivation for tobacco-dependence counseling. *Health Educ Res.* 2003;18(5):538-553.

70. Marcy TW, Skelly J, Shiffman RN, Flynn BS. Facilitating adherence to the tobacco use treatment guideline with computer-mediated decision support systems: physician and clinic office manager perspectives. *Prev Med.* 2005;41(2):479-487.
71. Rennard SI, Daughton DM. Smoking cessation. *Chest.* 2000;117(5 Suppl 2):360S-4S.
72. Conroy MB, Majchrzak NE, Regan S, Silverman CB, Schneider LI, Rigotti NA. The association between patient-reported receipt of tobacco intervention at a primary care visit and smokers' satisfaction with their health care. *Nicotine Tobacco Res.* 2005;7(Suppl 1):S29-34.
73. Memorandum of Agreement Between the Ontario Medical Association and the Ministry of Health and Long-Term Care. 2007.
74. Ministry of Health and Long-Term Care. Schedule of Benefits for Physician Services under the Health Insurance Act. Ministry of Health and Long-Term Care Web site.
http://www.health.gov.on.ca/english/providers/program/ohip/sob/physserv/physse rv_mn.html. Updated 2010. Accessed July 5, 2010.
75. Shojania KG, McDonald KM, Wachter RM, Owens DK. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies, Volume 1 - Series Overview and Methodology. Technical Review 9 (Contract No. 290-02-0017 to

the Stanford University-UCSF Evidence-based Practices Center). 2004; AHRQ 04-0051-1.

76. Best M, Neuhauser D. Avedis Donabedian: father of quality assurance and poet. *Quality & Safety in Health Care*. 2004;13(6):472-473.

77. Donabedian A. The quality of medical care: a concept in search of a definition. *J Fam Pract*. 1979;9(2):277-284.

78. Donabedian A. Evaluating the quality of medical care. 1966. *Milbank Q*. 2005;83(4):691-729.

79. Donabedian A. Commentary on some studies on the quality of care. *Health Care Financ Rev*. 1987(Spec No):75-85.

80. Committee on Quality of Health Care in America, Institute of Medicine. *To Err is Human: Building a Safer Health System*. 2000.

81. Committee on Quality Health Care in America, Institute of Medicine. *Crossing the Quality Chasm: a new health system for the 21st century*. 2001.

82. Cabana MD, Rand CS, Powe NR, et al. Why don't physicians follow clinical practice guidelines? A framework for improvement. *JAMA*. 1999;282(15):1458-1465.

83. Fiore MC, McCarthy DE, Jackson TC, et al. Integrating smoking cessation treatment into primary care: an effectiveness study. *Prev Med.* 2004;38(4):412-420.

84. Farmer AP, Legare F, Turcot L, et al. Printed educational materials: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev.* 2008(3):004398.

85. Bero LA, Grilli R, Grimshaw JM, Harvey E, Oxman AD, Thomson MA. Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings. The Cochrane Effective Practice and Organization of Care Review Group. *BMJ.* 1998;317(7156):465-468.

86. Smith WR. Evidence for the effectiveness of techniques To change physician behavior. *Chest.* 2000;118(2 Suppl):8S-17S.

87. Grol R, Wensing M. What drives change? Barriers to and incentives for achieving evidence-based practice. *Med J Aust.* 2004;180(6 Suppl):S57-60.

88. Bain KT. Barriers and strategies to influencing physician behavior. *American Journal of Medical Quality.* 2007;22(1):5-7.

89. Shojania KG, Ranji SR, McDonald KM, et al. Effects of quality improvement strategies for type 2 diabetes on glycemic control: a meta-regression analysis. *JAMA*. 2006;296(4):427-440.
90. Shojania KG, Grimshaw JM. Still no magic bullets: pursuing more rigorous research in quality improvement. *Am J Med*. 2004;116(11):778-780.
91. Shojania KG, Grimshaw JM. Evidence-based quality improvement: the state of the science. *Health Aff*. 2005;24(1):138-150.
92. Ting HH, Shojania KG, Montori VM, Bradley EH. Quality improvement: science and action. *Circulation*. 2009;119(14):1962-1974.
93. Auerbach AD, Landefeld CS, Shojania KG. The tension between needing to improve care and knowing how to do it. *N Engl J Med*. 2007;357(6):608-613.
94. Grimshaw JM, Shirran L, Thomas R, et al. Changing provider behavior: an overview of systematic reviews of interventions. *Med Care*. 2001;39(8 Suppl 2):2-45.
95. Grimshaw JM, Thomas RE, MacLennan G, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess*. 2004;8(6).
96. Shojania KG, Grimshaw JM. Evidence-based quality improvement: the state of the science. *Health Aff*. 2005;24(1):138-150.

97. Lemmens KM, Nieboer AP, van Schayck CP, Asin JD, Huijsman R. A model to evaluate quality and effectiveness of disease management. *Quality & Safety in Health Care*. 2008;17(6):447-453.
98. Epstein RS, Sherwood LM. From outcomes research to disease management: a guide for the perplexed. *Ann Intern Med*. 1996;124(9):832-837.
99. Dellby U. Drastically improving health care with focus on managing the patient with a disease: the macro and micro perspective. *Int J Health Care Qual Assur*. 1996;9(2):4-8.
100. Ellrodt G, Cook DJ, Lee J, Cho M, Hunt D, Weingarten S. Evidence-based disease management. *JAMA*. 1997;278(20):1687-1692.
101. Faxon DP, Schwamm LH, Pasternak RC, et al. Improving quality of care through disease management: principles and recommendations from the American Heart Association's Expert Panel on Disease Management. *Circulation*. 2004;109(21):2651-2654.
102. Schrijvers G. Disease Management: A proposal for a new definition. *International Journal of Integrated Care*. 2009;9(Mar).
103. Peytremann-Bridevaux I, Burnand B. Disease Management: A proposal for a new definition. *International Journal of Integrated Care*. 2009;9(May).

104. DMAA The Care Continuum Alliance. Disease Management Definition. .
http://www.dmaa.org/dm_definition.asp. Updated 2010. Accessed February 7,
2010.
105. Wagner EH, Austin BT, Von Korff M. Improving outcomes in chronic illness.
Manag Care Q. 1996;4(2):12-25.
106. Wagner EH, Austin BT, Von Korff M. Organizing care for patients with
chronic illness. *Milbank Q*. 1996;74(4):511-544.
107. Wagner EH. Chronic disease management: what will it take to improve care
for chronic illness?. *Effective Clinical Practice*. 1998;1(1):2-4.
108. Wagner EH, Davis C, Schaefer J, Von Korff M, Austin B. A survey of leading
chronic disease management programs: are they consistent with the literature?.
Manag Care Q. 1999;7(3):56-66.
109. Eccles M, McColl E, Steen N, et al. Effect of computerised evidence based
guidelines on management of asthma and angina in adults in primary care:
cluster randomised controlled trial. *BMJ*. 2002;325(7370):941.
110. Shojania KG, McDonald KM, Wachter RM, Owens DK. Closing the Quality
Gap: A Critical Analysis of Quality Improvement Strategies - Volume 2: Diabetes
Mellitus Care. . 2004;04-0051-2.

111. California Health Care Foundation. Electronic Health Records versus Chronic Disease Management Systems: A Quick Comparison. . www.chcf.org/~media/Files/PDF/E/EHRvsCDMSFactSheet.pdf. Updated 2008. Accessed July 24, 2010.
112. Boyle R, Solberg LI. Is making smoking status a vital sign sufficient to increase cessation support actions in clinical practice?. *Annals of Family Medicine*. 2004;2(1):22-25.
113. Piper ME, Fiore MC, Smith SS, et al. Use of the vital sign stamp as a systematic screening tool to promote smoking cessation. *Mayo Clin Proc*. 2003;78(6):716-722.
114. Dickey LL, Gemson DH, Carney P. Office system interventions supporting primary care-based health behavior change counseling. *Am J Prev Med*. 1999;17(4):299-308.
115. McEwen A, West R, Preston A. Triggering anti-smoking advice by GPs: mode of action of an intervention stimulating smoking cessation advice by GPs. *Patient Education & Counseling*. 2006;62(1):89-94.
116. Nease DE, Jr, Ruffin MT, 4th, Klinkman MS, Jimbo M, Braun TM, Underwood JM. Impact of a generalizable reminder system on colorectal cancer screening in diverse primary care practices: a report from the prompting and reminding at encounters for prevention project. *Med Care*. 2008;46(9 Suppl 1):S68-73.

117. Shojania KG, Jennings A, Mayhew A, Ramsay CR, Eccles MP, Grimshaw J. The effects of on-screen, point of care computer reminders on processes and outcomes of care. *Cochrane Database Syst Rev.* 2009(3):001096.

118. Ahluwalia JS, Gibson CA, Kenney RE, Wallace DD, Resnicow K. Smoking status as a vital sign. *Journal of General Internal Medicine.* 1999;14(7):402-408.

119. Chang HC, Zimmerman LH, Beck JM. Impact of chart reminders on smoking cessation practices of pulmonary physicians. *American Journal of Respiratory & Critical Care Medicine.* 1995;152(3):984-987.

120. McAfee T, Grossman R, Dacey S, McClure J. Capturing tobacco status using an automated billing system: steps toward a tobacco registry. *Nicotine Tobacco Res.* 2002;4(Suppl 1):S31-7.

121. Mosen D, Elliott CG, Egger MJ, et al. The effect of a computerized reminder system on the prevention of postoperative venous thromboembolism. *Chest.* 2004;125(5):1635-1641.

122. Shuter J, Kalkut GE, Pinon MW, Bellin EY, Zingman BS. A computerized reminder system improves compliance with Papanicolaou smear recommendations in an HIV care clinic. *Int J STD AIDS.* 2003;14(10):675-680.

123. Dexter PR, Perkins S, Overhage JM, Maharry K, Kohler RB, McDonald CJ. A computerized reminder system to increase the use of preventive care for hospitalized patients. *N Engl J Med*. 2001;345(13):965-970.

124. Andrews JO, Tingen MS, Waller JL, Harper RJ. Provider feedback improves adherence with AHCPR Smoking Cessation Guideline. *Prev Med*. 2001;33(5):415-421.

125. Bentz CJ, Bayley KB, Bonin KE, et al. Provider feedback to improve 5A's tobacco cessation in primary care: a cluster randomized clinical trial. *Nicotine Tobacco Res*. 2007;9(3):341-349.

126. Wadland WC, Holtrop JS, Weismantel D, Pathak PK, Fadel H, Powell J. Practice-based referrals to a tobacco cessation quit line: assessing the impact of comparative feedback vs general reminders. *Annals of Family Medicine*. 2007;5(2):135-142.

127. Hung DY, Shelley DR. Multilevel analysis of the chronic care model and 5A services for treating tobacco use in urban primary care clinics. *Health Serv Res*. 2009;44(1):103-127.

128. P-PROMPT Chronic Disease Management System.

<http://www.figpsoft.com/P-PROMPT.htm>. Accessed September 5, 2008.

129. Sebaldt RJ, Kaczorowski J, Burgess K, Donald F, Goeree R, Lohfeld L. P-PROMPT: Provider & Patient Reminders: Multi-strategy Prevention Tools.

American Medical Informatics Association Annual Meeting. 2007.

130. St. Joseph's Healthcare. A Study of the Effect of a Chronic Disease Management System on Diabetes Care Within Multidisciplinary Primary Care Practices in Ontario. ClinicalTrials.gov Web site.

<http://clinicaltrials.gov/ct2/show/NCT00914706>. Published June 4, 2009. Updated 2010. Accessed June 25, 2010.

131. Wagner EH. Chronic disease care. *BMJ*. 2004;328(7433):177-178.

132. Wagner EH, Davis C, Schaefer J, Von Korff M, Austin B. A survey of leading chronic disease management programs: are they consistent with the literature?.

Manag Care Q. 1999;7(3):56-66.

133. Wagner EH, Bennett SM, Austin BT, Greene SM, Schaefer JK, Vonkorff M.

Finding common ground: patient-centeredness and evidence-based chronic illness care. *Journal of Alternative & Complementary Medicine*. 2005;11(Suppl 1):S7-15.

134. Arnold DM, Burns KE, Adhikari NK, et al. The design and interpretation of pilot trials in clinical research in critical care. *Crit Care Med*. 2009;37(1

Suppl):S69-74.

135. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract.* 2004;10(2):307-312.
136. Campbell MK, Fayers PM, Grimshaw JM. Determinants of the intracluster correlation coefficient in cluster randomized trials: the case of implementation research. *Clinical Trials.* 2005;2(2):99-107.
137. Killip S, Mahfoud Z, Pearce K. What is an intracluster correlation coefficient? Crucial concepts for primary care researchers. *Annals of Family Medicine.* 2004;2(3):204-208.
138. Guittet L, Ravaud P, Giraudeau B. Planning a cluster randomized trial with unequal cluster sizes: practical issues involving continuous outcomes. *BMC Medical Research Methodology.* 2006;6:17.
139. Baskerville NB, Hogg W, Lemelin J. The effect of cluster randomization on sample size in prevention research. *J Fam Pract.* 2001;50(3):W241-6.
140. Murray DM, Varnell SP, Blitstein JL. Design and analysis of group-randomized trials: a review of recent methodological developments. *Am J Public Health.* 2004;94(3):423-432.
141. Klar N, Donner A. Current and future challenges in the design and analysis of cluster randomization trials. *Stat Med.* 2001;20(24):3729-3740.

142. The R Project for Statistical Computing. The R Project for Statistical Computing Web site. <http://www.r-project.org>.
143. Personal Health Information Protection Act. *S O 2004, Chapter 3 Schedule A*. 2004.
144. Ministry of Health and Long-Term Care. Personal Health Information Protection Act, 2004: An Overview for Health Information Custodians. 2004.
145. Fisher E, Musick J, Scott C, et al. Improving clinic- and neighborhood-based smoking cessation services within federally qualified health centers serving low-income, minority neighborhoods. *Nicotine Tob Res*. 2005;7(Suppl 1):S45-56.
146. Patrick DL, Cheadle A, Thompson DC, Diehr P, Koepsell T, Kinne S. The validity of self-reported smoking: a review and meta-analysis. *Am J Public Health*. 1994;84(7):1086-1093.
147. Parazzini F, Davoli E, Rabaiotti M, et al. Validity of self-reported smoking habits in pregnancy: a saliva cotinine analysis. *Acta Obstet Gynecol Scand*. 1996;75(4):352-354.
148. Studts JL, Ghate SR, Gill JL, et al. Validity of self-reported smoking status among participants in a lung cancer screening trial. *Cancer Epidemiol Biomarkers Prev*. 2006;15(10):1825-1828.

149. Pell JP, Haw SJ, Cobbe SM, et al. Validity of self-reported smoking status: Comparison of patients admitted to hospital with acute coronary syndrome and the general population. *Nicotine Tob Res.* 2008;10(5):861-866.
150. Park SW, Kim JY. Validity of self-reported smoking using urinary cotinine among vocational high school students. *J Prev Med Pub Health.* 2009;42(4):223-230.
151. Takeuchi T, Nakao M, Shinozaki Y, Yano E. Validity of self-reported smoking in schizophrenia patients. *Psychiatry Clin Neurosci.* 2010;64(3):274-278.
152. From Attebring M, Herlitz J, Berndt AK, Karlsson T, Hjalmarson A. Are patients truthful about their smoking habits? A validation of self-report about smoking cessation with biochemical markers of smoking activity amongst patients with ischaemic heart disease. *J Intern Med.* 2001;249(2):145-151.
153. Green CJ, Fortin P, Maclure M, Macgregor A, Robinson S. Information system support as a critical success factor for chronic disease management: Necessary but not sufficient. *Int J Med Inf.* 2006;75(12):818-828.
154. Leatt P, Shea C, Studer M, Wang V. IT solutions for patient safety--best practices for successful implementation in healthcare. *Healthc Q.* 2006;9(1):94-104.

155. Terry AL, Giles G, Brown JB, Thind A, Stewart M. Adoption of electronic medical records in family practice: the providers' perspective. *Fam Med*. 2009;41(7):508-512.
156. Linder JA, Rigotti NA, Schneider LI, Kelley JH, Brawarsky P, Haas JS. An electronic health record-based intervention to improve tobacco treatment in primary care: a cluster-randomized controlled trial. *Arch Intern Med*. 2009;169(8):781-787.
157. Renders CM, Valk GD, Griffin S, Wagner EH, Eijk JT, Assendelft WJ. Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings. *Cochrane Database Syst Rev*. 2001(1):001481.
158. Weber V, Bloom F, Pierdon S, Wood C. Employing the electronic health record to improve diabetes care: a multifaceted intervention in an integrated delivery system. *J Gen Intern Med*. 2008;23(4):379-382.
159. Rundall TG, Shortell SM, Wang MC, et al. As good as it gets? Chronic care management in nine leading US physician organisations. *BMJ*. 2002;325(7370):958-961.
160. Casalino L, Gillies RR, Shortell SM, et al. External incentives, information technology, and organized processes to improve health care quality for patients with chronic diseases. *JAMA*. 2003;289(4):434-441.

161. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving chronic illness care: translating evidence into action. *Health Aff.* 2001;20(6):64-78.

162. Bonomi AE, Wagner EH, Glasgow RE, VonKorff M. Assessment of chronic illness care (ACIC): a practical tool to measure quality improvement. *Health Serv Res.* 2002;37(3):791-820.

163. Pearson ML, Wu S, Schaefer J, et al. Assessing the implementation of the chronic care model in quality improvement collaboratives. *Health Serv Res.* 2005;40(4):978-996.

Appendices

Appendix 1: Physician interview questionnaire to inform intervention development

(1) The understanding and use of P-PROMPT CDMS in the practice were investigated using the following items:

- a. How would you describe P-PROMPT CDMS to a colleague?
- b. Do you personally use P-PROMPT CDMS?
 - i. If YES,
 1. Please describe when and where you would typically use it
 2. Do you mostly use it for preventive care or for chronic disease management? Or do you use it for both preventive care and chronic disease management evenly?
 - ii. If NO,
 1. Who uses P-PROMPT CDMS in the office? (nurse, administrative assistant, etc.)
 2. When and where is it usually used?
 3. Is it used mostly for preventive care or for chronic disease management? Or is it used for both preventive care and chronic disease management evenly?

(2) Opinions regarding P-PROMPT CDMS were investigated using the following items:

- a. Do you feel P-PROMPT CDMS already does or has the potential to help you provide more chronic disease management? Why or why not?
 - b. If you use P-PROMPT CDMS:
 - i. Would you mind showing me what you like about it? What don't you like? What added features would help you provide more chronic disease management?
- If you don't use P-PROMPT CDMS:
- ii. Would you mind if I went through it with you? I would greatly value any questions or opinions you may have about the use of P-PROMPT CDMS

Appendix 2: Physician prompts for smoking cessation counselling

<p>Prompt #1</p>	<p>Consider this: The 2008 update of the clinical practice guideline for treating tobacco use and dependence has concluded that tobacco use is unique since “...it is difficult to identify any other condition that presents such a mix of lethality, prevalence, and neglect, despite effective and readily available interventions.”</p>
<p>Prompt #2</p>	<p>You can do this! Clinicians can positively influence their patients’ smoking behaviour with even a minimal (less than 3 minutes) intervention.</p>
<p>Prompt #3</p>	<p>Every effort counts! Research demonstrates that even when patients are not willing to make a quit attempt immediately, clinician-delivered brief interventions enhance the patient’s motivation and increase the likelihood of future quit attempts.</p>
<p>Prompt #4</p>	<p>It can’t get any better than this! Tobacco users are being primed to consider quitting by a wide range of factors in society and their environment (e.g., public health messages, policy changes, cessation marketing messages, family members).</p>
<p>Prompt #5</p>	<p>Value added! Smokers who receive clinician advice and assistance with smoking cessation report greater satisfaction with their health care than those who do not.</p>
<p>Prompt #6</p>	<p>You can make a difference! While long-term tobacco use has a high case fatality rate, the delivery of timely and effective tobacco dependence interventions, significantly reduces the smoker’s risk of suffering from smoking-related disease.</p>

Appendix 3: Physician prompt in P-PROMPT CDMS (Intervention Group)

The screenshot shows the P-PROMPT CDMS web interface. At the top, there is a header with the P-PROMPT logo, the text "P-PROMPT CDMS Chronic Disease, Screening & Prevention Management System", a logo for "CP", and the text "Powered by Clinical Data Pipeline® on dinforma.net". A "Sign out" link is also present. Below the header, the user ID is "natalie.010" and the patient name is blank. A "Notices" icon is visible. The main content area has three tabs: "Patient", "Registry", and "Roster". The "Patient" tab is active. On the left, there are two sub-tabs: "Care Status" and "Care History". The "Care Status" sub-tab is active, showing the text "Select patient: View or update Care Status". Below this, there are four dropdown menus: "MD:" with "Dr. A. Bluebeard", "As of:" with "Now", "Patient:" with "-- select patient --", and "Sort by:" with "Name". There is also a "Patient name filter:" input field with a "Click to apply filter" link and a "Click to roster a new patient" link. A large black oval highlights a text prompt: "Every effort counts! Research demonstrates that even when patients are not willing to make a quit attempt immediately, clinician-delivered brief interventions enhance the patient's motivation and increase the likelihood of future quit attempts." Below this prompt is the text "Clinical Practice Guideline, Centre for Disease Control". The browser's address bar and status bar are visible at the bottom.

P-PROMPT **P-PROMPT CDMS** Powered by Clinical Data Pipeline® on *dinforma.net* Sign out

Chronic Disease, Screening & Prevention Management System

User ID: natalie.010 Patient: Notices

Patient Registry Roster

Care Status
Care History

Select patient: View or update *Care Status*

MD: Dr. A. Bluebeard As of: Now

Patient: -- select patient -- Sort by: Name

Patient name filter: » Click to apply filter » Click to roster a new patient

Every effort counts! Research demonstrates that even when patients are not willing to make a quit attempt immediately, clinician-delivered brief interventions enhance the patient's motivation and increase the likelihood of future quit attempts.

Clinical Practice Guideline, Centre for Disease Control

Internet 150%

Appendix 4. Sample patient prompt text

As part of my commitment to the ongoing health of my patients, I am reminding them that smoking has many negative health consequences. If you or a family member is a smoker, I would like to invite you to consider talking to me about smoking cessation.

A visit to the office to discuss smoking does not require an immediate commitment to quit. If you or any of your family members are considering smoking cessation during the next year, it is ideal to begin a discussion with me at this time.

Effective behavioral and pharmacological treatments are available to help you or any of your family members quit smoking. I am confident that I can help improve the health of my patients who smoke and prevent the onset of preventable disease.

As your primary care physician, if you or a family member is a smoker, I am concerned about your health. I highly recommend that you contact my office at [inserted physician's office number] to make an appointment to receive smoking cessation counselling and discuss your options.

Please consider calling the office to make an appointment.

Sincerely,

Dr. _____

Appendix 5: Registration of a patient into the smoking registry – the new smoking status box (Intervention Group)

P-PROMPT **P-PROMPT CDMS** Powered by *Clinical Data Pipeline* on *clinorma.net* Sign out
Chronic Disease, Screening & Prevention Management System

User ID: natalie.010 Patient: Alastname090394, First1118a Notices

Patient Registry Roster

Care Status
Care History

Select patient: View or update *Care Status*

MD: Dr. A. Bluebeard As of: Now
Patient: Alastname090394, First1118a Sort by: Name

Patient name filter: » Click to apply filter
» Click to deroster this patient
» Click to roster a new patient

15F 1118 Main St, Town880
8809 031 118
Dr. A. Bluebeard

Current smoking status: Never asked

Update: Never a smoker
 Currently a smoker ► cigs/day
 Previously a smoker: quit on ► (y-m-d)
 Clear

» Export Patient Visit Note: Click: ► Interview + Exam Interview + Exam + Management Interview + Exam + Mana
» Print Patient Visit Note: Click: ► Chronic Disease Mgmt Chronic Disease + Preventive Care Chronic Disease + Preve
» Print Patient MCH Form: Click: ► Laboratory Requisition Roster Enrollment Form Roster Form

Internet 150%

Appendix 6: Sample Smoker Identification Card (SSIC)

Front side of SSIC

First and Last Name Initials: _____ **Health card number:** _____

Please circle your smoking status:

- **Never a smoker**

- **Currently a smoker**
 - How many years have you been smoking? _____
 - How many cigarettes do you smoke per day? _____
 - Have you tried to quit? _____
 - If yes, when was most recent attempt?

- **Previously a smoker**
 - How long has it been since you quit smoking? _____

Back side of SSIC

Dr. _____

Card # 001

Appendix 7: Pre-study physician questionnaire

How often do you ask your patients about their smoking status? Please answer with a percentage.

How often do you provide complete smoking cessation treatment according to the 5A's standard (Ask, Advise, Assess, Assist, Arrange)? Please answer with a percentage.

What do you consider a barrier(s) to providing smoking cessation counselling?

How often do you bill for the smoking cessation counselling you provide? Please answer with a percentage.

...If less than 100%, please explain why:

Do you have a smoking cessation program in place? If yes, please describe:

What resources do you feel you need in order to provide consistent smoking cessation counselling?

Thank you!

Appendix 8: Post-study physician questionnaire

1) Please fill-out the following information regarding physician characteristics:

Name: _____ Age: _____ Sex: _____

School from which medical degree was earned:

Year of graduation: _____ Number of years in practice:

What is your smoking status? 1) Never smoker; 2) Current smoker; 3) Previous smoker

2) Please fill-out the following information regarding primary care practice characteristics:

Number of patients on your roster: _____

Are you a solo practice or are you part of a group practice (please specify)?

Number of physicians in the primary care practice: _____

Number of registered nurses in the primary care practice: _____

Number of nurse practitioners in primary care practice: _____

Number of receptionists/administrative assistants: _____

Please list the two *types* of staff members that use P-PROMPT CDMS the most (ex. nurse, administrative assistant, yourself, etc.):

1) _____ 2) _____

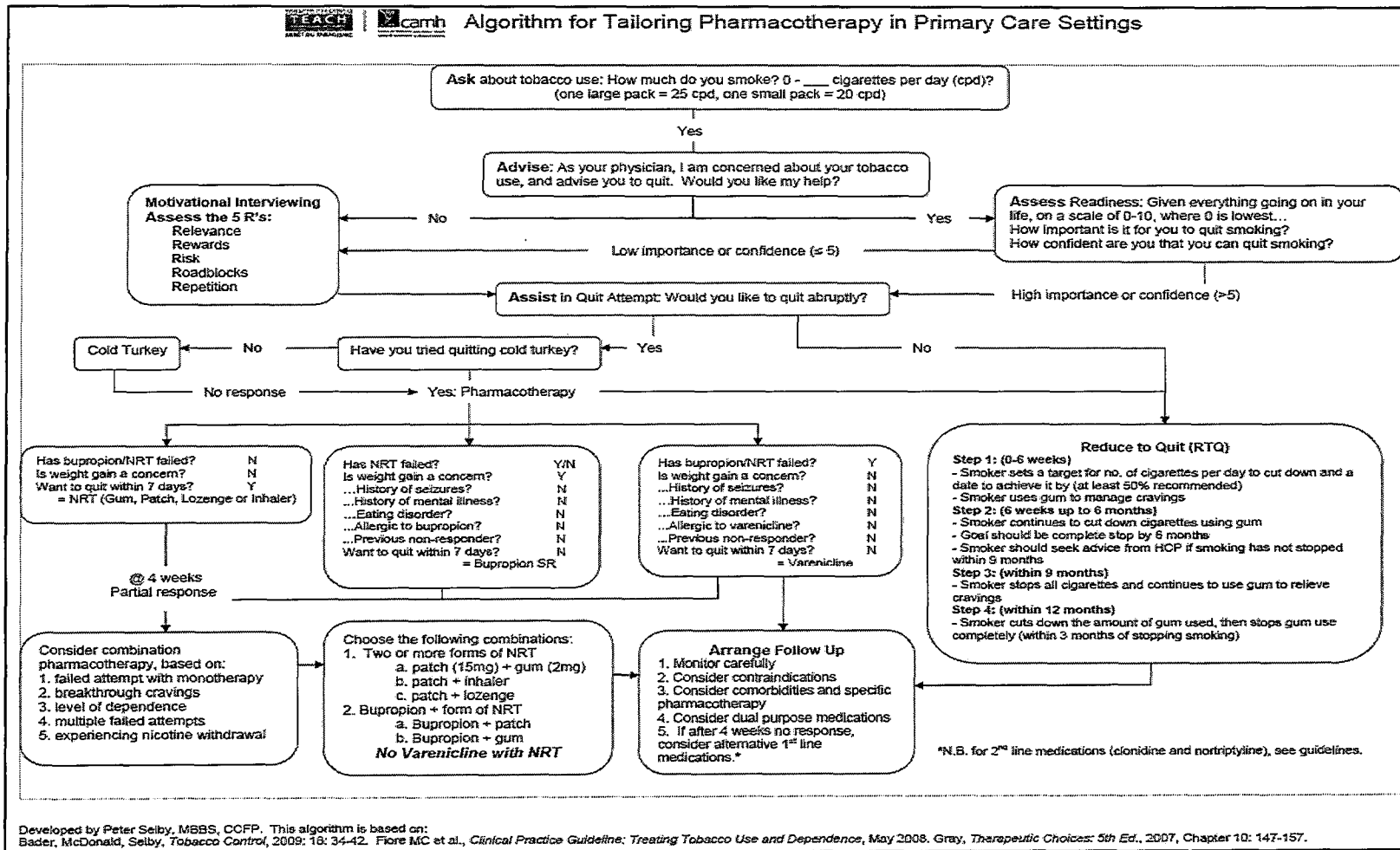
3) Please fill-out the following section regarding P-PROMPT CDMS:

Have you personally used P-PROMPT CDMS to help in the delivery of systematic smoking cessation counselling? Please briefly explain why or why not:

What do you like about P-PROMPT CDMS? What do you find limits your use of the program?

Any further feedback?

Appendix 9: Algorithm for Tailoring Pharmacotherapy in Primary Care Settings



Appendix 10: For Patient Unwilling to Quit–5R’s Enhancing Motivation to Quit*

Motivation	Description
Relevance	<p>Encourage the patient to indicate why quitting is personally relevant, being as specific as possible.</p> <p>Motivational information has the greatest impact if it is relevant to a patient’s disease status or risk, family or social situation (eg, having children in the home), health concerns, age, gender, and other important patient characteristics (eg, prior quitting experience, personal barriers to cessation).</p>
Risks	<p>The clinician should ask the patient to identify potential negative consequences of tobacco use; the clinician may suggest and highlight those that seem to be the most relevant to the patient; the clinician should emphasize that smoking low-tar/low-nicotine cigarettes or use of other forms of tobacco (eg, smokeless tobacco, cigars, and pipes) will not eliminate these risks. Examples of risks are:</p> <p><u>Acute risks:</u> shortness of breath, exacerbation of asthma, harm to pregnancy, impotence, infertility, increased serum carbon monoxide</p> <p><u>Long-term risks:</u> heart attacks and strokes, lung and other cancers (larynx, oral cavity, pharynx, esophagus, pancreas, bladder, cervix), chronic obstructive pulmonary diseases (chronic bronchitis and emphysema), long-term disability and need for extended care</p> <p><u>Environmental risks:</u> increased risk of lung cancer and heart disease in spouses; higher rates of smoking by children of tobacco users; increased risk for low birth weight, Sudden Infant Death Syndrome (SIDS), asthma, middle ear disease, and respiratory infections in children of smokers</p>
Rewards	<p>The clinician should ask the patient to identify potential benefits of stopping tobacco use, the clinician may suggest and highlight those that seem to be the most relevant to the patient. Examples of rewards follow:</p> <p>Improved health; Food will taste better; Improved sense of smell; Save money; Feel better about yourself; Home, car, clothing, breath will smell better; Can stop worrying about quitting; Set a good example for kids; Have healthier babies and children; Not worry about exposing others to smoke; Feel better physically; Perform better in physical activities; Reduced wrinkling/aging of skin</p>

Appendix 10 continued: For Patient Unwilling to Quit–The 5R’s Enhancing Motivation to Quit*

Motivation	Description
Roadblocks	<p>The clinician should ask the patient to identify barriers or impediments to quitting and note elements of treatment (ie, problem-solving, pharmacotherapy) that could address barriers. Typical barriers might include:</p> <p>Withdrawal symptoms; Fear of failure; Weight gain; Lack of support; Depression; Enjoyment of tobacco</p>
Repetition	<p>The motivational intervention should be repeated every time an unmotivated patient visits the clinic setting; tobacco users who have failed in previous quit attempts should be told that most people make repeated quit attempts before they are successful.</p>

*This table is adapted from Fiore MC, Bailey WC, Cohen SJ, et al. Treating tobacco use and dependence: clinical practice guideline. Rockville, MD:US Department of Health and Human Services, Public Health Service, 2000.

Appendix 11: SSICs Data Documentation Sheets

SSIC data collection from Dr. _____'s office

1	Never a smoker	Currently a smoker	Previously a smoker
2	Never a smoker	Currently a smoker	Previously a smoker
3	Never a smoker	Currently a smoker	Previously a smoker
4	Never a smoker	Currently a smoker	Previously a smoker
5	Never a smoker	Currently a smoker	Previously a smoker
6	Never a smoker	Currently a smoker	Previously a smoker
7	Never a smoker	Currently a smoker	Previously a smoker
8	Never a smoker	Currently a smoker	Previously a smoker
9	Never a smoker	Currently a smoker	Previously a smoker
10	Never a smoker	Currently a smoker	Previously a smoker
11	Never a smoker	Currently a smoker	Previously a smoker
12	Never a smoker	Currently a smoker	Previously a smoker
13	Never a smoker	Currently a smoker	Previously a smoker
14	Never a smoker	Currently a smoker	Previously a smoker
15	Never a smoker	Currently a smoker	Previously a smoker
16	Never a smoker	Currently a smoker	Previously a smoker
17	Never a smoker	Currently a smoker	Previously a smoker
18	Never a smoker	Currently a smoker	Previously a smoker
19	Never a smoker	Currently a smoker	Previously a smoker
20	Never a smoker	Currently a smoker	Previously a smoker
21	Never a smoker	Currently a smoker	Previously a smoker
22	Never a smoker	Currently a smoker	Previously a smoker
23	Never a smoker	Currently a smoker	Previously a smoker
24	Never a smoker	Currently a smoker	Previously a smoker
25	Never a smoker	Currently a smoker	Previously a smoker
26	Never a smoker	Currently a smoker	Previously a smoker
27	Never a smoker	Currently a smoker	Previously a smoker
28	Never a smoker	Currently a smoker	Previously a smoker
29	Never a smoker	Currently a smoker	Previously a smoker
30	Never a smoker	Currently a smoker	Previously a smoker
31	Never a smoker	Currently a smoker	Previously a smoker
32	Never a smoker	Currently a smoker	Previously a smoker
33	Never a smoker	Currently a smoker	Previously a smoker
34	Never a smoker	Currently a smoker	Previously a smoker
35	Never a smoker	Currently a smoker	Previously a smoker
36	Never a smoker	Currently a smoker	Previously a smoker
37	Never a smoker	Currently a smoker	Previously a smoker
38	Never a smoker	Currently a smoker	Previously a smoker
39	Never a smoker	Currently a smoker	Previously a smoker
40	Never a smoker	Currently a smoker	Previously a smoker

Appendix 12: Agreement respecting disclosure

Agreement Respecting Disclosure

This agreement is to confirm that the researcher agrees to comply with conditions and restrictions, if any, that the Health Information Custodian, Dr. _____ imposes relating to the use, security, disclosure, return or disposal of the personal health information involved in this study.

Please specify the conditions or restrictions imposed by the Health Information Custodian:

Further, this agreement confirms that the study will only use the information for the purposes set out in the research plan as approved by the research ethics board.

Natalie T. MacLeod
Principal Investigator

Date

Health Information Custodian (HIC)
(Please print name)

HIC Signature

Date

If you have any questions regarding this document please call **Natalie MacLeod** at xxx-xxx-xxxx or email her at _____.