Evaluation of two multi-component interventions for integrating smoking cessation treatments into routine primary care practice: A cluster-randomized trial

by

Sophia Papadakis

A thesis
presented to the University of Waterloo
in fulfillment of the
thesis requirement for the degree of
Doctor of Philosophy
in
Health Studies and Gerontology

Waterloo, Ontario, Canada, 2010

AUTHOR'S DECLARATION

I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

I understand that my thesis may be made electronically available to the public.

Abstract

Background and Rationale: There is a well-documented practice gap in the rates at which evidence-based smoking cessation treatments are delivered to patients in primary care settings. Multi-component intervention that combine practice, provider, and patient-level supports have been shown to increase the rates at which primary care providers deliver smoking cessation treatments to patients and increase rates of smoking abstinence amongst patients. The incremental value of adjunct telephone-based smoking cessation counselling when delivered as part of a multi-component intervention has not been examined.

Aim: The primary objective of this study was to determine whether adjunct telephone-based smoking cessation follow-up counselling (FC), when delivered as part of a multi-component intervention program within primary care clinics is associated with increases in (a) the delivery of evidence-based smoking cessation treatments, (b) patient quit attempts, and (c) patient smoking abstinence when compared to the provision of practice and provider supports (PS) alone. The secondary objective of this study was to determine whether the introduction of a multi-component smoking cessation program is associated with increased delivery of evidence-based smoking cessation treatments by primary care providers and patient smoking outcomes, compared to pre-intervention rates. The study also sought to examine the association between patient, provider, clinic and implementation factors, and study outcomes.

Methods: A two-group, pre-post cluster randomized controlled trial was conducted. Eligible clinics were randomly assigned to the PS group or FC group. Both groups were supported with implementing a multi-component intervention program that involved outreach facilitation visits, provider training, real time provider prompts and patient tools, and performance feedback. Clinics assigned to the FC group were also

able to refer patients who smoke to a telephone-based follow-up support program for supplemental counselling support. An exit survey was completed with a cross-sectional sample of patients who smoked daily at each study clinic before and after the introduction of the intervention program, and all patients were contacted 4 months later to complete a brief telephone-based interview. Outcome measures included the rate at which evidence-based smoking cessation treatments (5As: ask, advise, assess, assist, arrange) were delivered to patients, the number of patients who made a quit attempt, and patient smoking abstinence at the 4-month follow-up. All data was analyzed using multi-level hierarchical modelling.

Results: Seven family medicine clinics and 115 providers were enrolled in the study. A total of 12,585 patients were screened, and 835 eligible patients (mean age 45.8 SD± 14.6, 41% male) who smoke participated in the study. Contrary to the study hypothesis, a higher and statistically significant 7-day point prevalence abstinence (OR 6.8, 95% CI 2.1-21.7; p=<0.01) and continuous abstinence (OR 13.7, 95% CI 2.1-128.3; p=<0.05) rate was observed in the PS group compared to the FC group at the post-assessment after controlling for differences in smoking cessation rates between intervention groups during the baseline period. The introduction of the multi-component intervention program was associated with higher rates of provider 5As delivery and patient quit attempts compared to baseline, with no differences between groups documented. The odds ratios (OR) and 95% confidence intervals (CI) for 5As delivery between the pre- and post-intervention assessments for both intervention groups combined were: “ask” (OR 1.5; 95% CI 1.1, 2.0); “advise” (OR 2.0; 95% CI 1.5, 2.7); “assess” (OR 2.1; 95% CI 1.6, 2.9); “assist” with cessation (OR 2.30; 95% CI 1.70, 3.12); “arrange” (OR 1.9; 95% CI 1.2, 3.0); and “patient quit attempts” (OR 1.4; 95% CI 1.04, 1.94). Differences in 7-day point prevalence abstinence were not statistically significant between the pre- and post-intervention assessments (OR 1.5; 95% CI 0.94, 2.5). The study documented intra-provider variability in the rates at which evidence-based smoking cessation

treatments are delivered to patients. Patient characteristics (readiness to quit, time to first cigarette, previous quit attempt in the last year), and the purpose of the clinic visit being for an annual health exam were associated with higher rates of 5As delivery.

Conclusion: This is the first study to evaluate a multi-component smoking cessation intervention within the primary health care setting in Canada. The study findings demonstrate that the introduction of a multi-component intervention program in primary care settings was associated with significant improvements in the rates at which providers deliver evidence-based smoking cessation treatments, and increase patient quit attempts. The added value of adjunct telephone counselling was not evident at the 4-month follow-up. The conclusions that can be drawn from the present study are limited by the study design and sample size. A larger trial is required to conclusively determine the impact of the program on long-term smoking abstinence and examine the importance of clinic-level variables in explaining observed differences between study clinics.

Acknowledgements

I have been privileged to have as mentors many of Canada's leading tobacco control researchers and practitioners. I am grateful to Paul McDonald for his ongoing guidance and support in the completion of my doctoral work and perhaps as importantly for exposing me to new ideas, concepts, and possibilities. I am grateful to Andrew Pipe for the incredible support he has provided to my career and for all of the opportunities provided to me. It has truly been a privilege to work with you and learn from you. I am grateful to Bob Reid for the support shown to me over the last 12 years and for sharing your knowledge and expertise. So much of what I know I have learned from you. Thank you to Roy Cameron and Barb Riley for sharing your knowledge and insights with me. It has been such a pleasure to learn from you. Thank you to Scott Leatherdale and Steve Brown for their mentorship in the completion of this research study. To my colleagues at the University of Ottawa Heart Institute Prevention and Rehabilitation Centre and the University of Waterloo go my sincere thanks for the ongoing support that has been shown to me. I am grateful to the amazing team involved in the completion of this study including Debbie Aitken, Sophia Gocan, Roxanne Assi, Kimberly Skulsky, and Marie Gharib. This study would not have been possible without the close cooperation of all the staff in the seven clinics involved in this study. Thank you for allowing us to learn from your experiences.

Thank you to all my family and friends for your support. In particular to Margaret and Marianthi Papadakis for being by my side in my journey through life and learning. To Carolyn Carson, Connie Beaulieu, Nancy Dasouki, Vaso Kakassi, and Donna Belanger-Hynes for the incredible support you have shown me over the years – I could not have done it without you.

This study was supported by the Canadian Tobacco Control Research Initiative (Idea Grant #19826 and Student Research Grant #19813), the Ontario Tobacco Research Unit, and the Ontario Ministry of Health and Long-Term Care. Sophia Papadakis was supported with doctoral fellowships from the Canadian Institute for Health Research Strategic Training Program in Tobacco Research (2005-2009) and the Canadian Institute for Health Research Training Program in Population Intervention in Chronic Disease Prevention (2009-2010).

Appendix A of this document includes a paper published by the student author in Preventive Medicine. Preventive Medicine provides authors with permission to post their version of the article to their personal website or institutional repository.

Dedication

This thesis is dedicated to all those who have lost a loved one to smoking.

Table of Contents

List of Figures

List of Tables

Chapter 1 Introduction to the Problem

1.1 The burden of tobacco use in Canada

Tobacco use in Canada has declined dramatically over the past 40 years, with the prevalence falling by 21% in the last decade alone to less than 19% in 2009 (CTUMS 2010). Much of the decline can be attributed to significant population-level policy interventions and changes in social norms associated with smoking in Canada. Despite the dramatic decline in tobacco use, an estimated 4.8 million Canadians continue to smoke (18% of the population) (CTUMS 2010). This translates to almost one in five Canadians over the age of 12 who smoke (CTUMS 2010).

Smoking remains the leading cause of premature morbidity and mortality in Canada (Makomaski Illing and Kaiserman 2004, 38-44). Each year, more than 37,000 Canadians die from tobacco-related illness, representing 22% of all deaths (Makomaski Illing and Kaiserman 2004, 38-44; Rehm et al. 2006). People who use tobacco have a 50-70% greater chance of dying from stroke or coronary heart disease than people who do not use tobacco (USDHHS 1984; USDHHS 2004;). Tobacco use is also a significant risk factor for other major causes of death in Canada including cancer, chronic obstructive pulmonary disease, and lower respiratory tract infections (USDHHS 2004; World Health Organization 2009a). Moreover, tobacco use exacts a large economic burden on the Canadian health care system. The total annual cost of tobacco use in Canada is estimated to be $17 billion, which includes $4.3 billion in direct health care costs (Rehm et al. 2006). The excess lifetime medical costs resulting from tobacco use is estimated to range from $47,121 to $132,280 for low and high consumption smokers, respectively (Coleman 2000).

1.2 Benefits of smoking cessation

There is overwhelming evidence to support both health and economic benefits of smoking cessation. Quitting smoking reduces the excess risk of smoking-related coronary heart disease by approximately 50% within one year, and to normal levels within five years (USDHHS 1984; Benowitz 2003, 91-111; Doll and Hill 2004, 1519; discussion 1533; Kenfield et al. 2008, 2037-2047). A significant reduction in fatal strokes is also observed within five years after cessation of cigarette smoking (Shinton and Beevers 1989, 789-794). Quitting smoking at any age has been shown to reduce the relative risk of developing lung cancer compared to continued smoking (Peto et al. 2000, 323-329). Doll et al. (2004) estimate that cessation at age 60, 50, 40, or 30 years will result in a gain of 3, 6, 9, or 10 years of life expectancy, respectively, compared to continued tobacco use (Doll et al. 2004, 1519). Smoking cessation is also considered the "gold standard" among preventive interventions in terms of its cost-effectiveness (Gaziano, Galea, and Reddy 2007, 1939-1946; Kahn et al. 2008). The cost per life-year saved for smoking cessation is estimated to be between $2000 and $4000, thereby making it one of the more cost-effective preventative interventions available to clinicians (Tengs et al. 1995, 369-390; Cromwell et al. 1997, 1759-1766; Franco et al. 2007, 71-79; Eddy et al. 2009, 241-249).

1.3 Smoking cessation in clinical settings has superior cost-effectiveness than many common preventative interventions

Smoking cessation interventions compare favourably against other preventative interventions. Franco et al. (2007) compared interventions for the primary prevention of heart disease using data from the Framingham Heart Study and found smoking cessation to be more cost-effective therapy than anti-hypertensives, aspirin, and statins (Franco et al. 2007, 71-79). The number needed to treat (NNT) to save one life among male smokers is estimated to be nine (Woolf 1999, 2358-2365). This is far superior to the NNT for many common clinical interventions, including lipid lowering by 10

percentage points (NNT=16), blood pressure control with dieuretics (NNT=34), mammography (NNT=205), papanicolaou smear (NNT=578), and pneumococcal vaccine (NNT=716). Smoking cessation has also been found to be of greater benefit than many secondary prevention interventions, including beta-blockers and aspirin use among patients with heart disease (Woolf 1999, 2358-2365). Kahn et al. (2008) evaluated the impact of preventative interventions on cardiovascular disease and found that smoking cessation is the only preventative intervention that provides a cost savings over a 30-year follow-up period (Kahn et al. 2008, 1686-1696).

1.4 Most people who smoke want to quit but are not accessing evidence-based cessation supports

The majority (54%) of people who smoke in Ontario report intentions to quit smoking, and 25% report serious intentions to quit in the next 30 days (Ismailov and Leatherdale 2010, 282-285; CTUMS 2005). It is estimated that each year, almost half of all people who smoke will make a serious quit attempt; however, only 4-7% are successful with long-term cessation (Zhu et al. 2000, 305-311; Fiore et al. 2008). There is strong clinical trial evidence that combining strategic counselling and first-line smoking cessation medications, such as nicotine replacement therapy, bupropion, and varenicline, can double or triple long-term smoking abstinence (Cahill, Stead, and Lancaster 2007, CD006103; Hughes, Stead, and Lancaster 2007, CD000031; Stead et al. 2008a, CD000146; Cahill, Stead, and Lancaster 2008, CD006103; Fiore et al. 2008). However, few people who smoke are using these evidence-based cessation aids, with most (>80%) attempting to quit without assistance, therefore resulting in fewer successful quit attempts (Hammond et al. 2004, 1042-1048; Ismailov and Leatherdale 2010, 282-285; McIvor 2009, 21-26). Increasing access to and use of evidence-based cessation interventions among people who smoke is an important strategy for increasing long-term abstinence and improving the health of the population.

1.5 Family physicians are well positioned to enhance motivation to quit

Seventy-five per cent of Canadians will visit a primary care practitioner at least once annually (Health Canada 1999; Jaakkimainen et al. 2006). These data are consistent with data from the Institute of Clinical and Evaluative Science (ICES) in Ontario, which found 76% of Ontarians under the age of 65 and 90% of Ontarians 65 years and older saw a family physician in the last year (Health Canada 1999; Jaakkimainen et al. 2006;). In Ontario alone, 140,000 residents will visit a primary care physician daily; suggesting primary care settings may provide access to a large number of individuals who smoke (Jaakkimainen et al. 2006; Health Canada 1999). Moreover, a family doctor's advice to quit has been shown to increase the motivation to quit for a person who smokes (Pederson 1982, 71-84; Ossip-Klein et al. 2000, 364-369; Eckert and Junker 2001, 521-526; Kreuter, Chheda, and Bull 2000, 426-433; Fiore et al. 2008; Stead, Bergson, and Lancaster 2008b, CD000165). One large study found that over half of patients who quit smoking reported their practitioners' advice to quit as having influenced their decision to quit "extremely" or "quite a lot" (Ossip-Klein et al. 2000, 364-369). Thus, physicians and other clinicians are uniquely positioned to intervene with patients who smoke and may play an important role in motivating a quit attempt and accelerating the quitting process.

1.6 Smoking cessation interventions delivered in clinical settings increase long-term smoking abstinence

Two meta-analyses have been published that summarize the evidence regarding the efficacy of practitioner advice and counselling on smoking abstinence. The United States Department of Human Health Service (USDHHS) Clinical Practice Guidelines for Treating Tobacco Use and Dependence reported the pooled odds ratio (OR) of long-term cessation (6 to 12 months) for physician advice to quit compared to no advice was 1.3 [95% CI 1.01, 1.6] for brief counselling (< 3 minutes); 1.6 [95%

CI 1.2-2.0] for low intensity counselling (3 to 10 minutes); and 2.3 [95% CI 2.0-2.7] for higher intensity counselling (>10 minutes) (Fiore et al. 2008). This is equivalent to an increase in the rate of cessation of approximately 2.5%, 5%, and 11.2%, respectively, compared to controls.

A second meta-analysis published by the Cochrane Collaboration, comparing physician advice to controls, reported on the efficacy of *minimal advice* and intensive cessation interventions delivered by physicians (Stead, Bergson, and Lancaster 2008b, CD000165). Within the review, *minimal advice* was defined as advice provided during a single consultation lasting less than 20 minutes with up to one follow-up visit. *Intensive intervention* was considered to involve a greater time commitment at the initial consultation, the use of additional materials other than a leaflet, or more than one follow-up visit. Similar to the USDHHS guideline, the review found a significant increase in the rate of quitting relative risk (RR) 1.66 [95% CI 1.42-1.94] for *minimal advice* and RR 1.84 [95% CI 1.60-2.13] for *intensive intervention* (Stead, Bergson, and Lancaster 2008b, CD000165).

It is important to note that only a subset of these trials examined in both the USDHHS and Cochrane review were conducted in the primary care setting. A secondary analysis of only those trials conducted in the primary care setting found the pooled odds ratio of cessation advice was 1.85 [95% CI 1.64, 2.09].

1.7 Evidence-based cessation interventions in clinical settings

The USDHHS Clinical Practice Guidelines for Treating Tobacco Use and Dependence is a highly regarded and frequently cited reference manual concerning smoking cessation treatment in clinical settings (Fiore et al. 2008). The guideline clearly recommends five strategies as the basis for smoking cessation interventions in clinical settings. The so-called “five As” (5As) strategies are: *ask* (i.e., systematically identify all tobacco users at each visit); *advise* all people who smoke to quit; *assess* the person’s readiness to make a quit attempt; *assist* the person who smokes in

making a quit attempt (i.e., set a quit date, provide self-help materials, prescribe medications); and *arrange* follow-up contact. The 5As strategies provide a structured approach for intervening with patients who smoke in clinical settings that are based on evidence (Fiore et al. 2008).

1.8 Family doctors are not intervening with patients who smoke at optimal rates

Despite the evidence supporting the importance of smoking cessation, there is a well-documented practice gap in the rates at which smoking cessation is being addressed by practitioners. In Canada, between 40-57% of people who smoke report receiving cessation advice from their physicians in the previous 12 months (CTUMS 2006; McIvor 2009, 21-26). This is consistent with other international studies, which have reported rates at which patients are advised to quit are between 36-95% (Gottlieb et al. 2001, 343-351; Young and Ward 2001, 14-20; Shaohua et al. 2003; Longo et al. 2006, 180-184; Tong et al. 2010, 724-733). Although advice to quit may be delivered at moderate rates, studies have shown clinicians are not as good at providing patients with assistance (i.e., counselling, providing self-help materials, prescribing quit smoking medications, and arranging follow-up) with quitting. The rates at which assistance with quitting is provided has been shown to be much lower at 3-20% (Gottlieb et al. 2001, 343-351; Shaohua et al. 2003; Longo et al. 2006, 180-184; Tong et al. 2010, 724-733). Thus, a key challenge remains to increase the number of practitioners adopting evidence-based cessation treatments (5As) and the degree to which these strategies are integrated into the routines of family doctors' offices.

1.9 Strategies for increasing the rates of cessation intervention in primary care practice

A systematic review and meta-analysis of the literature examining strategies for increasing the uptake of smoking cessation interventions in primary care practice settings was conducted to inform the design of the present study and recently published (see Appendix A). The meta-analysis identified several intervention strategies that play an important role in supporting the integration of smoking cessation interventions within the primary care setting (Papadakis et al. 2010, 199-213). These strategies include screening tools, real-time counselling prompts for providers, provider performance feedback, and extended adjunct follow-up counselling for patients, as well as multi-component interventions.

1.9.1 Multi-component interventions are among the most promising strategies

Multi-component interventions that combine two or more intervention strategies have been shown to be the most effective method for increasing provider performance in the delivery of smoking cessation treatments and have been shown to improve cessation rates among patients (Grimshaw et al. 2001, II2-45; Anderson and Jane-Llopis 2004, 299-312; Fiore et al. 2008; Papadakis et al. 2010, 199-213). Multiple large-scale controlled trials have demonstrated a significant impact of multi-component interventions in increasing the rates at which primary care providers deliver evidence-based smoking cessation treatments to patients as well as patient cessation rates. Among the seven trials that examined the effect of a multi-component intervention on smoking outcomes among patients identified in primary care settings, the pooled odds ratio compared to a control group was 2.2 [95% CI 1.7, 2.8] for long-term smoking abstinence (Papadakis et al. 2010, 199-213).

1.9.2 We do not know the optimal mix of intervention components

There has been considerable variability in the choice of intervention components used within evaluations of multi-component intervention programs. Interventions tested to date have included a combination of provider training (100%), screeners (40%), desktop resources (20%), performance feedback (40%), academic detailing (40%), adjunct counselling (50%), and cost-free pharmacotherapy (50%) (Papadakis et al. 2010, 199-213). Despite strong evidence to support the efficacy of multi-component interventions, it is unclear which individual intervention components are necessary to produce the desired outcomes as well as the optimal mix of intervention components. Understanding whether higher-cost intervention strategies, such as extended follow-up counselling, are in fact necessary to produce increased rates of smoking cessation requires further investigation.

1.9.3 Extended follow-up counselling

The provision of extended follow-up counselling for patients making a quit attempt has been shown to increase success with quitting (Rigotti, Munafo, and Stead 2007, CD001837; Fiore et al. 2008; Stead, Bergson, and Lancaster 2008b, CD000165; Papadakis et al. 2010, 199-213). Given the limited time available in the primary care setting, linking patients to follow-up counselling conducted by individuals external to the practice can serve as a feasible method to "extend treatment" when delivered in conjunction with initial intervention provided by primary care providers (Zhu et al. 2002, 1087-1093; Smith et al. 2009, 47-53). There is good evidence that linking patients identified in primary care settings to supplemental, external smoking cessation counselling is effective in increasing smoking abstinence, as well as increasing the frequency at which providers "arrange" follow-up counselling (Papadakis et al. 2010, 199-213). Borland and colleagues (2008) found referral of primary care smokers to a quit line doubled quit rates compared to the standard in-clinic primary care treatment (Borland et al. 2008, 382-389). Five multi-component interventions have included

extended adjunct counselling in addition to practice and provider-level intervention strategies; each trial was able to document a positive impact on smoking abstinence. However, these data are confounded by the fact that cost-free pharmacotherapies were also provided to patients in all but one of these trials.

1.10 The Ottawa Model for Smoking Cessation (OMSC) in hospitals

The Ottawa Model for Smoking Cessation (OMSC) is a systematic approach to the identification, treatment, and follow-up of hospitalized patients who smoke (Reid, Pipe, and Quinlan 2006, 775-780). The model was developed based on the experience of the University of Ottawa Heart Institute and reflects an application of a 5As approach to cessation (ask, advise, assess, assist, and arrange) customized for the hospital setting (Fiore et al. 2008). The aim of the OMSC is to increase the number of patient who smoke who achieve long-term abstinence following hospitalization. This is accomplished by systematically identifying and documenting the smoking status of all admitted patients; providing evidence-based, best practice clinical interventions for tobacco dependence, including counselling and pharmacotherapy; and ensuring post hospitalization follow-up. Patients are followed after discharge using a unique interactive voice response (IVR) mediated telephone follow-up system (Reid et al. 2007a, 319-326). An evaluation conducted at the University of Ottawa Heart Institute found long-term quit rates increased by 15% (from 29% to 44%) among patients hospitalized for cardiovascular-related illness following implementation of the OMSC (Reid, Pipe, and Quinlan 2006, 775-780). Based on the success of the OMSC, the program has expanded to hospitals across Ontario and Canada, and, in 2010, the OMSC was in place in nearly 70 hospitals in Canada. Reid et al. (2010) recently published an evaluation of the OMSC within nine hospitals in the Champlain District of Ontario. The evaluation found that the introduction of the OMSC in these community hospitals was associated with an increase in long-term smoking abstinence by 11.1% (from 18.3% to 29.4%) at 6-

month follow-up (Reid et al. 2010, 11-18). This evaluation included a more generalized patient population of hospitalized patients who smoke. A multi-component intervention program has been used to introduce the OMSC into hospitals that includes educational outreach visits, provider reminder systems and integration into institutional clinical processes, provider training, and ongoing audit and feedback (Reid et al. 2010, 11-18).

1.11 What new knowledge will be gained through the present study?

In the present study, an adaptation of the OMSC, a multi-component intervention program was tested for use in busy primary settings. Similar multi-component intervention programs have been shown to be effective in increasing the delivery of evidence-based smoking cessation treatments by primary care providers as well as smoking abstinence among patients (Anderson and Jane-Llopis 2004, 299-312; Fiore et al. 2008; Papadakis et al. 2010, 199-213). Multi-component interventions tested to date have used a combination of intervention strategies to influence provider and patient behaviours and create supportive practice environments. Given that many primary care practices report relatively low rates of extended follow-up counselling to patients who smoke, it was hypothesized that creating stronger links to cessation interventions outside of the primary care setting, as part of a systems approach to cessation, may serve to increase the delivery of follow-up counselling and smoking abstinence among patients when delivered as part of a multi-component intervention program. As such, the aim of this study is to compare two interventions for integrating smoking cessation into routine primary care practice as measured by the proportion of patients receiving evidence-based smoking cessation treatments as well as patient quit attempts and smoking abstinence. More specifically, the study seeks to examine the incremental benefit of follow-up counselling (FC) for smokers compared to providing training and practice supports (PS) alone. To my knowledge, this will be the first randomized controlled trial that attempts to isolate the value of patient-level follow-up counselling in the primary care setting when delivered as part of a multi-level intervention. This study will also be the first published evaluation of a multi-component cessation intervention program for primary care tested within the Canadian health care system. The study will provide new knowledge that will assist with informing the design of future programs and policies related to the design and delivery of smoking cessation treatments in primary care settings.

Chapter 2 Research Objectives and Hypotheses

2.1 Study objectives

1. The primary objective of this study was to determine whether adjunct telephone-based smoking cessation follow-up counselling (FC), when delivered as part of a multi-component intervention, is associated with increases in:
   a. the delivery of evidence-based smoking cessation treatments (5As) by primary care providers;
   b. patient quit attempts; and
   c. patient smoking abstinence compared to providing practice and provider supports (PS) alone.

2. The secondary objective of this study was to compare before and after the introduction of the multi-component smoking cessation program increases in:
   a. the delivery of evidence-based smoking cessation treatments (5As) by primary care providers;
   b. patient quit attempts; and
   c. patient smoking abstinence.

3. The study also sought to examine the association between patient, provider, clinic, and implementation factors and study outcomes.

2.2 Hypotheses to be tested

1. Compared to the PS group, clinics assigned to the follow-up counseling group will:

    a. Have a greater increase in the rates at which follow-up support is arranged for patients compared with the PS group with no other changes in 5As delivery;

    b. an increase in the number of patients who report having made a quit attempt at the 4-month follow-up;

    c. a significant increase in patient smoking abstinence measured at the 4-month follow-up .

2. The introduction of both multi-component intervention programs will be associated with increased provider delivery of evidence-based smoking cessation treatments, patient quit attempts, and smoking abstinence compared to pre-intervention rates.

Chapter 3 Considerations for the Design of Smoking Cessation Interventions in Primary Care

3.1 Factors influencing patient behaviours and outcomes

An understanding of the patient characteristics that are known to influence patient motivation to quit and success with smoking abstinence is relevant to the design and interpretation of findings for the present study. A brief summary of knowledge in this area is reviewed here.

Older age and higher levels of education or income have been shown to predict greater success with smoking cessation (Coambs, Li, and Kozlowski 1992, 240-246; D'Angelo et al. 2001, 418-422; Hyland et al. 2004, S363-9; Lee and Kahende 2007, 1503-1509; Haug et al. 2010, 57-64). Mixed information has been published in regards to gender differences in regards to smoking abstinence, with several authors having reported greater cessation rates among males and other studies reporting no differences (Senore et al. 1998, 412-421; Monso et al. 2001, 165-169; National Center for Chronic Disease Prevention and Health Promotion. Office on Smoking and Health. 2001; Burgess et al. 2009, 1439-1447; Haug et al. 2010, 57-64). On average, women smoke fewer cigarettes per day than their male counterparts and have reported greater sensitivity to adverse effects of quitting, such as withdrawal and weight gain (National Center for Chronic Disease Prevention and Health Promotion. Office on Smoking and Health. 2001; Burgess et al. 2009, 1439-1447; Haug et al. 2010, 57-64). Studies have also found cessation pharmacotherapies, such as nicotine replacement therapy, to be more effective in men than in women, which is likely associated with the lower levels of nicotine dependence reported by female smokers compared to male smokers (Cepeda-Benito, Reynoso, and Erath 2004, 712-722). An interaction between gender and employment has been observed in the

literature with quit rates being higher among men who are employed and among women who are employed (Burgess et al. 2009, 1439-1447).

The co-occurrence of smoking with anxiety, depression, and other mental health disorders is well known, with rates of nicotine dependence being three to six times higher in these individuals than in those with no mental health illness (Glassman et al. 1990, 1546-1549; Grant et al. 2004, 1107-1115). A large U.S. population-based survey found that approximately half of those with drug abuse or dependence and 66% of individuals with alcohol abuse or dependence also smoked tobacco (Lasser et al. 2000, 2606-2610). Quit attempts and smoking abstinence among those with anxiety, depression, and other mental health illnesses, as well as substance related disorders, have also been shown to be lower than for the general population of people who smoke (Lasser et al. 2000, 2606-2610; Breslau and Johnson 2000, 1122-1127; Schorr et al. 2009, 347-354; Piper et al. 2010, 13-23).

Nicotine dependence has also been reported as an important factor in predicting long-term cessation in smokers. Individuals with higher levels of nicotine dependence report fewer quit attempts and less success with quitting (Breslau and Johnson 2000, 1122-1127; Hyland et al. 2006, iii83-94; Piper, McCarthy, and Baker 2006, 339-351; Burgess et al. 2009, 1439-1447). Interestingly, those with higher levels of nicotine dependence or those who smoke a greater number of cigarettes have been shown in several trials to benefit from intervention, in particular pharmacotherapies, to a greater extent than those with lower levels of nicotine dependence in regards to success with quitting (Breslau and Johnson 2000, 1122-1127; Hyland et al. 2004, S363-9; Shiffman, Dresler, and Rohay 2004, 83-92; Piper, McCarthy, and Baker 2006, 339-351). The severity of withdrawal and cravings experienced when quitting are also associated with quit rates (Piper et al. 2008a, 94-105; Piper et al. 2008b, 747-761).

One of the best predictors of future smoking abstinence is a patient's confidence (self-efficacy) in his or her ability to quit smoking successfully (Haug et al. 2010, 57-64; Schnoll et al. 2010). Past experience with quitting has been shown to be related to patient self-efficacy. Having made a quit attempt in the last year as well as the duration of past quit attempts has been shown to be positively correlated to success with quitting (Hyland et al. 2006, iii83-94).

Finally, exposure to environmental smoking cues, such as others who smoke in the home, has been shown to be predictive of both fewer quit attempts and poorer cessation outcomes (Garvey et al. 2000, 53-63; Lee and Kahende 2007, 1503-1509; Haug et al. 2010, 57-64). The behavioural cues, social persuasion, and access to tobacco products associated with regular contact with other individuals who smoke, tend to be associated with lower levels of self-efficacy for quitting and exposes the patient to a greater risk for relapse when they do quit.

3.2 Populations reached in the primary care setting

There has been some suggestion that primary care settings may offer exposure to only a limited segment of smokers most likely to seek medical advice (Jaakkimainen et al. 2006). The Institute of Clinical Evaluative Science (ICES) has documented important trends regarding the population of residents who visit a primary care physician annually. Older adults have been found to have more physician office visits than younger adults, with the average number of visits to a family physician for residents under the age 65 being four compared to seven for residents over the age of 65 (Jaakkimainen et al. 2006). Individuals with a chronic disease, including diabetes mellitus, congestive heart failure, or history of heart attack, will visit general practitioners more often than the general population. (Jaakkimainen et al. 2006). There are also groups of residents that tend to access primary care services at lower rates. ICES found the lowest rates of primary care visits are reported among men aged 20-39 years, with one-third of individuals not having seen a General Practitioner (GP) in the

previous 12-months (Jaakkimainen et al. 2006). This is particularly significant given that men are smoking at higher rates than women, and in particular males aged 25-29 have the highest rates of smoking (39%) (CTUMS 2010). This data suggests that the primary care setting may be more likely to reach younger women and older adults, as well as those with an existing disease. Interestingly, there are relatively few differences noted in access to primary services across socio-economic groups (Jaakkimainen et al. 2006). Primary care clinics have access to approximately 64% of residents of any age, gender, or socio-economic grouping, at least once annually. There are limited data to assist with understanding if people who smoke are visiting primary care physicians at the same rate as people who do not smoke (CTUMS 2006).

3.3 Factors influencing provider behaviours in primary care

3.3.1 Mediators and moderators

3.3.1.1 Patient-level

Patient-level factors have been found to influence the rate at which evidence-based cessation treatments are delivered by providers in clinical settings. Studies have also found that patients who have been advised to quit smoking in the primary care setting are most often those with a smoking-related illness (Wynn et al. 2002, 997-999; Martinson et al. 2003, 125-132; Steinberg et al. 2006, 405-412; Azuri et al. 2009, 710-717), are older, (Lucan and Katz 2006, 16-23; Grandes et al. 2003, 101-107), and have higher levels of education (Lucan and Katz 2006, 16-23). Patients who reported higher levels of nicotine dependence and previous quit attempts were also found to receive cessation advice more often (Grandes et al. 2003, 101-107). Advice to quit smoking has been found to be delivered less frequently to men, with young men being advised to quit least often (Lucan and Katz 2006, 16-23).

Increased age, higher socio-economic status, consuming more cigarettes, and having attempted to quit in the past 12 months are associated with receiving assistance with quitting (Browning et al. 2008, 55-61). Steinberg and colleagues (2006) also found that women and older adults are less likely to receive prescriptions for cessation medications (Steinberg et al. 2006, 405-412).

3.3.1.2 Practitioner-level

The delivery of cessation advice has been found to occur at higher rates when the physician reports high levels of self-efficacy to counsel patients (ie., providers' beliefs about their capabilities to effectively counsel patients and/or produce effects) (O'Loughlin et al. 2001, 627-638; Schnoll et al. 2006, 233-239). There has been mixed information regarding the influence of a physician's age on the delivery of cessation interventions, with some studies indicating that younger GPs perform better (Ulbricht et al. 2006, 232-238), whereas other studies have concluded that older physicians are delivering cessation counselling at higher rates (Schnoll et al. 2006, 233-239). Referrals for follow-up support were more commonly arranged by female primary care providers relative to male physicians (O'Loughlin et al. 2001, 627-638; Schnoll et al. 2006, 233-239). Prescribing smoking cessation pharmacotherapies is more common among younger providers with greater self-efficacy (O'Loughlin et al. 2001, 627-638; Schnoll et al. 2006, 233-239).

3.3.1.3 Practice-level

At the level of the practice, higher rates of provider delivery of some evidence-based smoking cessation interventions have been found in practices that have an identified champion (Bentz et al. 2007, 341-349), high clinic volumes, and a higher case mix of patients who smoke (Bentz et al. 2007, 341-349), as well as a higher number of patients in the contemplation stage of quitting (Ulbricht et al. 2006, 232-238) or intentions to quit (Quinn et al. 2005, 77-84).

3.3.2 Barriers to the delivery of cessation treatments in primary care

It has been reported that many practitioners find it difficult to deliver cessation interventions in busy primary care practice environments (Gottlieb et al. 2001, 343-351; Vogt, Hall, and Marteau 2005, 1423-1431; Fiore et al. 2008). In a review of 19 studies, Vogt, Hall, and Marteau (2005) reported several

negative beliefs and attitudes associated with non-compliance with smoking cessation guidelines in the primary care setting (Vogt, Hall, and Marteau 2005, 1423-1431). These factors can be categorized into four main areas: patient, practitioner, practice, and system. The summary of barriers reported at each of these levels is further examined here.

3.3.2.1 Patient-level

Several surveys have identified both patient resistance and a lack of motivation among patients as a frequent barrier reported by primary care providers to the delivery of smoking cessation interventions (Young and Ward 2001, 14-20; Vaughn et al. 2002, 17-31; Marcy et al. 2005, 479-487; Meredith et al. 2005, 929-934; Cantrell and Shelley 2009, 81).

3.3.2.2 Practitioner-level

Multiple surveys conducted in both Canada and internationally have documented low levels of knowledge (Marcy et al. 2005, 479-487; Kunzel et al. 2005, 1144-53; Twardella and Brenner 2005, 140-145; Vogt, Hall, and Marteau 2005, 1423-1431) and self-efficacy (O'Loughlin et al. 2001, 627-638; Vogt, Hall, and Marteau 2005, 1423-1431; Schnoll et al. 2006, 233-239) related to the delivery of smoking cessation counselling among physicians as barriers to the delivery of evidence-based treatments. In particular, a lack of skills and self-efficacy for dealing with low levels of motivation to quit has been documented (Coleman, Cheater, and Murphy 2004, 159-163). The low levels of self-

efficacy and knowledge related to smoking cessation treatments reported by primary care providers may be the result of the lack of training provided in medical and other health professional training programs (Boily, Lavato, and Murphy 2006). A survey conducted by the Canadian Lung Association found that 18% of family physicians have had any formal training in smoking cessation counselling, which would be considered a low percentage (Canadian Lung Association 2003).

Physician beliefs and attitudes are also important correlates of smoking cessation counselling (O'Loughlin et al. 2001, 627-638). In particular, it has been reported that many physicians consider smoking cessation peripheral to their role (Kunzel et al. 2005, 1144-53; Meredith et al. 2005, 929-934; Tong et al. 2010, 724-733). Low expectations among physicians regarding the outcome of their counselling have also been identified as a factor limiting the delivery of cessation treatments (McIlvain et al. 2002, 114-119; Vogt, Hall, and Marteau 2005, 1423-1431). In addition, providers reported a concern regarding damage to their patient-provider relationship when addressing tobacco use (Vaughn et al. 2002, 17-31).

3.3.2.3 Practice-level

Surveys have found time constraints to be a consistent barrier to the delivery of smoking cessation interventions in the primary care setting (Marcy et al. 2005, 479-487; Twardella and Brenner 2005, 140-145; Vogt, Hall, and Marteau 2005, 1423-1431). Meta-analysis data published by Vogt, Hall, and Martineau (2005) found 42% of physicians surveyed reported that discussions about smoking cessation are too time consuming (Vogt, Hall, and Marteau 2005, 1423-1431). Moreover, smoking cessation counselling often competes with other clinical tasks, and few organizational supports are typically found in primary care settings to support systematic interventions with patients who smoke (Okene et al. 1987, 237-340; Steinberg et al. 2006, 405-412; Rothemich et al. 2008, 60-68; Tong et al.

2010, 724-733). Specifically, limitations of internal information systems for flagging, prompting, and performance measurement have been identified as rate limiting (Cantrell and Shelley 2009, 81).

3.3.2.4 System-level

Barriers have also been noted at the level of the health care system that can impede the delivery of smoking cessation treatments. First, primary care practice has been traditionally problem-oriented with a focus on acute or episodic care rather than preventative care (Coleman and Wilson 2000, 1001-1004). In this regard, smoking cessation interventions may be more frequently addressed when a patient presents with a smoking-related illness and/or symptoms rather than with seemingly healthy individuals, therefore detracting from the overall reach of cessation interventions. Second, many physicians report unrealistic expectations placed on them regarding the delivery of preventative health services (Yarnall et al. 2003, 635-641). A lack of smoking cessation experts to whom patients can be referred has also been cited as a barrier for involvement in tobacco treatments (Helgason and Lund 2002, 141-147). Furthermore, a lack of familiarity with the available community-based resources to help patients quit has also been cited in the literature as a barrier, and this has been correlated to low rates of arranging follow-up (O'Loughlin et al. 2001, 627-638; Marcy et al. 2005, 479-487).

The lack of provider incentives and accountabilities for the delivery of evidence-based smoking cessation treatments has been identified as potential impediments to the delivery of cessation services in primary care (Okene et al. 1987, 237-340; Steinberg et al. 2006, 405-412; Curry et al. 2008, 411-428; Rothemich et al. 2008, 60-68). In Ontario, where the present study was conducted, there are two health insurance plan billing codes to support the delivery of smoking cessation services by primary care providers (Ontario Ministry of Health and Long-Term Care 2009). This includes a $15.00 billing fee for providing advice to quit smoking, which can be billed once annually. A second

$34.00 billing fee is available for follow-up smoking cessation counselling. Practices working in group-based models receive an additional bonus of $8.00 for smoking cessation counselling.

3.4 Strategies to enhance provider delivery of smoking cessation treatments

Several strategies have been tested with respect to their roles in increasing the uptake of evidence-based smoking cessation treatments by primary care practitioners as well as increasing smoking abstinence among patients in primary care settings. A systematic review and meta-analysis was undertaken to identify the impact of available controlled trial evaluations that reported on the impact of available strategies on the rates at which primary care providers deliver 5As treatments to patients as well their impact on patient smoking abstinence. The review methods and detailed results have been published elsewhere (see Appendix A) (Papadakis et al. 2010, 199-213). A synopsis of the findings are discussed here and presented in Table 1.

3.4.1 Extended adjunct counselling

Evidence was found to support the importance of linking patients who smoke, as identified in primary care settings, to supplemental smoking cessation counselling delivered outside of the standard medical appointments. Extended adjunct telephone counselling has been shown to increase smoking abstinence, as well as increase the frequency at which providers are arranging follow-up counselling (Rigotti, Munafo, and Stead 2007, CD001837; Fiore et al. 2008; Stead, Bergson, and Lancaster 2008b, CD000165; Papadakis et al. 2010, 199-213). The pooled odds ratio of long-term (> 6-months) smoking abstinence for adjunct counselling compared to controls was 1.7 [95% CI 1.5, 2.0] (Papadakis et al. 2010, 199-213).

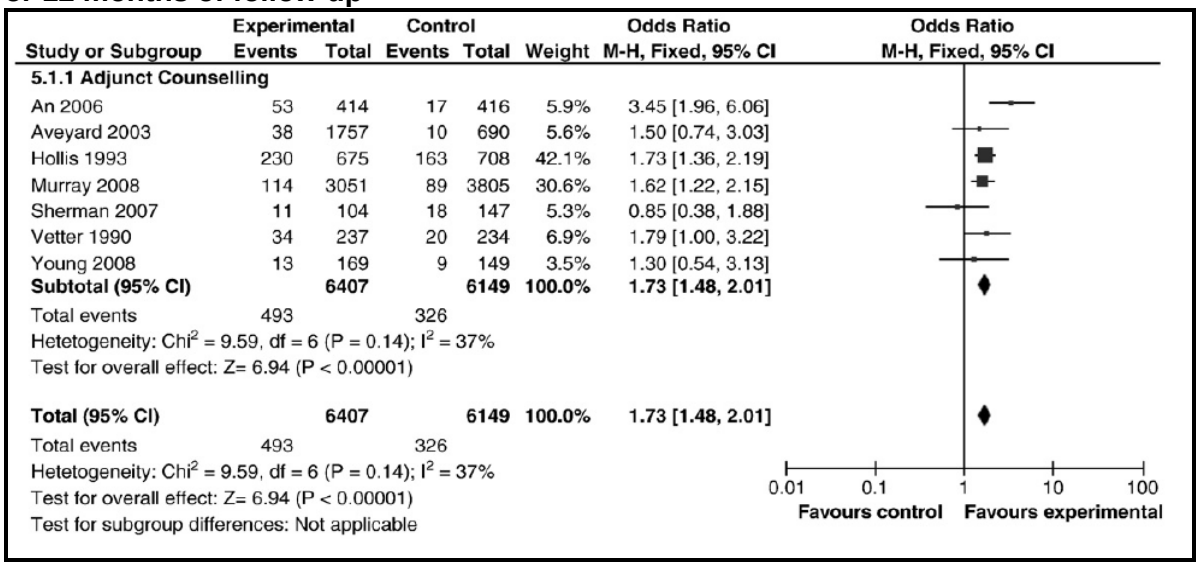
Table 1: Pooled odds ratio of 5As delivery for patient-level, physician-level, practice-level, system-level and multi-component intervention strategies delivered in primary care settings

Intervention	Smoking Abstinence		Ask		Advise		Assess		Assist Meds		Assist Quit Date		Assist		Arrange	
	k	*OR [95%CI]*	*k*	*OR [95%CI]*	*k*	*OR [95%CI]*	*k*	*OR [95%CI]*	*k*	*OR [95%CI]*	*k*	*OR [95%CI]*	*k*	*OR [95%CI]*	*k*	*OR [95%CI]*
Patient-Level																
Adjunct Counselling	7	1.7 [1.5, 2.0]	1	2.0 [1.7, 2.3]	1	1.6 [0.9, 2.8]	-	-	2	6.3 [4.5 ,8.8]	-	-	-	-	3	13.8 [9.9, 19]
Tailored Print	2	1.5 [1.1, 2.1]	-		-	-	-	-	-	-	-	-	-	-	-	-
Practitioner-Level																
Training	2	0.9 [0.62,1.3]	1	1.3 [1.0, 1.7]	-	-	-	-	-	-	-	-	-	-	-	-
Performance Feedback		-	2	2.9 [0.8, 11.2]	2	1.4 [0.8, 2.3]	1	2.9 [1.4, 5.9]	-	-	-	-	2	9.4 [5.2, 17.2]	1	47.4 [2.8, 795]
Practice-Level																
Screeners/Vital Stamp	2	0.9 [0.8, 1.0]	3	1.4 [1.3, 1.6]	3	0.6 [0.5, 0.6]	-	-	1	0.6 [0.5, 0.8]	1	0.6 [0.4, 0.7]	-	-	1	0.3 [0.2, 0.4]
Checklist	-	-	-	-	-	-	-	-	-	-	-	-	1	6.9 [3.8, 12.6]		-
Electronic Prompts	-	-	4	1.7 [1.4, 1.9]	1	1.4 [1.2, 1.6]	2	2.3 [2.0, 2.6]		-		-	2	1.2 [1.0, 1.3]	1	2.3 [1.9, 2.8]
Academic Detailing	1	1.0 [0.63, 1.5]		-	1	1.3 [1.0, 1.6]		-		-		-		-	1	0.7 [0.6, 0.9]
System-Level																
Provider Incentives	1	1.2 [1.0, 1.5]	1	1.4 [1.2, 1.6]	1	1.1 [0.8, 1.5]	-	-	-	-	-	-	-	-	1	2.9 [2.6, 3.3]
Multi-Component	7	2.2 [1.7, 2.8]	6	1.8 [1.6, 2.1]	7	1.6 [1.4, 1.8]	3	1.9 [1.4, 2.7]	5	3.5 [2.8, 4.2]	4	9.3 [6.8, 12.8]	1	1.2 (0.8-1.9)	1	8.5 [5.1, 14.2]

Source: Papadakis, S., et al. 2010. Strategies to increase the delivery of smoking cessation treatments in primary care settings: A systematic review and meta-analysis. *Preventive medicine* 51, no. 3-4:199-213.
Includes studies published before January 1, 2009.
k=number of studies. Odds ratios (OR) and 95% CI have been adjusted to reflect clustering for all trials who reported ICC values within the publication.

Figure 1 presents a forest plot for the seven randomized controlled trials that reported on the efficacy of adjunct counselling delivered to patients identified in primary care settings on smoking abstinence. It is worth noting that several of these trials did not document a significant effect resulting from extended counselling. Many of the trials have varied in the intensity, format, and population of people who smoke involved. Additional research is required to strengthen evidence to support the value of adjunct counselling in enhancing 5As delivery; at present, the main impact appears to be on the rates of long-term patient smoking abstinence.

Figure 1: Forest plot for adjunct smoking cessation counselling delivered in the primary care setting compared to control group on smoking abstinence measured at 6 or 12 months of follow-up



Source: Papadakis, S., et al. 2010. Strategies to increase the delivery of smoking cessation treatments in primary care settings: A systematic review and meta-analysis. *Preventive medicine* 51, no. 3-4:199-213.
Includes studies published before January 1, 2009.

3.4.2 Provider training

Provider training has been shown to have limited influence on patient smoking abstinence when delivered in isolation (Kottke et al. 1989, 2101-2106; Lennox et al. 1998, 140). The two published controlled trials of training-based interventions delivered to primary care practitioners did not include 5As delivery as a study outcome. A review by the Cochrane Collaboration, which included quasi-experimental designs, found that practitioner training was associated with a positive effect on the rates of delivery of cessation interventions; however, only two of the eight trials were able to document an increase in smoking abstinence resulting from training-based interventions (Lancaster, Silagy, and Fowler 2000, CD000214). A second review found insufficient evidence to recommend provider education systems as stand-alone interventions, but did recommend provider education when delivered as part of other system changes such as system-prompts (Fiore et al. 2008). These findings are consistent with a review by the
Cochrane Collaboration regarding the efficacy of educational meetings on a broader array of professional practice areas and health outcomes that found training-based interventions alone are not likely to be effective for changing complex behaviours (Forsetlund et al. 2009, CD003030). Thus, evidence would suggest training is necessary, but not sufficient to achieve meaningful influence on key smoking outcomes.

3.4.3 Provider performance feedback

Two trials evaluated the efficacy of audits and practitioner feedback on performance in the delivery of smoking cessation treatments as compared to peer-established benchmarks (Andrews et al. 2001, 415-421; Bentz et al. 2007, 341-349). Bentz et al. (2007) found a significant increase in rates of

"asking" or "advising" compared to controls (Bentz et al. 2007, 341-349). Andrews and colleagues (2001) were not able to document an increase in rates or "asking" or "advising"; however, they did show an increase in rates of "assisting" and "arranging" follow-up compared to controls (Andrews et al. 2001, 415-421). A review that included a broader array of preventative interventions delivered in primary care settings documented a small to moderate benefit of performance-feedback on provider behaviours, with the greater effectiveness observed among providers with low baseline compliance to the recommended practice and among those trials in which feedback was delivered more intensively (Jamtvedt et al. 2006, CD000259). Further research is required to better understand the possible impact of performance-feedback on 5As delivery and also on rates of smoking cessation.

3.4.4 Practice supports

Screening systems such as waiting room screeners and the inclusion of smoking status on the clinic vital signs stamp have been found to be effective in increasing the rates of "asking" and "advising", but no effect was documented in the rates at which other 5As strategies are delivered by primary care providers (Papadakis et al. 2010, 199-213; Rothemich 2010, 367-374; Seale et al. 2010, 18). These findings suggest screening tools must be coupled with other strategies as part of any systematic approach to addressing smoking.

Real-time provider prompts have been found to increase the delivery of evidence-based smoking cessation by primary care providers. Dubey and colleagues (2006) looked at the effect of a one-page reminder checklist that prompted practitioners to provide evidence-based recommendations for preventive interventions and found a significant increase in the rate at which cessation "assistance" was documented in patient charts (Dubey et al. 2006, 44). Milch et al. (2004) found that an expanded screener, which included five questions for assessing patient smoking status, readiness to quit, and counselling prompts, outperformed both control group and vital stamp group in increasing smoking

abstinence (Milch et al. 2004, 284-294). Evidence from four trials found electronic medical-record (EMR) prompts increased the rates at which practitioners are “asking” about smoking status [OR 1.65; 95% CI 1.4, 1.9] (Weingarten, Bazel, and Shannon 1989, 120-124; Bonevski et al. 1999, 478-486; Frank, Litt, and Beilby 2004, 87-90; Szpunar et al. 2006, 665-673). Furthermore, evidence from a smaller pool of trials was also found to support the value of EMR prompts on the delivery of the other 5As strategies in primary care clinic settings. Further research is required to confirm the added value of EMR prompts in increasing smoking outcomes.

3.4.5 Outreach facilitation and academic detailing

Outreach facilitation or academic detailing is a form of educational outreach in which intervention is provided to practitioners in their offices by a trained health care provider to support quality improvement in a particular area of practice (Goldstein et al. 2003, 185-196). A single controlled trial has been published that examined the efficacy of an academic detailing intervention on smoking cessation in the primary care setting. The intervention included visits to the clinic during which support with developing a quality improvement plan, support facilitating changes to the practice, and feedback and monitoring during implementation of practice changes was addressed (Yano et al. 2008). The study documented a significant impact on rates of “advising”. A small observational pilot study involving four primary care clinics found an outreach facilitation intervention for supporting the uptake of tobacco control guidelines was acceptable to primary care providers and resulted in improvements in the delivery of smoking cessation treatments to patients (Swartz et al. 2002, S38-S44). Although there is limited experience with outreach facilitation in tobacco control, there is a significant body of evidence to support the efficacy of outreach facilitation in increasing the delivery of other evidence-based guidelines and prevention practices in primary care settings (

Goodwin et al. 2001, 20-28; Lemelin, Hogg, and Baskerville 2001, 757-763; O'Brien et al. 2007, CD000409; Hogg et al. 2008, 40-48; Hogg et al. 2008, 40-48).

3.4.6 Financial incentives

Two randomized controlled trials examined the impact of financial incentives for practitioners within the primary care setting. Roski et al. (2003) found no effect on smoking abstinence rates was achieved by providing providers with a performance bonus for achieving performance targets for 5As delivery, but they did document a small increase in the rates at which providers "asked" patients about smoking status (Roski et al. 2003, 291-299). A second trial found incentives increased the rates at which providers referred patients to a quit line (An et al. 2008, 1993-1999). This finding supports reports by previous authors that financial incentives alone do not address the barriers to delivering cessation intervention in primary care practice and, as such, are insufficient to transform outcomes of interest (Coleman et al. 2001, 435-436; Coleman 2010).

3.4.7 Cost-free cessation medications

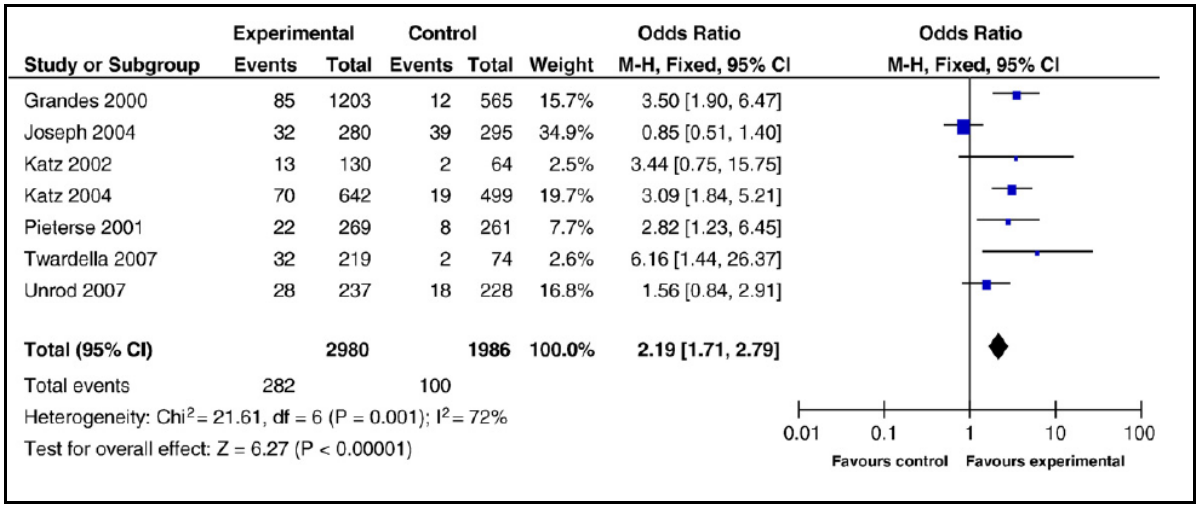
No published studies have examined, in isolation, the provision of cost-free medication to patients in the primary care setting. Several multi-component interventions included cost-free NRT in addition to other interventions and are described below (Grandes, Cortada, and Arrazola 2000, 803-807; Katz et al. 2002, 293-301; Young, D'Este, and Ward 2002, 572-583; Katz et al. 2004, 594-603; Twardella and Brenner 2007, 15-21;).

3.4.8 Multi-component interventions

Multi-component interventions appear to hold the most promise for influencing practitioners' behaviours and have been shown to improve cessation rates among patients. Multiple large-scale

controlled trials have demonstrated an impact on physician behaviours and patient cessation rates. Ten studies involving 13,831 patients were identified that evaluated multi-component interventions. The pooled OR calculated for multi-component interventions compared to control for provider performance showed significant increases in 5As delivery within intervention practices: “ask” [1.79, 95% CI 1.6, 2.1], “advise” [1.6, 95% CI 1.4, 1.8], “assess” [1.9, 95% CI 1.4, 2.7], “assist” with medications [3.45, 95% CI 2.8, 4.2], “assist” with setting a quit date [9.3, 95% CI 6.8, 12.8], and “arrange” [8.5, 95% CI 5.1, 14.2] (Papadakis et al. 2010, 199-213). The pooled OR of smoking cessation calculated for a multi-level intervention compared to control is 2.2 [95% CI 1.7, 2.8] (Papadakis et al. 2010, 199-213). The forest plot for smoking abstinence among identified controlled trials of multi-component interventions in the primary care setting is presented in Figure 2. These findings are consistent with an earlier review that found that multi-component interventions, which combine education and practice-based supports, to be more effective than single component programs involving either education or practice-based approaches alone (Anderson and Jane-Llopis 2004, 299-312).

Figure 2: Forest plot for multi-component intervention program delivered in primary care settings compared to control group on smoking abstinence measured at 6 or 12 months of follow-up



Source: Papadakis, S., et al. 2010. Strategies to increase the delivery of smoking cessation treatments in primary care settings: A systematic review and meta-analysis. *Preventive medicine* 51, no. 3-4:199-213.
Includes studies published before January 1, 2009

All of the multi-component interventions identified in the review employed between two and six sub-component strategies within the intervention. The two trials that used only two intervention components produced ORs for smoking abstinence of less than 2.0; those that employed three or more components resulted in ORs for smoking abstinence between 2.8 and 6.4. There was considerable variability in the components evaluated within the multi-component intervention models (see Figure 3).

Figure 3: Overview of the intervention components used within multi-component smoking cessation interventions in primary care settings

Author (publication year)	Patient level	Provider level		Practice level			System level		Number of intervention components	Number of levels targeted
	Counselling	Training	Feedback	Screener	Desktop resource/tools	Academic detailing	Incentive	Free NRT		
Puschel et al. (2008)		•				•			2	2
Unrod et al. (2007)		•			•				2	2
Twardella and Brenner (2007)		•					•	•	3	2
Joseph et al. (2004)		•				•			2	2
Katz et al. (2004)	•	•	•	•				•	5	4
Young et al. (2002)	•	•	•	•		•		•	6	4
Katz et al. (2002)	•	•	•	•				•	5	4
Pieterse et al. (2001)	•	•		•					3	3
Grandes et al. (2000)	•	•			•			•	4	4
Kottke et al. (1992)		•	•			•			3	2

Source: Papadakis, S., et al. 2010. Strategies to increase the delivery of smoking cessation treatments in primary care settings: A systematic review and meta-analysis. *Preventive medicine* 51, no. 3-4:199-213.
Includes studies published before January 1, 2009

3.5 The role of behavioural theory in guiding intervention design

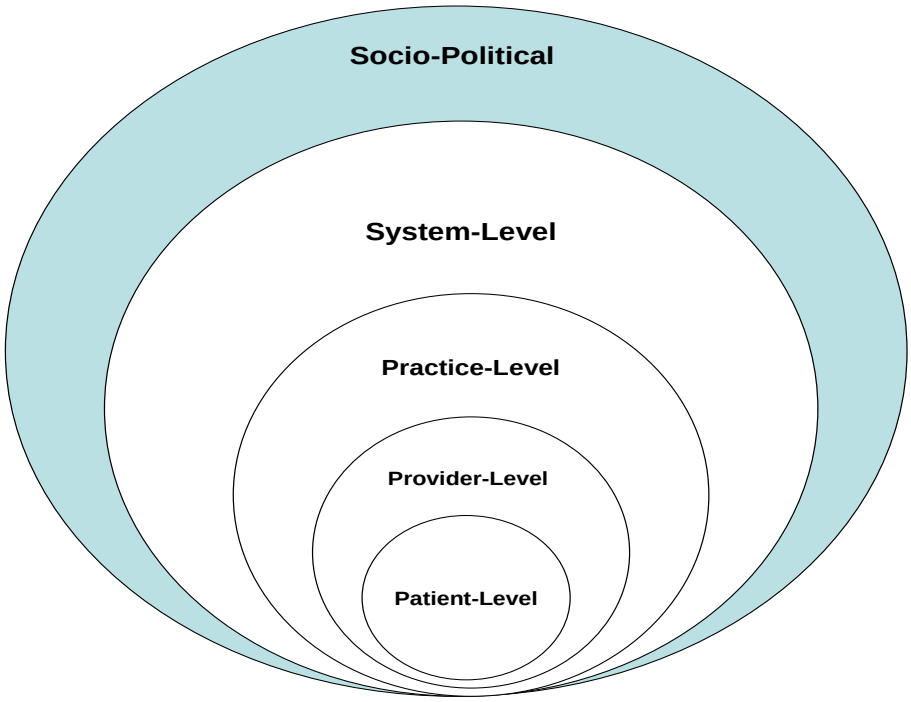
Clinical practice is a form of human behaviour and, as such, theories of human behaviour may provide a basis for developing a scientific rationale for the choice of intervention that would be most useful in influencing primary care providers' behaviours. Two behavioural theories (Socio-Ecological Theory and Social Cognitive Theory) and one adoption theory (Diffusion of Innovation) were selected to guide intervention design. These theories have been rigorously evaluated and assist with examining behaviour in terms of factors amenable to change (Glanz, Rimer, and Lewis 2002). Systems theory was also used to inform intervention design. Systems theory has been shown to be useful when designing interventions in complex settings such as that encountered in primary care practice (Plek 2000, 309-17). These theoretical perspectives are examined here with respect to their roles in informing the design of interventions to influence primary care practitioners' behaviour in the delivery of evidence-based smoking cessation treatments.

3.5.1 Ecological theory

Ecological theory suggests that behaviours are affected by multiple levels of influence, each of which can positively or negatively influence individuals (Bronfenbrenner 1976). Figure 4 depicts a multi-level perspective on key sources of influence on smoking cessation in primary care. This model has been adopted from the model originally introduced by McLeroy and colleagues (McLeroy et al. 1988, 351-377). The figure depicts five levels of influence that affect a physician or other health provider's behaviour. These levels include: (1) patient-level (interpersonal); (2) practitioner-level (intrapersonal factors); (3) practice-level (micro-system factors); (4) system-level (macro-system

factors); and (5) socioeconomic and political factors (exo-system). It is hypothesized that a multi-level intervention will have greater impact on smoking behaviours than focusing on one particular level by itself (Emmons 2000, 242-266; Sallis and Owen 1999, 404-424). According to ecological theory, in order to maximize desired behaviours, interventions must be organized to positively affect the multiple levels of influence to create the conditions necessary to support desired behaviour change (Bronfenbrenner 1976).

Figure 4: Ecological model: Levels of influence on primary care provider behaviours related to the delivery of smoking cessation treatments (Adapted from McLeroy 1988)



3.5.2 Social cognitive theory

Bandura's Social Cognitive Theory (SCT) suggests that personal factors, behavioural factors, and environmental factors interact to produce human behaviour (Bandura 1986). SCT has an important role to play in the design of interventions that target individual level behaviour change and can be useful in identifying modifiable factors associated with the desired behaviour that should be targeted as part of the intervention program. According to SCT, physician and/or patient behaviour is mediated by cognition, and that important determinants of behaviour are: behavioural capabilities (knowledge and skill), outcome expectations (anticipated outcomes of a behaviour), expectancies (value one places on the outcome), self-efficacy (confidence in the ability to perform the behaviour), and perceived environmental facilitators and impediments (Bandura 1986; Glanz, Rimer, and Lewis 2002). Applying SCT to practitioner behaviours suggests that practitioners are most likely to engage in smoking cessation interventions if they believe it is important that they do so, if they believe they are capable of doing so, if they believe they will have a positive effect on patients' smoking cessation, if they have a supportive environment, and if they are rewarded for doing so. Self-efficacy, one's confidence in performing a particular behaviour, is considered within SCT to be the most important personal factor in behaviour change (Bandura 2004, 143-64). Self-efficacy is primarily determined by one's personal experience with the behaviour or other similar behaviours. There are several suggested strategies for increasing self-efficacy for a desired behaviour: (1) skills training; (2) mastery experience (learning from doing); (3) setting incremental goals (breaking behaviours down into small steps to maximize success); (4) behavioural contracting (being specific about the behaviour change); (5) modelling or vicarious experience (learning from others); and (6) social persuasions and environmental supports (encouragements/discouragements) (Bandura 2004, 143-64).

3.5.3 Diffusion of innovation theory

Roger's diffusion of innovations theory provides insight into how best to support wide dissemination of an innovative program such as the delivery of smoking cessation interventions in primary care (Rogers 2003). Diffusion theory can serve to assist with designing the phases of the diffusion process from innovation development, through to matching interventions to environmental context, and integrating smoking cessation activities into the routines of practitioners (Oldenburg and Parcel G. 2002). The theory identifies the important factors to consider in the diffusion process as the characteristics of the intervention, messenger, adopter, system linkages, organizational context, and broader environmental context. Rogers also emphasized the importance between the fit between the intervention and the environmental context. According to the theory, there are several key factors that serve to influence the speed at which an innovation will be adopted and diffused. These factors can be used to guide the selection of possible intervention approaches to maximize appeal and speed of the innovation's diffusion in the target population. Innovations that are most likely to be diffused rapidly are those that are least complicated to implement (complexity), provide an advantage over the existing practice (relative advantage), are most compatible with the intended audience's needs and environment (compatibility), can demonstrate tangible results (observability), and can be tried on an experimental basis (trialability).

3.5.4 Complexity Theory

Primary care practices have been described in the literature as "complex organizations" because they consist of collections of individuals that have the freedom to act in ways that are not always predictable and whose actions are interconnected (Litaker et al. 2006, S30-4; Miller et al. 2001, 872-878). This is particularly true amongst group practices in which a large number of independent providers are housed within the same physical space and may or may not share similar protocols or

processes (Plek 2000, 309-17). Moreover, the attitudes, skills, and self-efficacy of individuals may differ greatly among providers in a single clinic setting, and no two clinics may operate in the same way, therefore making it challenging for simple "one-size-fits-all" approaches to be effective in all primary care settings (Tallia et al. 2003, 45-59; discussion 60-1). Complexity theory emphasizes the importance of adapting to the context within which a practice is situated by encouraging flexibility and local adaptation (Hawe, Shiell, and Riley 2004, 1561-1563; Litaker et al. 2006, S30-4). This can be achieved by identifying characteristics that should be considered in tailoring an interaction to a clinic setting or individual provider within a clinic setting (Stange et al. 2003, 296-300). Having a menu of tools and approaches for achieving a desired outcome is suggested for complex organizations (Hawe, Shiell, and Riley 2004, 1561-1563; Litaker et al. 2006, S30-4). Community organizing and participatory models may also be useful in tailoring intervention to complex settings. Participatory models involve a process by which groups are helped to identify common problems, mobilize resources, and develop and implement strategies to achieve goals (National Cancer Institute 2005). The process focuses on building consensus and capacity and involves social planning and social action. The involvement of key opinion leaders, expert practitioners, and end users in this process has been identified as an important factor in influencing success in achieving intervention goals (National Cancer Institute 2005).

3.6 How theory and evidence was used to inform intervention design

The intervention program was designed using best available evidence regarding the delivery of cessation interventions in the primary care settings. The conceptual model for the intervention program is presented as Figure 5. The model outlines the three levels (patient, provider, and practice) at which the intervention was designed to intervene. Consistent with ecological theory, the intervention aims to create synergies so that the practices, practitioners, and patients are all enabled to

make the required behaviour changes. Social cognitive theory (SCT) was used to further define the intermediary behavioural targets at the level of the practitioner and patient by ensuring the required cognitive factors are in place to support the desired behaviour, including self-efficacy, knowledge and skill, outcome expectancies, goal setting, environmental cues, and social support. Intervention strategies were further informed by strategies known to be effective in introducing process change in complex organizations

At the level of the practice, intervention strategies were informed by strategies known to be effective increasing the uptake of process change in complex organizations. Using the principles of complexity theory and diffusion of innovations, the practice-level strategies were selected to assist with simplifying the delivery of the 5As strategies as a part of routine practice at the clinic (complexity) and create a supportive practice environment. Outreach facilitation visits were used to tailor the 5As delivery to each clinic's practice setting (compatability). This process involved the engagement of clinic staff in the problem solving process and setting behavioural goals for health professionals in supporting 5As delivery. Effort was made to simplify the responsibilities of the physician to advising and assessing readiness of patients to quit. Effort was also made to introduce practice-level supports to assist with the delivery of the remaining 5As (ask, assist, arrange follow-up support). This included specific roles and responsibilities for allied health professionals, flow charts, and the introduction of real time prompts and patient resources. Audit and feedback was provided to the clinic task force and staff as a call to action, and the feedback was provided during the early stages of implementation to assist with identifying gaps between targets and actual performance by clinic staff (observability and relative advantage).

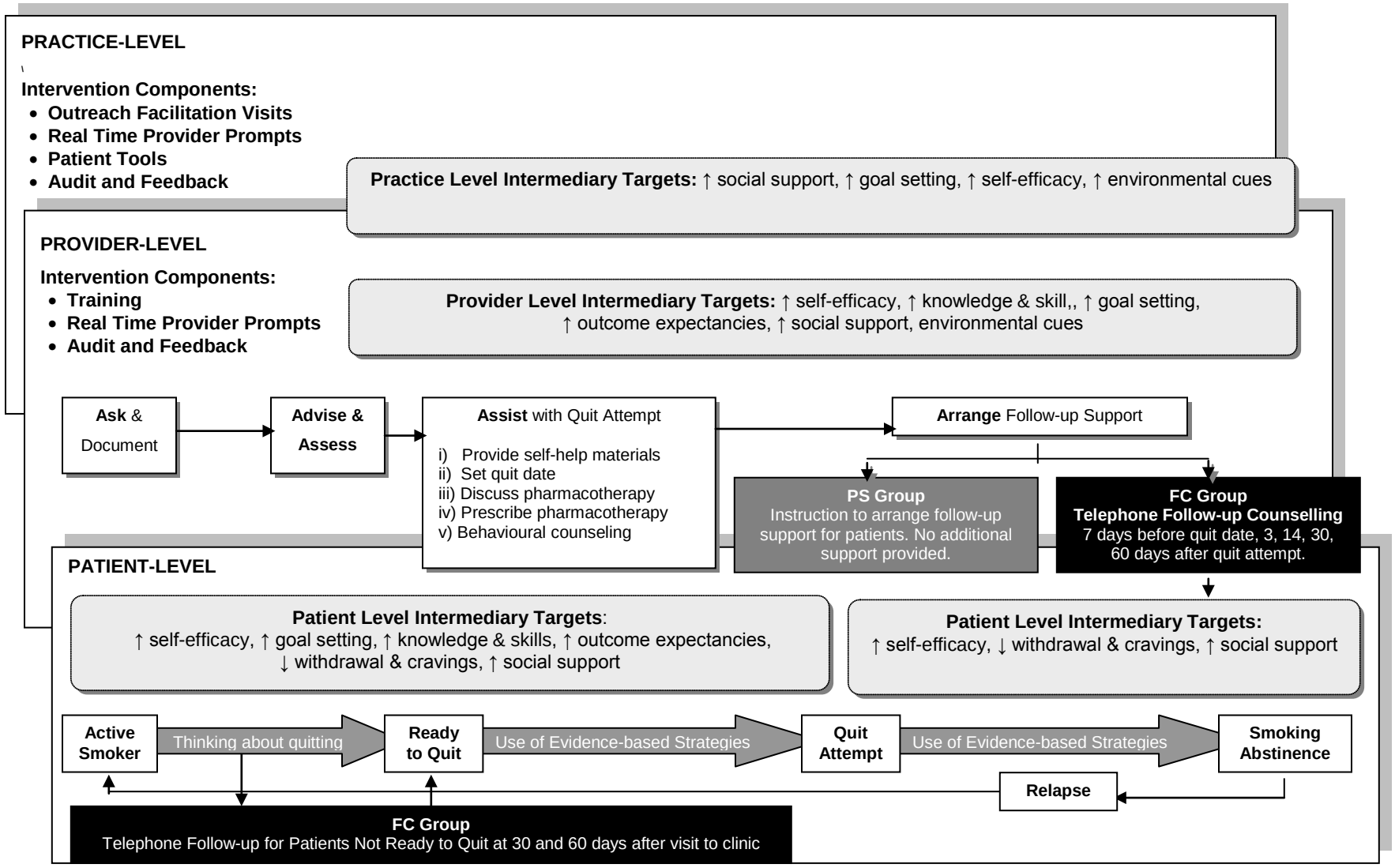
At the level of the provider, three strategies were used to support the delivery of the 5As. These were the introduction of real time provider prompts to cue 5As delivery, smoking cessation

training, and audit and feedback. The intervention strategies were designed to enhance provider self-efficacy, knowledge and skill, outcome expectancies, and provide both practice targets (goals) and environmental cues and supports for the delivery of the 5As tobacco cessation treatments to all patients at all scheduled non-urgent visits.

At the level of the patient, the intervention aims to generate more supported quit attempts by patients identified in the primary care setting. This is achieved by having primary care providers systematically identifying and delivering cessation advice during teachable moments in order to motivate a patient to make a quit attempt and then link patients to evidence-based assistance with quitting (i.e. behavioural counselling and pharmacotherapy) so as to increase the likelihood of successful smoking abstinence.

For practices assigned to the FC group, telephone follow-up counselling support aimed to support patient self-efficacy during the critical early quitting period in which risk for relapse is highest and assist with managing patient withdrawal and cravings. The delivery of this follow-up counselling support was hypothesized to result in more quit attempts and ultimately higher rates of smoking abstinence among patients. FC group clinics were also able to register patients not ready to quit smoking with the telephone follow-up program. The intent was to provide a cue to patients to make a quit attempt and provide more information on available supports to enhance self-efficacy. It was hypothesized that delivering follow-up contacts to patients not ready to quit when seen in clinic was to increase the likelihood that these patients would make a quit attempt relative to patients in the PS group.

Figure 5: Conceptual model for multi-level, multi-component intervention on provider and patient behaviours



Chapter 4 Methods

4.1 Study design

A two-arm pre-post cluster randomized trial design was used to compare two multi-component interventions for integrating smoking cessation treatments into primary care practice routines among family medicine clinics in the Champlain District of Ontario. The study grant allowed for a maximum of eight clinics to be enrolled in the present study. Given that numerous trials have documented the efficacy of multi-component intervention programs compared to a standard-care control group, no control group comparator was employed in the present study. Pre-post measurements were used to document improvements in 5As delivery, quit rates, and smoking abstinence before and after the multi-component intervention program was implemented and comparisons between intervention groups made to isolate the incremental impact of follow-up counselling support delivered to FC study clinics. The study received ethics approval from the Office of Research Ethics at the University of Waterloo and the Human Research Ethics Board at the University of Ottawa Heart Institute. The Consort Flow Diagram for the study is presented as Figure 6.

4.2 Clinic recruitment and sampling

To be eligible to take part in the present study, clinics were required to be involved in a group-practice (i.e., health team, family health group, or family health network) with a minimum of five full-time physicians on staff and all physicians within the practice be willing to participate in the study. The criteria related to the minimum of five providers was selected to ensure adequate patient flow through the clinic to ensure data collection activities could be completed within the study timelines. Permission was granted from the Department of Family Medicine (DFM) at the University of Ottawa to access the distribution list for family physicians practicing in the Champlain District. At the time of recruitment into the present study, the DFM was also recruiting clinics for another study in sub-regions of the Champlain District. At the request of the DFM, only primary care practices from three

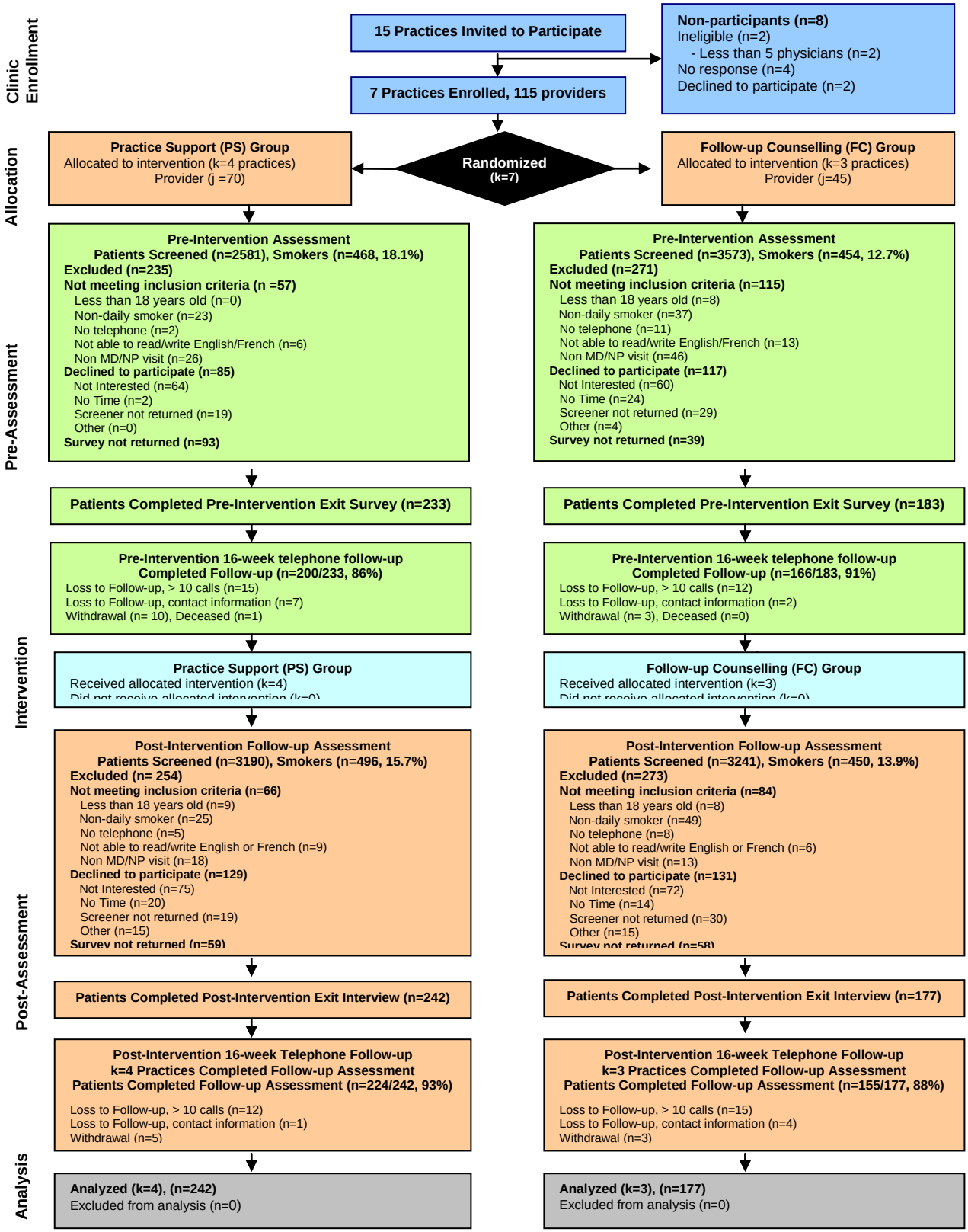
geographic sub-regions within the Champlain District which were not part of the DFM's trial were approached about participating in the present study. A total of 15 group-based family medicine clinics from three sub-regions (Eastern Counties, South Ottawa, and Ottawa Central) in the Champlain District who had five or more physicians were invited to participate in the study in January 2009. A study-invitation letter and program summary was sent to the lead physicians of these clinics (see Appendices B and C).

Of the 15 clinics invited to participate, two had less than five physicians practicing at the clinic during the study time period and were considered ineligible. An additional two clinics declined participation and no response was received from four of the invited clinics. Seven family medicine practices with 115 providers were enrolled in the study between January 2009 and April 2009. This represents an enrollment rate among eligible practices of 54% (7/13). All physician providers from participating clinics were asked to sign the study information sheet and consent form (see Appendix D). All practitioners at participating clinics were asked to complete a survey to assess variables of interest (see Appendix E). The following practitioner-level factors were evaluated: age; gender; self-rated importance of smoking cessation; knowledge of evidence-based smoking cessation interventions; self-efficacy with delivering each of the 5As; and previous cessation training.

4.3 Allocation to treatment and concealment

Randomization occurred at the level of the practice (k) i.e., cluster. Eligible practices were randomly assigned (1:1) to one of two intervention groups: Practice Support (PS) or Follow-up Counselling (FC). Four practices were randomly assigned to the PS group, and three were assigned to the FC group. Randomization was performed with a table of random numbers generated by a researcher not involved in the study and who was blind to the identity of the practices. Randomization numbers were placed in a sealed envelope and opened by a representative from the practice site following the completion of the baseline data collection. The group assignment was verified by the third party researcher to verify that randomization occurred according to protocol.

Figure 6: CONSORT (Consolidated Standards of Reporting Trials) diagram



Patients and research assistants collecting data from patients were blinded to the clinic's group assignment. It was not feasible to blind the outreach facilitator assigned to the clinic and members of the clinic staff to the intervention group assignment.

4.4 Clinical framework used for the delivery of evidence-based (5As) smoking cessation treatments to patients

All clinics were supported with the implementation of an adaptation of the "Ottawa Model for Smoking Cessation" designed for use in the present trial. Practices were encouraged to systematically deliver a standardized smoking cessation intervention that included: (1) *asking* all patients at every visit about smoking status; (2) delivering clear, personalized *advice* to quit smoking to all patients who smoke and *assess* readiness to quit in the next 30 days; (3) providing *assistance* to patients ready to quit smoking in the next 30 days by conducting a quit plan consultation session during which a quit date is selected, options for quit smoking medications and instructions are discussed and prescription provided as appropriate, and strategic behavioural counselling to address cravings, withdrawal, and social-environmental factors related to quitting smoking; (4) offering patients ready and not ready to quit smoking follow-up support (*arrange*). In order to increase feasibility of delivering all aspects of the Ottawa Model for Smoking Cessation, clinics were encouraged to integrate the protocol into existing clinic routines and to develop a team-based approach in which non-physician clinic staff would share the responsibility for delivering evidence-based smoking cessation treatments with physicians. Table 2 provides a description of the recommended intervention components to be delivered to patients as part of the clinics' tobacco control protocol.

Table 2: Summary of the recommended patient-level intervention activities for FC and PS groups

Intervention Components	Time	Recommended Team Member	Description
Ask and document smoking status of all patients	30 seconds	Reception or Triage Nurse	- All patients asked about current smoking status ateach visit, using the following two screening questions: *"Have you used any form of tobacco in last 7 days?" "Have you used any form of tobacco in last 6 months?"* - Recommendation to have asking and documenting of patient smoking status conducted by non-physician staff.
Advise all smokers to quit	1 minute	Physician or Nurse Practitioner	- Clear, personalized, non-judgmental advice to quit with offer of support with quitting delivered in 1 to 2 minutes by physician or nurse practitioner.
Assess readiness to quit and support motivation	1-3 minutes	Physician or Nurse Practitioner	- Readiness to quit assessed: *"Are you willing to set a quit date in the next 30 days?" Yes or No* - Provide brief 1 to 2 minutes of motivational intervention for smokers not ready to quit. - Schedule quit plan consult session for smokers ready to quit.

Quit plan consult (Assist)	15 to 25 minutes	Allied Health Professional (Nurse, Nurse Practitioner, Pharmacist) or Physician	- A 15-20 minute consult scheduled to develop a personalized quit plan with patients, including:
			  - Select quit date;
			  - Select pharmacotherapy;
			  - Prepare environment and social supports;
			  - Discuss management of cravings, withdrawal, triggers and temptation to smoke;
			  - Discuss follow-up support.
			- Recommendation to have quit plan consult sessions delivered by non-physician staff.

Arrange follow-up support and counselling	Varies		Recommendation that provider arrange for follow-up support in accordance with best practice guidelines 2 to 4 weeks following the patient's quit attempt.

4.5 Intervention comparators

4.5.1 Practice Support (PS) Group

Clinics assigned to the PS intervention group were supported in implementing the 5As strategies using a multi-component intervention program that involved four components: (1) real time provider prompts and patient tools; (2) training; (3) audit and performance feedback; and (4) coaching and outreach facilitation visits. The intervention components were selected based on a review of the literature of evidence-based strategies for integrating smoking cessation into primary care settings (see Chapter 2). Each intervention component was designed to address a barrier that is known to limit the delivery of smoking cessation treatments in primary care settings. The conceptual model of the expected impact of each intervention component on the underlying behavioural constructs at the level of the patient, provider, and practice was presented as Figure 5. A description of each of the intervention components is provided here and summarized in Table 3.

Real time provider prompts and patient tools: Practices were provided with five tools to support the integration of evidence-based cessation practices into brief clinical encounters as part of a practice-level strategy including: (1) a tobacco use survey; (2) smoking cessation consult form; (3) patient quit smoking plan; (4) booklet for smokers not ready to quit; and (5) clinic posters. The intervention tools were designed to minimize the amount of time required for clinicians to provide basic counselling on smoking cessation and provide real time prompts to guide the delivery of evidence-based smoking cessation treatments. All of the practice tools were developed for the present study and adapted from existing publicly available Canadian tools to meet the needs of busy primary care clinics. Clinics were able to adapt the tools to conform to the clinic's tobacco control protocol. The *Tobacco Use Survey* is designed to assess the current smoking status of patients and to gather information regarding a patient's smoking history and readiness to quit (see Appendix F).

Table 3: Summary of multi-component intervention program components for PS and FC groups

Intervention Components	PS	FC	Description
Outreach Facilitation Visits	X	X	- Formation of clinic smoking cessation task force; - Review of current clinic practices in the delivery of evidence-based smoking cessation intervention and needs assessment; - Provide information and recommendations on the integration of evidence-based smoking cessation strategies into clinical practice; - Facilitate development of clinic tobacco control protocol for integrating evidence-based smoking cessation strategies into all clinic appointments; - Define roles and responsibilities of clinic staff in delivering evidence-based smoking cessation treatments; - Support communications and training activities for members of the clinic staff.
Practice Tools and Real Time Reminders	X	X	- Standardized smoker identification intake questions; - Tobacco Use Survey; - Smokers Consult Form; - Patient Quit Plan for Smokers Ready to Quit; - Booklet for Smokers Not Ready to Quit; - Clinic waiting room posters and materials.
Training Clinic Staff	X	X	- 1 to 3-hour training workshop on smoking cessation and the intervention program for all clinic providers (physicians, nurses, allied health professionals); - A 1-day workshop to designated clinic staff who will be responsible for counselling smokers ready to quit.
Audit and Feedback	X	X	- Feedback report on results of pre- and post-intervention assessments; - Audit and feedback of implementation activities 1 to 2 months following initiation of intervention program.
Follow-up Support and Counselling	X		**Practice Support (PS) Group:** - Clinics provided with guide for conducting follow-up visits with smokers ready to quit and recommendation made to provide 1 to 2 follow-up contacts over a 2-month period. - No further support provided.
		X	**Follow-up Counselling (FC) Group:** - Ability to refer patients ready to quit smoking to the telephone-based Smoker's Follow-up System which includes five triage calls over a 2- month period delivered by Interactive Voice Response System with support for patients struggling with their quit attempt by trained smoking cessation counsellors. - Ability to refer smokers not ready to quit to receive two automated Interactive Voice Response calls to reassess readiness to quit and link patients who are interested in making a quit attempt to a smoking cessation counsellor.

The smoking cessation *Consult Form* (see Appendix G) is designed to provide clinicians with real-time prompts for the delivery of evidence-based cessation strategies. The *Quit Smoking Plan* consists of an

18-page booklet that is designed for clinicians to use when creating a quit plan with patients ready to quit smoking, including the selection of pharmacotherapy, the identification of a quit date, and behavioural counselling in preparation for the quit date (see Appendix H). *Posters* for clinic waiting rooms were also provided to serve as environmental cues (see Appendix I).

Provider Smoking Cessation Training: All clinic providers were invited to take part in a 3-hour training workshop on smoking cessation. One workshop was organized for each clinic and best effort made to have all or most providers who would be involved in the clinic's tobacco control protocol attend. The goal of the provider training was to increase knowledge, motivation, and self-efficacy regarding the delivery of evidence-based smoking cessation treatments within a busy primary care practice, including brief counselling and advice and pharmacotherapy. The workshop was delivered by the student investigator and a physician with expertise in smoking cessation who is considered a key opinion leader (A. Pipe). The training provided information on nicotine addiction, the importance of smoking cessation, an overview of available quit-smoking medications and indications for use, recommended methods for identifying and advising smokers to quit, assessing readiness to quit, and providing minimal intervention counselling for smoking cessation and follow-up support. All core training materials were standardized, and supplemental information was tailored to the unique needs of the clinic as required. During the workshop, representatives from the clinic smoking task force presented the clinic's tobacco control protocol to participants and the roles and responsibilities of clinic staff. The workshop was accredited

by the College of Family Physicians of Canada. Each clinic also identified one to six staff to attend a

one-day workshop on smoking cessation counselling. This workshop targeted staff designated to deliver the quit plan visits with smokers from their clinic who were ready to quit in the next 30 days. The training workshop provided participants with didactic training on counselling techniques using a motivational interviewing framework, first-line smoking cessation pharmacotherapies, and the use of the intervention practice tools. The workshop also provided practical experience in conducting counselling sessions with mock patients using a set of eight standardized patient case studies. Actors were used to play the role of patients who smoke during the mock patient interviews and all providers were guided through how to effectively conduct a quit plan visit and were provided feedback on their counselling techniques. A total of six 1-day workshops were delivered by the student investigator (S. Papadakis) and a nurse (S. Gocan) with expertise in smoking cessation.

Audit and Feedback: All practices received feedback on the results of the pre-intervention assessment conducted within their practices (see Appendix J). This feedback included prevalence of smoking among clinic patients, patient-rated importance of provider advice to quit, characteristics of smokers, and baseline rates of 5As delivery by clinic staff. The goal of the audit and feedback was to increase provider self-efficacy in the delivery of smoking cessation interventions, raise awareness of the current delivery of evidence-based cessation practices, identify areas for improvement, and motivate providers to deliver evidence-based treatments. The practices were provided with regular feedback on the design of the intervention protocol against known best practices and feedback on at least one audit of the practice implementation by the facilitator. Practices were also audited on implementation of the 5As on two separate dates during the first two months of implementation. The purpose of the audit was to identify any areas of the clinic protocol that were not implemented as planned or areas for improvement. All practices also received a feedback report on the results of the

clinic audits. Clinics also received the results of the post-intervention assessment at the conclusion of the study (see Appendix K).

Coaching and Outreach Facilitation Visits: Each practice received one to five days of support over a three-to six-month period to support the implementation of the intervention components. A member of the investigative team served as the practice facilitator and conducted on-site visits with patients to support the implementation of the intervention components. The purpose of the outreach facilitation visits was to guide practices with the integration of evidence-based cessation practices into existing clinic routines, including a clinic specific tobacco control protocol. A seven-step workplan was used to guide the facilitation process (see Appendix L). Practices were first asked to complete a needs assessment that would be used to understand the profile and current activities of the clinic related to smoking cessation and clinical flow (see Appendix M). Practices were also asked to identify representatives from the clinic staff to sit on a smoking cessation task force to guide the adoption of a tobacco control protocol for the clinic and support implementation activities. The task force met with the outreach facilitator between three and six times. At the first meeting of the clinic task force, the facilitator delivered a brief presentation of evidence-based strategies for smoking cessation and reviewed the intended use of the practice support tools and the workplan for guiding implementation activities. At the second and third outreach facilitation meetings, the clinic task force was guided through the development of tobacco control protocol for their clinic based on the 5As strategies. The goal of the protocol was to define roles and responsibilities of members of the clinic staff in delivering the 5As strategies to all smokers at each visit. The task force members were responsible for implementing the agreed upon protocol into practice and working with the facilitator to coordinate communications to staff regarding roles and responsibilities and program logistics.

Clinics assigned to the PS intervention group were asked to consider a process by which patients could receive one to two follow-up visits by phone or in person within the first 2 to 4 weeks of a quit attempt as per the USDHHS Clinical Practice Guidelines for Treating Tobacco Use and Dependence (Fiore et al. 2008). Clinics were provided with a written guide on how to structure the follow-up appointments. No further support was provided.

4.5.2 Follow-up Counselling (FC) Group

Clinics assigned to the FC group received the same multi-component intervention program delivered to the PS group. In addition FC intervention clinics were able to refer patients to a smoker's telephone follow-up counselling program. The smoker's follow-up counselling program was facilitated by the use of an interactive voice response (IVR)-mediated telephone follow-up system. The IVR system contacts registered patients via telephone 7 days before their target quit date and 3, 14, 30, and 60 days after their quit date. During the 7-day call, patients were asked to confirm they intended to quit on their scheduled quit date and rank their confidence with quitting. Patients received educational messages that reinforced the importance of quitting and strategies for staying quit, and the availability of support should they struggle with their quit attempt and require the assistance of trained smoking cessation counsellors. During all subsequent calls, the IVR system posed a series of questions concerning current smoking status, confidence in staying smoke-free over the time period until the next planned call, and the use of pharmacotherapy, self-help materials, and other forms of cessation support. Patient responses to the questions posed by the IVR system were monitored by a trained smoking cessation counsellor daily. If the patient indicated that his or her confidence in remaining smoke-free was low (less than 4 on a 5-point scale) or if he or she had resumed smoking, the smoking cessation counsellor contacted the patient to conduct a counselling session. The counsellors tailored counselling according to patient need and worked with patients to develop strategies to deal with high risk situations using cue control, alternatives, pharmacotherapy and/or social support. A counselling

protocol with clinician scripts and protocols was used to guide all counselling contacts with patients. A modified version of the study consult form (see Appendix N) and patient quit plan (see Appendix O) were developed for FC clinics which included information of the smoker's follow-up counselling program.

Providers in the FC group were also able to refer patients who were not ready to quit in the next 30 days, but who reported a willingness to quit smoking in the next 6 months to receive two IVR follow-up telephone calls 30 and 60 days following their clinic visit to reassess readiness to quit. If a patient reported at the 30- or 60-day call a readiness to quit smoking in the next 30 days, he or she was linked back to the clinic to schedule a quit plan visit, or, if preferred, received a 10 to 20 minute counselling session with the smoking cessation counsellor in order to set a quit date and develop a personalized quit plan. The participant could then be enrolled in the 60-day IVR-mediated telephone follow-up and counselling program for patients ready to quit as described above. A *Booklet for Smokers Not Ready to Quit* was created for distribution to patients who indicated they were not ready to make a quit attempt in the next 30 days (see Appendix P). The booklet reinforced the importance of quitting and provided information about the Smoker's Telephone Follow-up Program as well as available community-based cessation programs.

4.6 Measures

4.6.1 Provider performance in the delivery of cessation treatments

Provider performance in the delivery of each of the 5As strategies (ask, advise, assist, assess, and arrange) was assessed via a self-administered survey amongst eligible consenting participants immediately following their clinic appointment. The survey asked participants to respond either "yes" or "no" or "don't know" regarding whether their physician asked them about their smoking status (ask); advised them to quit smoking (advise); assessed their readiness to quit (assess); provided

assistance with quitting (assist); and arranged follow-up support (arrange). The exit survey is presented in Appendix Q. For the "assist" strategy, supplemental data was collected regarding the provision of self-help materials , setting of a quit date , discussing available quit smoking medications, and prescribing quit smoking medications. Participants were also asked if any other member of the clinic staff (e.g., nurse) provided any of the 5As interventions identified above as part of their visit to the clinic that day. These questions have been previously assessed and found to yield reliable responses (Goldstein et al. 1997, 1313-1319). Previous research has also found patient exit surveys regarding 5As delivery to be well correlated with criterion measure of an audiotape assessment of the physician-patient interaction ($r= .67$, $p< .001$) (Pbert et al. 1999, 183-188). Several large trials of multi-component interventions in primary care have used patient exit interviews or surveys to assess rates of 5As delivery (Katz et al. 2002, 293-301; Katz et al. 2004, 594-603; Unrod et al. 2007, 478-484). During the 16-week telephone follow-up assessment, participants were again asked about the delivery of 5As treatments since recruitment into the study to assess the delivery of cessation treatments to patients following their visit to clinic (see Appendix R). It is common practice for a separate visit to be scheduled with patients ready to quit to conduct the "assist" component of the intervention.

4.6.2 Quit attempts

The number of patients who made a quit attempt lasting greater than 24 hours between the completion of the exit survey and the 16-week follow-up was recorded (see Appendix R). The total number of days to relapse for participants who made a quit attempt and returned to active smoking at the time of the 4-month follow-up was also recorded.

4.6.3 Smoking abstinence

Smoking status was assessed at 16 weeks (12 weeks after the estimated quit date) via telephone as defined by: (1) 7-day point prevalence abstinence; and (2) 12-week continuous abstinence. Seven-day point prevalence abstinence was defined as a self-report of not having smoked,not even a puff, in the past seven days measured at the four-month follow-up assessment (approximately 12 weeks after the estimated quit date). Continuous abstinence was defined as not having smoked, not even a puff,, in the previous 12 weeks (between weeks 4 and 16). The interview tool is presented as Appendix R. The NicAlert™ salivary cotinine test was used for bio-chemical validation of smoking status in patients reporting abstinence in the past 7 days. Cotinine is a major metabolite of nicotine and it has a relatively long half-life (10-40 hours). Cotinine has been shown to be more sensitive and specific than carbon monoxide (CO) testing for measuring smoking status (Benowitz 2003, 91-111; Jarvis et al. 1987, 1435-1438). The NicAlert™ salivary cotinine test has a sensitivity of 99% and a specificity of 96% compared to gas chromatography and can be self-administered by study participants (Cooke et al. 2008, 607-612). For patients who reported current use of a Nicotine Replacement Therapy, a CO breath sample was used for biochemical validation using the Smokerlyzer EC50-Micro III. Participants with saliva cotinine concentrations greater than 10ng/ml or a CO reading of <9ppm were considered smokers (Benowitz 2003, 91-111).

4.6.4 Program implementation

Implementation refers to the extent in which the program was implemented as intended (i.e., fidelity of program implementation). A pre- and post-implementation practice survey was completed with a representative from each of the intervention clinics to determine how successful practices were with implementing and maintaining intervention components, including number of providers who attended training, present use of practice tools at clinic, and adoption of the clinic tobacco control protocol. Descriptive data was analyzed and reported as the proportion of practices implementing each

practice strategy. For the FC clinics, data was collected on the number of patients referred to the telephone-based smoker's follow-up program. This data was abstracted directly from the smoker's follow-up system database.

4.6.5 Mediating and moderating variables

The role of patient, physician, and practice characteristics in mediating or moderating the delivery of evidence-based cessation treatments and smoking abstinence was examined. The selection of variables was determined *a priori* based on previously published research (See Chapter 2). The following patient-level factors were examined: age, gender, education, number of cigarettes smoked per day, years of smoking, time to first cigarette, readiness to set a quit date, exposure to second-hand smoke, number of quit attempts in last year, purpose of visit to the clinic, presence of co-morbidities, and identifying information for the physician or nurse practitioner whom they saw while in the clinic. Patient self-efficacy related to quitting ("On a scale of 1 to 10, how confident are you that you would be able to quit smoking?"), importance of quitting ("On a scale of 1 to 10, how important is quitting smoking to you?"), and the importance of their primary care provider's advice in motivating them to quit smoking ("How important is your primary care physician's/other member of the staff's advice in motivating you to want to quit smoking?") was also documented. The following practitioner-level factors were evaluated: age; gender; self-rated importance of smoking cessation; knowledge of evidence-based smoking cessation interventions; self-efficacy with delivering each of the 5As; and previous cessation training. Practice-level factors included the practice model type (family health team versus family health group), the size of the practice, the geographic location of the practice, presence of a nurse and physician champion, and baseline rates of asking and advising for the clinic.

4.7 Power calculations and sample size

Power calculations were conducted to determine the number of patients to be sampled from each clinic at the pre- and post-assessments based on the recruitment of between six and eight practices. The primary outcome measure for the power calculation was 7-day point prevalence abstinence. Given the clustered design, the design effect or inflation factor was used to enlarge the total sample size to account for loss in statistical power. The design effect formula is: Design effect = 1+ (n-1) * ICC (Donner and Klar 2000), where n is the mean sample size at the third hierarchical level (patient level) and ICC is the intra-class correlation. For the purposes of the power calculation, the intra-cluster correlation coefficient (ICC; between practice variation) was estimated to be relatively small (i.e., 0.01). Previously published data for primary care practices has found that the minimum and maximum ICC value for outcome measures was 0.01 and 0.05 respectively, and 0.05 and 0.15 for process measures (Baskerville, Hogg, and Lemelin 2001, W241-6; Campbell et al. 2004, 113-125). All calculations were based on a two-sided test, alpha level of 0.05, and the recruitment of between six and eight practices.

The power calculations indicate that with seven practices and 55 patients per practice, there would be >80% power to detect a 10% or 15% difference between groups if the post-intervention quit rate in the PS group is 0.05 and 0.10, respectively. Appendix S presents a summary of the scenarios used for power calculations. The PASS (2008) software package by NCSS was used to conduct power calculations (NCSS 2008). Among published multi-component interventions that involved follow-up counselling, reported quit rates were between 4% and 21% compared to control practices (see Appendix T). As such, it was understood that the present study might be underpowered to detect significant differences in smoking abstinence between groups if differences between intervention groups were less than 10%.

4.8 Patient recruitment

From each of the participating clinics, a cross-sectional sample of eligible patients was recruited pre- and post-intervention. Patients were eligible to participate in the study if they met the following criteria: currently smoking (≥1 cigarette per day on most days of the week); 18 years of age or older; have a scheduled appointment with a nurse practitioner or physician for annual exam or non-urgent medical appointment; able to complete exit survey and telephone interview in English or French; and have a home or mobile telephone that can be used to receive follow-up telephone calls. All eligible patients were asked to complete an exit survey at the end of their clinic appointment to assess provider performance in 5As delivery. Participants were followed prospectively for four months to assess smoking cessation outcomes.

Across the seven practices, 12,585 patients were screened and 1868 smokers identified at the pre- and post-assessment, of which 835 eligible smokers took part in the present study across the two study periods: pre-intervention period (January 28, 2009 to June 12, 2009) and post-intervention period (July 20, 2009 to December 24, 2009). During each study period a new cohort of patients from each clinic site was enrolled in the study until the enrollment target for the site was reached. The pre-intervention assessment was conducted prior to implementing the intervention program to establish pre-intervention rates of 5As delivery at the clinic and associated quit rates among patients, as well as allow comparisons to be made between intervention groups. The post-intervention assessment occurred approximately two months after the intervention program was implemented with patients at the clinic site. Table 4 presents summary data for study recruitment and data collection activities.

Table 4: Summary of recruitment and follow-up statistics for the pre- and post-intervention assessments by intervention group

Statistic	Overall n (%)	PS Group n (%)	FC Group n (%)	PS vs FC P=
Pre-Assessment				
Patients Screened	6154	2581	3573	-
Smokers Screened[a]	922 (15.0)	468 (18.1)	454 (12.7)	**
Eligible Smokers	752	413	339	-
Completed Exit Survey[b]	416 (55.3)	233 (56.4)	183 (54.0)	Ns
Completed 4-month Follow-up[c]	366 (88.0)	200 (85.8)	166 (90.7)	Ns
Post-Assessment				
Patients Screened	6431	3190	3241	-
Smokers Screened[a]	946 (14.7)	496 (15.5)	450 (13.9)	*
Eligible Smokers	796	430	366	-
Completed Exit Survey[b]	419 (52.6)	242 (56.2)	177 (48.4)	Ns
Completed 4-month Follow-up[c]	379 (90.5)	224 (92.6)	155 (87.6)	Ns

[a] Number of daily and non-daily smokers screened (percentage of patients who were smokers among all patients screened).
[b] Number of eligible patients who returned survey i.e., study participants (percentage of patients who returned survey among all eligible patients screened).
[c] Number of patients who completed telephone interview (percentage of study participants who completed telephone interview).
FC Time 1 vs Time 2 p = .347
PS Time 1 vs Time 2 p = .002
*p < .05. **p < .01. ***p <.001.

4.9 Data collection

A research assistant was located in the clinic waiting room and conducted all data collection activities. During the pre- and post-intervention screening periods, consecutive patients scheduled for an annual exam or non-urgent appointment with a physician or nurse practitioner were screened for eligibility upon check-in to the clinic. The clinic receptionist distributed an invite letter to patients and patients were asked to complete the eligibility screening questions and return the invite to the research assistant (see Appendix U). No information on the outcomes measures being assessed was provided in the invite letter distributed. Patients who were seen in the clinic for vaccination or for other services delivered only by a nurse or for urgent appointments were excluded. Urgent appointments were defined as medical appointments scheduled to treat serious acute illness such as bodily injury, severe illness, or transfer to hospital. The primary reason for ineligibility was non-daily smoking status (i.e., less than 1 cigarette per day smoked on average in last month), which was reported by 134 patients surveyed. Table 5 presents a summary of the reasons for patient ineligibility by study clinic.

4.9.1 Exit interview

Previous research has shown prompting patients prior to a clinic visit increases the likelihood of patient-provider discussions about smoking and, as such, all patient interviews were conducted upon exit from their clinic appointments (Coleman et al. 2007, 153). At the end of the patient visit to the clinic, the research assistant reviewed the study consent form and procedures with eligible patients. A copy of the patient information sheet and consent form is presented in Appendix V. Reasons for non-participation was documented by the research assistant. The most common reason for declining participation was the lack of interest or lack of time (74.2%). Table 6 presents a complete summary of reasons patients provided for declining participation in the study.

Patients willing to participate in the study were asked to complete a brief five- to ten-minute exit survey before leaving the clinic (see Appendix Q). Participants were provided with a gift card for a free coffee (value $2.00) as a token of appreciation for their time. Participants who indicated they were not able to complete the survey before leaving the clinic were provided with a copy of the survey and a stamped self-addressed envelope to return the survey. Up to three reminder calls were placed to patients who chose to take the survey home and did not return the survey within a week.

At the pre-assessment a total of 416 eligible smokers (233 smokers in the PS group and 183 in the FC group) completed the pre-assessment exit interview and were included in the study, representing 55.3% of all eligible smokers screened at study clinics. At the post-assessment a total of 419 eligible patients enrolled in the study and returned the exit survey (242 in the PS group and 177 in the FC group), representing 52.6% of all eligible patients. There was no differential rate of participation between the intervention groups. A significant number of patients (23%) who agreed to participate in the study did not return the exit survey by mail after three reminder call attempts. These patients were classified as declining participation for the purpose of study statistics.

Table 5: Summary of screening and recruitment statistics at the pre- and post-intervention assessment by clinic

Clinic	Patients Screened	Patients who report smoking in past 7 days		Ineligible patients					Eligible Smokers Invited	Declined	Eligible Smokers Recruited		Completed Exit Survey	
				<18 years old	Unable to Read Eng/Fr	No Phone Access	Non-daily smoker	Non MD/ NP Visit						
	n	*n*	*%*	*n*	*n*	*n*	*n*	*n*	*n*	*N*	*n*	*%*	*n*	*%*
Pre-Intervention														
Clinic 1	1887	230	12.2	5	6	9	22	40	148	82	66	44.6	56	84.9
Clinic 2	872	118	13.5	0	2	0	6	8	102	28	74	72.5	58	78.4
Clinic 3	689	120	17.4	0	3	2	5	6	104	29	75	72.1	55	73.3
Clinic 4	883	114	12.9	0	2	0	7	6	99	18	81	81.8	70	86.4
Clinic 5	623	115	18.5	0	1	0	10	2	102	22	80	78.4	56	70.0
Clinic 6	803	110	13.7	3	5	2	8	0	92	17	75	81.5	57	76.0
Clinic 7	397	115	29.0	0	0	0	2	10	103	6	97	94.2	64	66.0
PS Group	**2581**	**468**	**18.1**	**0**	**6**	**2**	**23**	**26**	**411**	**85**	**326**	**79.3**	**233**	**71.5**
FC Group	**3573**	**454**	**12.7**	**8**	**13**	**11**	**37**	**46**	**339**	**117**	**222**	**65.5**	**183**	**82.4**
Total	**6154**	**922**	**15.0**	**8**	**19**	**13**	**60**	**72**	**750**	**202**	**548**	**73.1**	**416**	**75.9**
Post-Intervention														
Clinic 1	1212	164	13.5	2	2	4	36	10	110	43	67	60.9	54	80.6
Clinic 2	808	122	15.1	1	1	0	10	11	99	25	74	74.7	60	81.1
Clinic 3	807	114	14.1	0	2	1	9	1	101	29	72	71.3	64	88.9
Clinic 4	1169	141	12.1	4	1	4	1	1	130	42	88	67.7	63	71.6
Clinic 5	890	103	12.0	1	1	4	2	4	91	19	72	79.1	52	72.2
Clinic 6	860	145	16.9	2	3	0	12	2	126	46	80	63.5	60	75.0
Clinic 7	685	157	22.9	7	5	0	4	2	139	57	82	59.0	66	80.5
PS Group	**3190**	**496**	**15.5**	**9**	**9**	**5**	**25**	**18**	**430**	**130**	**300**	**70.0**	**242**	**80.7**
FC Group	**3241**	**450**	**13.9**	**8**	**6**	**8**	**49**	**13**	**366**	**131**	**235**	**64.2**	**177**	**75.3**
Total	**6431**	**946**	**14.7**	**17**	**15**	**13**	**74**	**31**	**796**	**261**	**535**	**67.2**	**419**	**78.3**

Table 6: Reason for refusal among eligible patients screened at the pre-intervention and post-intervention assessments

Reason	Clinic 1	Clinic 2	Clinic 3	Clinic 4	Clinic 5	Clinic 6	Clinic 7	Overall
	n	*n*	*n*	*n*	*n*	*N*	*n*	*n*
Pre-Intervention Assessment								
Not interested	31	21	18	15	19	14	6	124
No time / Too busy	21	0	2	0	0	3	0	26
Left without completing screener	27	7	9	2	3	0	0	48
Leaving country soon, unable to complete follow-up	2	0	0	0	0	0	0	2
Not feeling well enough to complete	0	0	0	1	0	0	0	1
Will be leaving the country soon	1	0	0	0	0	0	0	1
Total Pre-Assessment	**82**	**28**	**29**	**18**	**22**	**17**	**6**	**202**
Post-Intervention Assessment								
Not interested	20	10	12	30	15	22	38	147
No time / Too busy	3	6	4	5	1	6	9	34
Left without completing screener	0	5	4	6	2	8	8	33
Screener received after patient left	14	0	0	0	0	2	0	16
Leaving country soon, unable to complete follow-up	0	1	0	0	0	5	0	6
Participated at baseline, not interested in repeating	0	0	3	1	0	0	1	5
Participating in another study	1	0	2	0	0	0	0	3
Confidentiality issues	0	1	0	0	0	0	0	1
Reason not provided	5	2	4	0	0	3	1	15
Total Post-Assessment	**43**	**25**	**29**	**42**	**19**	**46**	**57**	**259 261**

4.9.2 Four-month telephone follow-up interview

All consenting participants were contacted by telephone approximately 4 months (+/-2 weeks) after their clinic visit. The 4-month telephone follow-up assessment was completed with 89.2% of study participants. Table 7 provides a summary of the 4-month follow-up interview statistics for patients involved in the post-assessment sample. There were no significant differences in the rates of recruitment or loss to follow-up between intervention groups or between the pre- and post-assessment samples. During the telephone interview, smoking status (7-day point prevalence and 12-week continuous abstinence) and number of quit attempts since their visit to the clinic was assessed (see Appendix R). Supplemental smoking cessation services received at the clinic were also documented as part of the telephone follow-up assessment. For participants who reported active smoking, the current number of cigarettes smoked was recorded. For participants who reported an unsuccessful quit attempt, the primary reason for relapse was recorded. Participants who did not complete the 16-week exit interview were included in the analysis and coded as currently smoking for both 7-day point prevalence abstinence and continuous abstinence and responses for all other 16-week data was coded as missing. Biochemical validation of self-reported smoking abstinence was completed with 53.3% of patients who reported a smoke-free status. Participants were mailed the NicAlert™ test, instruction sheet, and a package for returning the kit. Participants were asked to return the kit to the research office in a sealed pre-paid stamped box. If a participant reported at the 16-week follow-up assessment that he or she was currently using nicotine replacement therapy, arrangements were made by the research assistant for a carbon monoxide (CO) breath sample to be taken. Forty-five percent of patients who agreed to provide a biochemical sample did not return the sample following multiple reminder contacts (see Table 8). No differences were noted in the completion of the bio-chemical validation at the pre- and post-intervention assessments nor were differences noted between intervention groups.

Table 7: Summary statistics for the 4-month follow-up interview by intervention group

Group	Complete		Withdrawal		Lost to FU > 10 calls		Lost to FU contact information		Deceased		Total
	n	%	N	%	n	%	n	%	n	%	n
Pre-Intervention Assessment											
FC Group	166	90.7	3	1.6	12	6.6	2	1.1	0	0	183
PS Group	200	85.8	10	4.3	15	6.4	7	3.0	1	0.4	233
Sub-total	**366**	**88.0**	**13**	**3.1**	**27**	**6.5**	**9**	**2.2**	**1**	**0.2**	**416**
Post-Intervention Assessment											
FC Group	155	87.6	3	1.7	15	8.5	4	2.3	0	0	177
PS Group	224	92.6	5	2.1	12	5.0	1	0.4	0	0	242
Sub-total	**379**	**90.5**	**8**	**1.9**	**27**	**6.4**	**5**	**1.2**	**0**	**0**	**419**
Total	**745**	**89.2**	**21**	**2.5**	**54**	**6.5**	**14**	**1.7**	**1**	**0.1**	**835**

Table 8: Biochemical validation statistics

Parameter	Overall n (%)	All Patients n (%)		PS Group n (%)		FC Group n (%)	
		Pre	Post	Pre	Post	Pre	Post
Validation Completed	38/71 (53.4)	15/29 (51.7)	23/42 (54.8)	2/4 (50)	11/20 (55)	13/25 (52)	11/22 (50)
Patient Refused to Provide Sample	1/71 (1.4)	0/29 (0)	1/42 (2.4)	0/4 (0)	0//20 (0)	0/25 (0)	1/22 (4.5)
Sample Not Returned	32/71 (45.0)	14/29 (48.3)	18/42 (42.9)	2/4 (50)	9/20 (45)	12/25 (48)	9/22 (41)

4.10 Statistical analysis

Data from all seven family medicine clinics and the 835 patients who completed the pre-and post-assessment data collection activities were included in the intention to treat analysis.

Differences in the distribution of provider and clinic characteristics between FC and PS groups were determined using the Pearson chi-square test for categorical variables and Student's t-test for continuous variables using SPSS 17.0 (SPSS Inc., Chicago, IL). This analysis was repeated to compare patient characteristics between the FC and PS groups at the pre-assessment and post-assessment. A three-level hierarchical model was used to compare patient characteristics between groups at the post-assessment, controlling for baseline differences and the cluster randomized design. A second three-level model was used to examine differences in patient characteristics between the pre-and-post assessment overall (i.e., both intervention groups combined).

Multi-level (or hierarchical) modelling was used for all statistical analysis using MLwiN version 2.02 (Institute of Education, London, UK) (Institute of Education). Individual patients were grouped by individual intake clinicians (who were grouped by clinic). A three-level model was constructed to fit for each outcome measure: the individual patients (level 1), provider (level 2), and clinic (level 3). Para-meters in the model were estimated using iterative generalized least squares method for model fitting

with binomial structure for binary data and the logit link function. Wald tests were used to obtain p-values. P-values were calculated using two-sided tests and a 5% significance level for fixed effects. One-sided tests were calculated for variance components.

The formulas used to examine the three-level logit model are presented below. In the models that were fit , there was more than one covariate at each level. The models given below contain only a single covariate to simplify the presentation.

Level 1

If πijk is the probability of the outcome for patient i of provider j in clinic k is then the patient level model is:

Logit (π_{ijk}) = $ß_{0jk} + ß_{1jk}x_{ijk}\ldots+_{\ldots}\beta_m x_{ijkm}$

where:

$ß_{0jk}$ is the intercept for provider j in clinic k.

$ß_{1jk}$ is the effect of x_{jk1} (fixed patient level variable 1) for provider j in clinic k, with other parameters defined similarly.

Level 2

At level 2 (provider level), the regression parameters in the level 1 model are assumed to be related to covariates at the level of the provider through the models:

$ß_{0jk} = \gamma_{00k} + \gamma_{10k}w_{jk1 + \ldots..} + u_{0jk;}$

$ß_{1jk} = \gamma_{10k} + \gamma_{11k}w_{jk1 + \ldots....} + u_{1jk};$

where:

γ_{00k} is the intercept for clinic k in predicting provider level differences in outcomes.

γ_{10jk} is the effect of w_{jk1} (e.g. fixed provider variable 1), etc.

u_{0jk} is the random effect of provider j in clinic k.

γ_{10k} is the intercept for clinic k the model describing how the effect of individual level predictor 1 depends on provider.

γ_{11jk} is the effect of the interaction between individual level predictor 1 and provider level predictor 1.

u_{1jk} is the random effect of provider j in clinic k in the model relating the effect of individual level variable 1 on the provider level 2 covariates.

Level 3

At level three, the level two regression parameters are modeled in terms of practice variables through the models:

$\gamma_{00k} = \delta_{000} + \delta_{001}z_{k1} + \ldots + v_{00k}$;

$\gamma_{01k} = \delta_{010} + \delta_{011}z_{k1} + \ldots + v_{01k}$;

$\gamma_{10k} = \delta_{100} + \delta_{101}z_{k1} + \ldots + v_{10k}$;

$\gamma_{11k} = \delta_{110} + \delta_{111}z_{k1} + \ldots + v_{11k}$;

where:

$\delta_{000,}\ \delta_{010},\ \delta_{100\,,}\ \delta_{110}$ are the intercepts in the clinic-level models for the γ at the provider-level.

$\delta_{001,}\ \delta_{100,}\ \delta_{110}$ and δ_{111} reflect how the effects of individual–level variables and practice-level variables, and their interaction depend on z, a clinic characteristic.

$v_{00k,}\ v_{01k}$, $v_{10k,}\ v_{11k}$ are the random effects reflecting deviation of clinic k from the overall mean for the particular clinic effects.

Combined Model

To illustrate the combined model, assume we have a single covariate (independent variable) at each of the three levels. Then putting the three equations above together gives:

Logit (π_{ijk}) = $Y_{ijk} = \delta_{000} + \delta_{001}z_k + \delta_{010}w_{jk1} + \delta_{100}x_{ijk1} + \delta_{011}z_{k1}w_{jk1} + \delta_{101}z_{k1}x_{ijk1} +$

$\delta_{110}w_{jk1}x_{ijk1} + \delta_{111}z_{k1}w_{jk1}x_{ijk1} + v_{00k} + v_{01k}w_{jk1} + v_{10k}x_{ijk1} + v_{11k}w_{jk1}x_{ijk1} + u_{0jk} +$

$u_{1jk}x_{ijk1}$

Odds ratios and 95% CI were used to summarize the effects of each explanatory variable in explaining variance in individual level effects**,** with similar definitions for the provider and practice level effects, giving the ratio of the odds of the outcome for two individuals whose value of the relevant co-variable differ by one unit, with all other co-variables held constant. For the random effects, variance components and their estimated standard errors are listed.

The intra-class correlation coefficient (ICC) was calculated to compare the variation between clusters to the total variation; this was measured on a scale from 0 to 1, with a value close to 0 indicating the clusters were all "similar". An intra-clinic and intra-provider ICC was calculated for each of the outcome variables examined. Given the present analysis used logistic models for binary outcomes, patient level variance was estimated to be equal to $\pi^2/3 = 3.29$ (Snijders and Bosker 1999).

Intra-Clinic ICC = clinic variance / total variance

$= \sigma^2_{0k} / (\sigma^2_{0k} + 3.29)$

Intra-Provider ICC = clinic variance + provider variance / total variance

$= (\sigma^2_{0k} + \sigma^2_{0j})/(\sigma^2_{0k} + \sigma^2_{u0} + 3.29)$

The first study objective was to compare the efficacy of the follow-up counselling group and practice support group on study outcomes. Modelling for each variable at baseline began by entering the random effects at the clinic and provider level (which are required because of the cluster design) along with three fixed effects: an "intercept" term, "dummy" variables for intervention group (FC vs. PS) and time (pre- vs. post-assessment), and an interaction effect for group x time. Again, a separate model was constructed for 7-day point prevalent abstinence, prolonged abstinence (weeks 4 to 16), quit attempts, and provider performance in each of the 5As strategies.

The second objective of the study was to examine the efficacy of the multi-component smoking cessation intervention program at the post-assessment on 5As delivery, quit attempts, and smoking abstinence compared to pre-assessment rates. The proportion of patients (# patients received strategy/total # patients) receiving each of the 5As (ask, advise, assess, assist, arrange) strategies was calculated for the pre-assessment and post-assessment. Pre- and post-intervention assessment rates were calculated for 5As delivery and smoking abstinence for all seven study clinics. The coefficients and standard errors for the three-level models constructed (as described above) were examined to assess the effect of time (pre- vs. post-assessment) on study outcomes when controlling for clinic and provider level clustering. A separate model was constructed for 7-day point prevalent abstinence, prolonged abstinence (weeks 4 to 16), quit attempts, and provider performance in each of the 5As strategies.

To understand the patient-provider and clinic-level factors associated with each outcome, a separate multi-level logistic regression analyses was performed. A multi-step modelling procedure was used for each outcome. Step (1), the model fit for each outcome variable of interest began by entering random effects for clinic and provider. The modelling of the fixed effects proceeded in blocks until a final model in which all fixed effects were significant was obtained. Possible mediating and moderating factors at the level of the practice and provider were entered as variables in the analysis.

Step (2), study design variables were entered for time, group, and the interaction between time and group. Step (3), level-3 practice-level factors (practice model, geographic location) and implementation factors (availability of nursing support; use of dedicated staff for cessation intervention) were entered. Step (4), level-2 practitioner-level factors were then entered for the clinician most responsible for patients' care in two blocks. The first block included demographic variables (age, gender, type of provider), and the second block included smoking-related variables (previous smoking cessation training, importance of smoking cessation, self-efficacy in the delivery of smoking cessation counselling). Step (5), level-3 patient variables were entered into the model and in three blocks. The first block included demographic variables (age, gender, education), followed by medical history (presence of a smoking-related illness, self-reported anxiety or depression), then smoking-related variables (time to first cigarette, number of cigarettes smoked per day, years smoking, presence of another person who smokes in the home, self-efficacy related to quitting smoking, importance of quitting, readiness to quit in the next 30 days), and, finally, purpose of visit to the clinic. Only significant variables ($p<0.05$) were retained. Step (6), a final model was then developed to examine the direct effects of only the significant ($p<0.05$) clinic, provider, and patient characteristics on outcomes (Final Model). Interaction effects were also examined between significant variables at each level. No adjustment to the significance value was made to account for the number of outcomes being assessed.

Chapter 5 Results

5.1 Descriptive characteristics

5.1.1 Clinic characteristics

A summary of the characteristics of clinics who participated in the study is presented in Table 9. The study sample included clinics from urban, suburban, and rural communities from within the Champlain District of Ontario. Approximately half of the practices had 10 or more physicians on staff. Four of the seven participating clinics were family health teams that receive funding from the Ministry of Health and Long-Term Care for allied health professional and administrative personnel.

Table 9: Characteristics of pilot clinics

Parameter	No of Physicians	Location	Practice Model[a]	Smoking Prevalence (%)[b]	Physician Champion[c]	Nurse Champion	Nurse Support
Clinic 1	16	Urban	FHT	12.7	Y	Y	Y
Clinic 2	7	Urban	FHT	14.3	N	N	N
Clinic 3	40	Urban	FHT	15.6	N	N	Y
Clinic 4	14	Suburban	FHT	12.4	Y-N	Y-N	N
Clinic 5	9	Urban	FHG	14.4	Y	Y	Y
Clinic 6	11	Suburban	FHG	15.3	N	N	N
Clinic 7	11	Rural	FHG	25.1	Y	N	N

[a] FHT = Family Health Team, FHG = Family Health Group.
[b] Percentage of total patients screened who reported being an active smoker ("used a tobacco product in previous seven days").
[c] A "clinician champion" was defined as a key opinion in the clinic who was actively involved as a member of the task force that was established at each clinic to support program implementation

.

Table 10 provides a comparison of the clinic characteristics by intervention group assignment. Intervention groups were well balanced in regards to practice size (i.e., number of physicians), practice type, geographic location, and presence of a physician champion for the study. Smoking prevalence rates varied significantly between study clinics ranging from 12% to 29%. The highest rate of smoking (25%) was documented in the single rural clinic. This pattern is consistent with previously reported rates of smoking for sub-regions within the Champlain District, which range from 14.1% in the City of Ottawa to 26% in surrounding public health regions (Statistics Canada 2009). There was a significantly higher rate of smoking among patients in the PS group at both the pre- and post-assessment, which can be attributed to the high rate of smoking in the single rural clinic assigned to the PS group. The overall rate of smoking prevalence documented at the post-assessment for each study group was similar to the pre-assessment (14.7% vs. 15.0%).

Clinics assigned to the PS group had a higher baseline rate of asking and advising patients to quit as compared to the FC group. These differences were not statistically significant.

Table 10: Characteristics of pilot clinics by intervention group

Parameter	Overall n (%)	PS Group n (%)	FC Group n (%)
Number of Physicians			
<10 Full TimeEquivalents	4 (57)	2 (50)	2 (66)
≥10 Full Time Equivalents	3 (43)	2 (50)	1 (33)
Location			
% Urban	4 (57)	3 (75)	1 (33)
% Suburban	2 (29)	0 (0)	2 (66)
% Rural	1 (14)	1 (25)	0 (0)
Practice Model			
Family Health Team	4 (57)	2 (50)	2 (66)
Family Health Group	3 (43)	2 (50)	1 (33)
Champion Physician			
Yes	3 (43)	2 (50)	1 (33)
No	4 (57)	2 (50)	2 (66)
Champion Nurse			
Yes	3 (43)	1(25)	2 (66)
No	4 (57)	3 (75)	1 (33)
Nursing Support			
Yes	4 (57)	3 (75)	1 (33)
No	3 (43)	1 (25)	2 (66)
Baseline Smoking Prevalence	15.0	18.1	12.7
Baseline Rate of Ask	52.2	53.7	47.6
Baseline Rate of Advise, Today	39.2	43.0	34.3
Baseline Rate of Advise, Last 12 months	70.0	72.4	66.7

Comparisons are based on the Pearson chi-square test for categorical variables and Student's t-test for continuous variables.

5.1.2 Provider characteristics

Provider surveys were completed by 74/115 (64.3%) of clinic providers who saw at least one patient during the pre- or post-assessment periods. Responding providers had a mean age of 45.2 (SD±11.3) years and 44.9% were male. No significant differences were found between intervention groups in regards to provider demographic characteristics. Table 11 provides a summary of the demographic characteristics of responding providers as well as an assessment of the self-reported importance of smoking cessation and self-efficacy of providers as it relates to the delivery of each of the 5As for smoking cessation treatments in clinical settings.

Significantly more providers in the FC group compared to the PS group reported receiving previous smoking cessation training (28% vs. 54% p=0.023). Self-reported participation in previous smoking cessation training ranged from 25% to 80% of providers among the participating clinics. The highest rates of participation were found in three of the four participating family health teams.

A significantly greater number of providers in the FC group were physicians compared to the PS group which had a higher number of medical residents. Despite these differences, the overall number of patients screened by residents during the course of the study was small (n=48 patients, 6.4% of study sample). The majority of providers reported smoking cessation was either extremely important or very important to both the clinic as well as to the providers' own practices. There were no differences between groups in the self-reported importance placed on smoking cessation with patients among clinic providers. The highest scores for self-efficacy were documented for advising patients to quit, the provision of brief counselling and prescribing of medications (all mean scores were greater than 8 on a 10-point scale). Slightly lower levels of self-efficacy were documented for other activities, such as setting a quit date with patients, the provision of extended smoking cessation counselling, and arranging follow-up. There were no significant differences between intervention groups in provider self-efficacy related to 5As delivery.

Table 11: Characteristics of providers by intervention group

Parameter	Overall n=74	PS Group n=30	FC Group n=44	p=
Type of Provider, %				
MD Physician	63.3	55.4	76.5	.000
Resident	26.8	41.1	2.9	
Nurse Practitioner	10.0	3.6	20.6	
Age, Mean (SD)	45.2 (11.3)	44.5 (11.9)	46.4 (10.6)	.514
Male, %	44.9	50.0	38.2	.300
Previous SC training, %				
Yes	47.3	28.2	54.3	.023
No	52.7	71.8	45.7	.
How would you describe the importance placed on smoking cessation within your clinic setting?, %				
Extremely important	46.1	42.2	51.6	.807
Very important	31.6	35.6	25.8	
Important	19.7	20.0	19.4	
Somewhat important	2.6	2.2	3.2	
Not important	0	0	0	
As a practitioner, how would you describe the importance you place personally on helping your patients quit smoking?, %				
Extremely important	48.7	44.4	54.8	.662
Very important	39.5	42.2	35.5	
Important	11.8	13.3	9.7	
Somewhat important	0	0	0	
Not important	0	0	0	
Self-efficacy (1 to 10 scale), Mean (SD)				
Advising patients to quit	8.6 (16)	8.4 (1.7)	8.9 (1.3)	.107
Brief counselling	8.3 (1.3)	8.1 (1.3)	8.6 (1.3)	.073
Prescribing medications	8.1 (1.6)	8.0 (1.5)	8.3 (1.8)	.483
Set quit date	7.7 (1.9)	7.8 (1.5)	7.5 (2.4)	.454
Extended counselling to quit	7.9 (1.7)	7.9 (1.4)	7.9 (2.2)	.997
Arrange follow-up support	7.0 (2.2)	7.2 (1.9)	6.9 (2.6)	.545

Survey data was received from 74/115 (64.3%) clinicians who saw patients during one of the assessment periods. Data were missing for those intake clinicians who were employed as “floating” (or locums) staff and those clinicians who did not return surveys after three reminders.
Comparisons are based on the Pearson chi-square test for categorical variables and Student’s t-test for continuous variables.

5.1.3 Patient characteristics

5.1.3.1 Demographics

Table 12 presents the demographic profile of patients at the pre- and post-intervention assessments. Study participants ranged in age from 18 to 85 years with a mean age of 45.8 years (SD±14.6). Forty-one percent of participants were male, with an average of 14 (SD±3.2) years of formal education. More than half of participants reported the presence of one or more smoking-related illnesses. At the pre-assessment, a larger proportion of patients reported the presence of a smoking-related illness relative to the post-assessment sample. A significant proportion of patients from the pre-post assessment samples reported the presence of anxiety (29%) or depression (27.5%). Significantly, more patients in the PS group identified themselves as depressed compared to the FC group at the pre-assessment (33.8% vs. 22.7%, p=0.041). A similar trend was observed at the post-assessment; however, observed differences were not statistically significant. The majority (83.8%) of patients were recruited when visiting the clinic for a follow-up appointment or visit other than the annual physical exam.

The unadjusted analysis documented significant differences in the mean age of participants (48.2 vs. 43.5 years, p=.001) between intervention groups at the pre-intervention assessment. Significant differences were also documented between intervention groups for the number of years of formal education reported by participants at both the pre- and post-assessment. However, after controlling for the cluster design and baseline differences between groups, there was no statistically significant difference noted in any of the demographic variables between intervention groups across time.

Table 12: Characteristics of participants at the pre- and post-intervention assessment by intervention group

Parameter	Pre-Intervention Assessment [a]				Post-Intervention Assessment [a]				PS vs FC [b]	Pre vs Post [b]
	Overall n=416	PS Group n=233	FC Group N=183	p=	Overall n=419	PS Group n=242	FC Group n=177	p=	p=	p=
Age, mean (SD)	46.2 (14.7)	48.2 (14.5)	43.5 (14.7)	**.001**	45.3 (14.5)	46.1 (14.1)	44.2 (15.0)	.203	ns	ns
Male, n (%)	169 (40.6)	89 (38.4)	80 (44.0)	.250	167 (41.1)	92 (38.3)	75 (45.2)	.168	ns	ns
Years of formal education, mean (SD)	14.2 (3.2)	13.8 (3.0)	14.7 (3.3)	**.007**	14.1 (3.2)	13.8 (3.1)	14.6 (3.1)	**.007**	ns	ns
Smoking related illness, (%)	317 (67.2)	158 (67.8)	159 (66.5)	.766	218 (52.7)	139 (57.7)	79 (45.7)	**.016**	ns	ns
Heart disease	35 (8.6)	24 (10.6)	11 (6.0)	**.034**	20 (4.9)	12 (5.1)	8 (4.7)	.962	ns	ns
Heart attack	25 (6.2)	18 (8.1)	7 (3.9)	**.099**	17 (4.2)	9 (3.8)	8 (4.7)	.797	ns	ns
Heart failure	2 (0.5)	2 (0.9)	0 (0.0)	.409	4 (1.0)	3 (1.3)	1 (0.6)	.683	ns	ns
Stroke	20 (5.0)	14 (6.3)	6 (3.3)	.405	11 (2.7)	8 (3.4)	3 (1.7)	.542	ns	ns
Diabetes	58 (14.3)	41 (18.2)	17 (9.4)	**.032**	41 (10.0)	28 (11.9)	13 (7.6)	.321	ns	ns
Cancer	10 (2.5)	3 (1.7)	7 (3.1)	.119	10 (2.5)	7 (3.0)	3 (1.7)	.524	ns	ns
Bronchitis	49 (12.2)	34 (15.2)	15 (8.4)	**.043**	39 (9.6)	26 (11.1)	13 (7.6)	.460	ns	ns
COPD	28 (6.9)	20 (8.9)	8 (4.4)	.138	23 (5.7)	14 (5.9)	9 (5.3)	.529	ns	ns
High blood pressure	113 (27.8)	78 (34.5)	35 (19.3)	**.003**	73 (17.8)	51 (21.4)	22 (12.9)	**.042**	ns	ns
High cholesterol	95 (23.5)	63 (28.3)	32 (17.7)	**.031**	70 (17.1)	42 (17.7)	28 (16.3)	.813	ns	ns
Mental health history, n (%)										
Anxiety	131 (32.3)	76 (33.8)	55 (30.6)	.574	114 (28.1)	76 (32.5)	38 (22.1)	.066	ns	ns
Depression	118 (32.3)	77 (33.8)	41 (22.7)	**.041**	112 (27.3)	73 (30.8)	39 (22.5)	.141	ns	ns
Diagnosed Mental Health Illness	35 (8.8)	21 (9.7)	14 (7.8)	.513	29 (7.3)	22 (9.6)	7 (4.1)	.109	ns	ns
Purpose of clinic visit, (%)										
Annual physical	58 (16.1)	37 (15.9)	21 (16.5)	.276	89 (21.6)	47 (19.7)	42 (24.1)	.108	ns	ns
Follow-up appointment	124 (34.4)	87 (37.3)	37 (29.1)		132 (32.0)	86 (36.1)	46 (26.4)			
Other	178 (49.4)	109 (46.8)	69 (54.3)		191 (46.4)	105 (44.1)	86 (49.4)			

ns=non-significant.

[a] Comparisons are based on the Pearson chi-square test for categorical variables and Student's t-test for continuous variables.

[b] Comparisons are based on hierarchical logistic regression models (adjusted for clinic and provider level variance).

5.1.3.2 Smoking history

A profile of the smoking history of respondents at both assessments points is presented in Table 13. Smoking history variables indicate that participants were relatively heavy smokers who had smoked for an extended period of time, consuming an average of 16.8 (SD±9.5) cigarettes per day for an average of 26 (SD±15) years. The majority of respondents reported smoking within 30 minutes of waking. Most respondents reported making one or more quit attempts in the last year. More than 40% of patients reported another person who smokes in their home.

A statistically significant difference between intervention groups was documented for both the number of cigarettes smoked per day, years of smoking, exposure to second-hand smoke, and self-efficacy at the pre-intervention assessment. There was a statistically significant difference between intervention comparators at the follow-up with respect to the average time to first cigarette, with PS participants more frequently reporting smoking within 5 minutes of waking, an indication of higher levels of addiction to nicotine. However, after controlling for the cluster design and baseline differences, there was no statistically significant difference noted between the smoking-related characteristics of patients between intervention groups.

5.1.3.3 Readiness to quit

Thirty-four percent of participants sampled reported they were ready to quit in the next 30 days at both assessment points. An additional 40% of participants reported that they were ready to quit smoking in the next 6 months. There were no differences between groups in the self-reported readiness to quit at either assessment point or between the pre- and post-assessment samples.

5.1.3.4 Self-efficacy and importance of quitting

Two questions assessed patient self-efficacy related to quitting smoking and importance of quitting on a 10-point scale. The mean level of confidence related to quitting was relatively low at 4.6 (SD±2.8) and 5.1 (SD±2.9) at the pre- and post-assessments, respectively. Patients in the FC group ranked self-efficacy for quitting higher than patients in the PS group at baseline with no differences noted between groups at the post-intervention assessment. The average score for the importance of quitting was 6.7 (SD±3.2) and 7.0 (SD±3.1), respectively, at the pre- and post-assessment, with no differences between groups.

5.1.3.5 Importance and satisfaction related to a health professional's advice to quit

Table 14 presents a summary of participant responses regarding the importance of their provider's advice on patient motivation to quit as well as patient satisfaction regarding the assistance provided by the clinic with quitting smoking. Approximately half of respondents indicated the advice of their primary care physician was either an "extremely important" or "important" factor in motivating them to quit smoking at the baseline assessment. This proportion increased to 60% at the post-assessment and was higher in the FC group relative to the PS group. At the post-assessment, approximately 45% of patients indicated they were either "extremely satisfied" or "satisfied" with the assistance they received at the clinic on that day related to smoking, and 27% indicated the assistance they received was "extremely helpful" or "helpful".

Table 13: Smoking profile of patients at pre- and post-intervention assessments by intervention group

Parameter	Pre-Intervention Assessment[a]				Post-Intervention Assessment[a]				PS vs FC[b]	Pre vs Post[b]
	Overall n=416	PS Group n=233	FC Group n=183	p=	Overall n=419	PS Group n=242	FC Group n=177	p=	p=	p=
Cigarettes/day, mean (SD)	15.6 (9.0)	16.5 (9.0)	14.4 (8.8)	**.02**	15.5 (9.4)	16.3 (9.6)	14.4 (8.9)	.05	ns	ns
Years smoked, mean (SD)	27.4 (15.2)	29.9 (14.6)	24.3(15.3)	**.00**	25.7(14.7)	25.9(14.3)	25.5 (15.3)	.77	ns	ns
Time to first cigarette, n (%)										
After 60 minutes	89 (21.4)	43 (18.5)	46 (25.3)	.08	102 (25.7)	48 (20.4)	54 (33.3)	**.03**	ns	ns
31-60 minutes	71 (17.1)	34 (14.6)	37 (20.3)		72 (18.1)	47 (20.0)	25 (15.4)			
6-30 minutes	145 (34.9)	90 (38.6)	55 (30.2)		123 (31.0)	74 (31.5)	49 (30.2)			
Within 5 minutes	110 (26.5)	66 (28.3)	44 (24.2)		100 (25.2)	66 (28.1)	34 (21.0)			
Readiness to quit, n (%)[c]										
Ready in next 30 days	141 (34.4)	79 (34.0)	62 (34.0)	.65	134 (33.9)	84 (35.9)	50 (31.1)	.59	ns	ns
Ready in next 6 months	167 (40.7)	98 (42.4)	69 (38.5)		158 (39.9)	92 (39.3)	66 (41.3)			
Not Ready	102 (24.9)	54 (23.4)	48 (26.8)		102 (25.8)	58 (24.8)	44 (27.5)			
Quit Attempts in last year, n (%)										
No attempts	173 (41.6)	105 (45.1)	68 (37.2)	.25	173 (43.5)	101 (42.8)	72 (44.4)	.85	ns	ns
1-2 attempts	161 (38.7)	86 (36.9)	75 (41.0)		159 (39.9)	97 (41.1)	62 (38.3)			
3 or more attempts	82 (19.7)	42 (18.0)	40 (21.9)		66 (16.6)	38 (16.1)	28 (17.3)			
Other smokers in the home, n (%)	200 (48.4)	117 (50.9)	83 (45.4)	.27	166 (41.6)	98 (41.0)	68 (42.5)	.77	ns	ns
Exposed to second-hand smoke, n (%)	190 (45.9)	117 (50.4)	73 (40.1)	**.04**	136 (36.0)	90 (39.5)	46 (30.7)	.08	ns	ns
Self-Efficacy, mean (SD)[d]	4.6 (2.8)	4.4 (2.7)	4.9 (2.9)	**.04**	5.1 (2.9)	5.0 (2.7)	5.2 (3.1)	.38	ns	ns
Importance of quitting, mean (SD)[e]	6.7 (3.2)	6.7 (3.2)	6.7 (3.3)	.84	7.0 (3.1)	7.1 (3.0)	6.9 (3.1)	.65	ns	ns

ns=non-significant.
[a]Comparisons are based on the Pearson chi-square test for categorical variables and Student's t-test for continuous variables.
[b]Comparisons are based on hierarchical logistic regression models (adjusted for clinic and provider level variance).
[c]Which of the following best describes your feelings about smoking right now?
[d]On a scale of 1 to 10 how confident are you that you would be able to quit smoking at this time? (1=not at all confident, 10=extremely confident)
[e]On a scale of 1 to 10 how important is it to you to quit smoking at this time? (1=not important at all, 10=extremely important)

Table 14: Self-reported importance of physician and clinic staff advice to quit and satisfaction with smoking cessation services provided at the clinic

Parameter	Pre-intervention				Post-intervention			
	Overall **n=416**	**PS Group n=233**	**FC Group n=183**	**p=[a]**	**Overall N=419**	**PS Group N=242**	**FC Group N=177**	***p*=[a]**
Motivation Doctor[b]								
Very important	106 (25.5)	60 (25.8)	46 (25.1)	.378	118 (28.3)	72 (29.9)	46 (26.1)	**.067**
Important	112 (26.9)	68 (29.2)	44 (24.0)		137 (32.9)	72 (29.9)	65 (36.9)	
Somewhat important	146 (35.1)	81 (34.8)	65 (35.5)		113 (27.1)	74 (30.7)	39 (22.2)	
Not at all important	52 (12.5)	22 (10.3)	28 (15.3)		49 (11.8)	23 (9.5)	26 (14.8)	
Motivation Staff[c]								
Very important	70 (17.3)	41 (18.0)	29 (16.4)	.357	67 (16.4)	42 (17.7)	25 (14.5)	.131
Important	85 (21.0)	44 (19.3)	41 (23.2)		105 (25.7)	55 (23.2)	50 (29.1)	
Somewhat important	117 (28.9)	61 (26.8)	56 (31.6)		125 (30.6)	81 (34.2)	44 (25.6)	
Not at all important	133 (32.8)	82 (36.0)	51 (28.8)		112 (27.4)	59 (24.9)	53 (30.8)	
Satisfaction[d]								
Extremely satisfied					79 (22.4)	49 (24.4)	30 (19.7)	**.006**
Very satisfied					78 (22.1)	38 (18.9)	40 (26.3)	
Satisfied					133 (37.7)	88 (43.8)	45 (29.6)	
Somewhat satisfied					26 (7.4)	12 (6.0)	14 (9.2)	
Not at all satisfied					37 (10.5)	14 (7.0)	23 (6.5)	
Helpful[e]								
Extremely helpful					41 (12.3)	25 (13.4)	16 (11.0)	.040
Very helpful					48 (14.5)	25 (13.4)	23 (15.8)	
Helpful					94 (28.3)	54 (29.0)	40 (27.4)	
Somewhat helpful					48 (14.5)	35 (18.8)	13 (8.9)	
Not at all helpful					101 (30.4)	47 (25.3)	54 (37.0)	

[a]Comparisons are based on the Pearson chi-square test for categorical variables and Student's t-test for continuous variables.
[b]How important is your doctor's advice to quit smoking in motivating you to want to quit?
[c]How important is the advice of other clinic staff (e.g., nurse) in motivating you to want to quit smoking?
[d]How satisfied were you with the support provided to you on smoking cessation while in clinic today?
[e]How helpful were the clinic staff to you today as it relates to addressing smoking?

5.1.3.6 Comparison of study sample with provincial and national data

Table 15 provides a comparison of the characteristics of study participants with available data on the population of people who smoke in Ontario and Canada. Overall, 13.8% of patients screened during the two study assessment periods reported using a tobacco product in the 7 days prior to their visits to the clinic. This rate is in line with rates of daily smoking in Ontario (14%) and Canada (13.5%) (Statistics Canada 2009).

Among study participants, the greatest proportion of smokers identified were men and women between the ages of 45 and 64. In Ontario and Canada, the largest overall number of smokers is also in the 45- to 64-year-old age category (CTUMS 2010; Ontario Tobacco Research Unit 2010). Among females, a relatively similar distribution of people who smoke was identified in the present study for all age categories relative to available provincial and national data. There was, however, a smaller proportion of males who participated in the study relative to the reported prevalence of males who smoke in Ontario, Canada. Study participants also tended to report higher levels of education than the known population of smokers in Ontario.

Participants recruited into the study consumed a similar number of cigarettes to that reported for people who smoke in Ontario. There were, however, several differences in the characteristics of study participants noted compared to available data for individuals who smoke in Ontario and Canada. For example, a larger proportion of patients in the present study reported a readiness to quit smoking in the next 6 months and the next 30 days compared to provincial and national data. Study participants were more likely to have made a quit attempt in the last year compared to data available for smokers in Ontario and Canada. Data also suggests a trend towards higher rates of nicotine dependence among people who smoke, screened as part of this study, relative to national data.

Table 15: Comparison of the demographic characteristics and smoking history of study participants with individuals who smoke in Ontario and Canada

Variable	% Pilot Study	% Ontario	% Canada
Daily Smoking Prevalence	13.8	14.0	13.5
Males			
20-34 years	18.3		31.6
35-44 years	19.8		19.2
45-64 years	53.6		35.8
65+ years	8.7		6.7
Females			
20-34 years	26.9		29.9
35-44 years	19.8		18.7
45-64 years	43.9		37.1
65+ years	9.5		8.0
Education			
<High School	14.5	27	-
High School	28.2	25	-
Some Post-secondary	36.5	24	-
University Degree	20.7	17	-
Number of Cigarettes	15.6	15.7	14.9
Readiness to Quit			
Next 6 months	75	52	54
Next 30 days	34	21	25
Time to first cigarette			
>60 mins	21.4	-	23.0
31-60 mins	17.1	-	35.1
5-30 minutes	34.9	-	18.1
Within 5 minutes	26.5	-	23.8
Quit Attempt in last year	58.4	49.0	49.4
Advised to quit in past 12 months	69.9[a]	64.0	54.0

Source: Ontario Tobacco Survey 2010; Canadian Tobacco Monitoring Survey 2008.

[a] Non-daily smoking rates should be interpreted with caution as only patients who reported smoking in last 7-days were screened for the present study. Provincial and National data is based on a broader definition for occasional smokers.
[a]Pre-assessment rates at which advice was delivered in the last 12 months.

5.2 Comparison between PS and FC intervention groups

5.2.1 Provider delivery of evidence-based smoking cessation treatments (5As)

The comparison between the PS and FC intervention groups for provider performance in 5As delivery is presented as Table 16. Summary statistics generated for the multi-level models for the interaction between group (PS vs. FC) and time (pre- vs. post-assessment) are presented as Table 17. As hypothesized, there were no significant differences between intervention groups in 5As delivery at the follow-up when controlling for the cluster design and baseline rates of 5As delivery. The intra-class correlations coefficients calculated indicate the majority of variation in 5As delivery was at the level of the providers. The intra-clinic ICC for "ask", "advise", "assess", and "assist" was 0, indicating no variance attributable to the cluster design. An ICC of 0.01 was documented for "discuss medications" and "arrange follow-up" indicating less clustering at the level of the clinic than expected. A slightly larger intra-clinic ICC value of 0.05 was calculated for the "prescribing medications" component of assist.

Table 18 presents the rates at which other clinic staff delivered evidence-based smoking cessation strategies for each of the intervention groups. No significant differences were found between groups in the rates at which other clinics staff delivered cessation support.

5.2.2 Support with quitting received between clinic visit and 4-month follow-up

Table 19 presents data by intervention group regarding smoking cessation services received between the exit survey and 4-month follow-up interview. In the PS group, there was a 16% increase in the number of patients who were recommended pharmacotherapy, with a 10% increase observed in the FC group.

Table 16: Provider delivery of tobacco treatment strategies (5As) between intervention groups

Parameter	PS Group			FC Group				P=
	Pre	***Post***	Δ	***Pre***	***Post***	Δ	**Δ FC - ΔPS**	
Ask								
Today's Visit	123/229 (53.7)	150/237 (63.3)	+9.6	89/187 (47.6)	104/171 (60.8)	+13.2	+3.6	ns
Last 12 months	-	202/232 (87.1)	-	-	138/165 (83.6)	-	-	
Advise								
Today's Visit	98/228 (43.0)	137/233 (58.8)	+15.8**	60/175 (34.3)	91/171 (53.2)	+18.9***	+3.1	ns
Last 12 months	168/232 (72.4)	188/233 (80.7)	+8.3*	120/180 (66.7)	135/169 (80.0)	+13.3**	+5.0	ns
Assess								
Today's Visit	80/229 (34.9)	117/232 (50.4)	+15.5***	60/177 (33.9)	92/168 (54.8)	+20.9***	+5.4	ns
Last 12 months	-	182/233 (78.1)	-	-	132/168 (78.6)	-	-	
Assist								
Today's Visit	64/230 (27.8)	109/232 (47.0)	+19.2***	53/177 (29.9)	78/167 (46.7)	+16.8**	-2.4	ns
Last 12 months	-	159/235 (67.7)	-	-	112/169 (66.3)	-	-	
Discuss Medications								
Today's Visit	50/230 (21.7)	85/230 (37.0)	+15.3***	46/177 (26.0)	53/167 (31.7)	+5.7	-9.6	
Last 12 months	-	150/234 (64.1)	-	-	92/166 (55.4)	-	-	
Prescribe Medications								
Today's Visit	31/230 (13.5)	40/227 (17.6)	+4.1	28/177 (15.8)	30/170 (17.6)	+1.8	-2.3	ns
Last 12 months	-	74/231 (32.0)	-	-	47/164 (28.7)	-	-	
Quit Date	18/233 (7.7)	30/239 (12.6)	+4.9	23/177 (13.0)	18/173 (10.4)	-2.6	-7.5	
Self-Help Material								
Today's Visit	17/228 (7.5)	57/233 (24.5)	+17.0***	16/177 (9.0)	45/171 (26.3)	+17.3***	+0.3	ns
Last 12 months	-	110/227 (48.5)	-	-	77/163 (47.2)	-	-	
Arrange	17/232 (7.3)	35/241 (14.5)	+7.2*	20/182 (11.0)	29/176 (16.5)	+5.5	-1.7	ns

Comparisons between PS and FC groups are based on hierarchical logistic regression models (adjusted for clinic and provider level variance).
*p < .05. **p < .01. ***p <.001.

Table 17: Outcome estimates for multi-level models examining differences between groups in 5As delivery when controlling for baseline differences between groups

Parameter	Odds Ratio	Lower 95% Confidence Interval	Upper 95% Confidence Interval	P=	Coeff.	SE	Wald Test	ICC Intra-Clinic	ICC Intra-Provider
Ask	1.03	0.58	1.84		0.03	0.297	0.01	0.00	0.04
Advise	0.89	0.49	1.59		-0.122	0.299	0.17	0.00	0.04
Assess	0.82	0.45	1.48		-0.201	0.302	0.44	0.00	0.07
Assist	1.18	0.64	2.17		0.163	0.312	0.27	0.00	0.05
Assist – Quit Date	2.42	0.95	6.21		0.885	0.480	3.40	0.00	0.13
Assist – Self-help	1.23	0.50	3.06		0.210	0.463	0.21	0.00	0.10
Assist – Discuss Medications	1.60	0.83	3.09		0.473	0.334	2.01	0.01	0.05
Assist – Prescribe Medications	1.21	0.57	2.59		0.191	0.388	0.24	0.05	0.06
Arrange	1.56	0.63	3.87		0.444	0.464	0.92	0.01	0.11

Controlling for clinic and provider level factors
CI= confidence interval
*p < .05. **p < .01. ***p <.001.

Table 18: Staff performance in the delivery of tobacco treatment strategies (5As) between intervention groups

Parameter	PS Group			FC Group			Diff
	Pre	***Post***	Δ	***Pre***	***Post***	Δ	**ΔFC - ΔPS**
Ask							
Today's Visit	26/204 (12.7)	70/234 (29.9)	+17.2***	16/146 (11.0)	58/171 (33.9)	+22.9***	+5.7
Last 12 months	-	91/231 (39.4)	-	-	66/164 (40.2)	-	-
Advise							
Today's Visit	9/205 (4.4)	29/234 (12.4)	+8.0**	16/144 (11.1)	17/170 (10.0)	-1.1	-9.1
Last 12 months	34/200 (17.0)	65/232 (28.0)	+11.0**	26/137 (19.0)	35/166 (21.1)	+2.1	-8.9
Assess							
Today's Visit	11/204 (5.4)	21/229 (9.2)	+3.8	7/141 (5.0)	23/167 (13.8)	+8.8*	+5.0
Last 12 months	-	59/236 (25.0)	-	-	47/168 (28.0)	-	-
Assist							
Today's Visit	3/203 (1.5)	15/229 (6.6)	+5.1*	12/144 (8.3)	17/168 (10.1)	+1.8	-3.3
Last 12 months	-	48/239 (20.1)	-	-	30/166 (18.1)	-	-

Staff refers to non-physician members of the clinic staff (nurse practitioners, nurses, pharmacists, reception).

Table 19: Use of smoking cessation treatments and support reported at the 4-month follow-up interview by intervention group

Parameter	PS Group			FC Group			Diff
	Pre	Post	Δ	Pre	Post	Δ	FC-UC
Has your family doctor or another member of the clinic staff advised you to quit smoking in the last 12 months?	127/167 (76.0)	125/158 (79.1)	+3.1	91/144 (63.2)	77/100 (77.1)	+13.9**	+10.8
Have you sought/received counselling for smoking cessation from your primary care physician office?	67/233 (28.8)	78/242 (32.2)	+3.4	60/183 (32.8)	48/177 (27.1)	-5.7	-6.3
In the last 12 months has your doctor or another member of the clinic staff recommended you use one of the available quit smoking medication?	80/165 (48.5)	101/157 (64.3)	+15.8**	69/144 (47.9)	57/98 (58.2)	+10.3	-5.5

*p < .05. **p < .01. ***p <.001

5.2.3 Quit attempts

A comparison of the pre- and post-assessment performance for the PS and FC intervention groups for smoking outcomes is presented in Table 20. Table 21 presents the multi-level model controlling for clinic- and provider-level variance as well as baseline difference between groups for smoking abstinence.

5.2.4 Smoking abstinence

Contrary to the study hypothesis, a higher and statistically significant 7-day point prevalence abstinence (OR 6.8, 95% CI 2.1-21.7; p= <0.01) and continuous abstinence (OR 13.7, 95% CI 2.1-128.3; p= <0.05) rate was observed in the PS group compared to the FC group at the 16-week follow-up. The extremely large confidence interval indicates significant uncertainty surrounding the point estimate. It should be noted that the 7-day point prevalence abstinence rate was significantly greater in the FC group compared to the PS group at the pre-intervention assessment; 2.1% for the PS group, and 14.8% for the FC group (p= <0.01). Although the post-intervention assessment documented a higher quit rate in the FC group, the overall change scores (pre-post) was greater in the PS group. There were no differences in quit attempts documented between intervention groups.

The ICC for 7-day point prevalence abstinence was also consistent with my estimates; however, both quit attempts and continuous abstinence had larger ICC than originally estimated, indicating a greater degree of clustering. Intra-provider ICC values ranged between 0.04 to 0.14, indicating most of the variation observed was between individual providers within a clinic.

Table 20: Smoking abstinence by intervention group at the pre- and post-intervention assessments

Parameter	PS Group			FC Group			ΔFC - ΔPS
	Pre	Post	Δ	Pre	Post	Δ	
Full Sample - Patients Reached							
Continuous Abstinence	1/200 (0.5)	9/210 (4.3)	+3.8	14/168 (8.3)	9/147 (6.1)	-2.2	-6.0
Prolonged Abstinence	4/200 (2.0)	9/210 (4.3)	+2.3	8/168 (4.8)	11/147 (7.5)	+2.7	+0.4
7-day ppa Abstinence	5/200 (2.5)	24/210 (11.4)	+8.9	23/167 (13.8)	19/147 (12.9)	-0.9	-9.8
Full Sample - Self-reported[a]							
Continuous Abstinence	1/233 (0.4)	9/242 (3.7)	+3.3	14/183 (7.7)	9/177 (5.1)	-2.6	-5.9
7-day ppa Abstinence	5/233 (2.1)	25/242 (10.3)	+8.1	27/183 (14.8)	23/177 (13.0)	-1.8	-9.9
Full Sample - Bio-chemically Validated [a]							
7-day ppa Abstinence	2/233 (0.9)	11/242 (4.5)	+3.6	13/183 (7.1)	12/177 (6.8)	-1.0	-4.6
Quit Attempt, n (%)	54/200 (27.0)	74/210 (35.2)	+8.2	61/167 (36.5)	62/147 (42.2)	+6.2	-2.0

[a] Patients who were not reached were classified as smokers.

ppa=point prevalence abstinence

Table 21: Outcome estimates for smoking abstinence and quit attempts for the multi-level models examining differences between groups when controlling for clinic and provider variance and baseline differences between groups

Parameter	Odds Ratio	Lower 95% Confidence Interval	Upper 95% Confidence Interval	P=	Coeff.	SE	Wald Test	ICC Intra-Clinic	ICC Intra-Provider
7-day point prevalence abstinence	0.15	0.05	0.47	**	-1.92	0.59	10.49	0.01	0.14
Continuous abstinence, 16 weeks	0.07	0.01	0.68	*	-2.62	1.14	5.26	0.05	0.05
Quit attempts	0.80	0.42	1.51		-0.26	0.33	0.48	0.02	0.04

Controlling for clinic and provider level factors.

CI = Confidence Interval.*p < .05. **p < .01. ***p <.001.

5.3 Comparison between pre- and post-intervention assessments

5.3.1 Changes in provider performance in 5As delivery

Figure 7 presents a comparison of rates of provider performance in the delivery of each of the 5As at the pre- and post-intervention assessment points. For this analysis, pre-post assessment data for both intervention arms was combined in order to estimate the associated benefits derived from the multi-component intervention program implemented. Following implementation of the intervention program, 80% of patients reported they were advised to quit by their physicians in the last 12 months compared to 70% at the pre-assessment. On the day of their last visit to clinic, 62% of respondents reported that they were asked about their smoking status, 56% reported receiving advice to quit, 52% were asked if they were asked about their readiness to quit smoking, and 47% received assistance with quitting. Table 22 presents the outcome estimates generated from the multi-level analysis comparing 5As delivery and smoking outcomes for the pre- and post-assessments. The multi-level analysis documented a significant increase in provider performance in the delivery of smoking cessation treatments at the post-intervention assessment for each of the 5As with the exception of setting a quit date and prescribing medications. The point estimates and 95% CI were: ask (OR 1.5, 95% CI 1.1-2.0); advise (OR 2.0, 95% CI 1.5-2.7); assess (OR 2.1, 95% CI 1.6-2.9); assist (OR 2.30, 95% CI 1.70-3.12); discuss medications (OR 1.8, 95% CI 1.3-2.5; provide self-help material (OR 4.0, 95% CI 2.6-6.3); and arrange (OR 1.9, 95% CI 1.2-3.0).

Table 22 also presents the ICC for intra-provider and intra-clinic variation. The ICC was 0.01 for “discuss medications” and “arranging follow-up”, indicating less clustering of final results than had been expected. A slightly larger ICC value of 0.05 was calculated for “prescribing medications” component of “assist”. The majority of variability observed was between providers within clinics.

Figure 7: Provider performance in 5As Delivery Pre- and Post-Implementation for all study participants [*=p<0.05, ** = p <0.01, ***p<0.001]

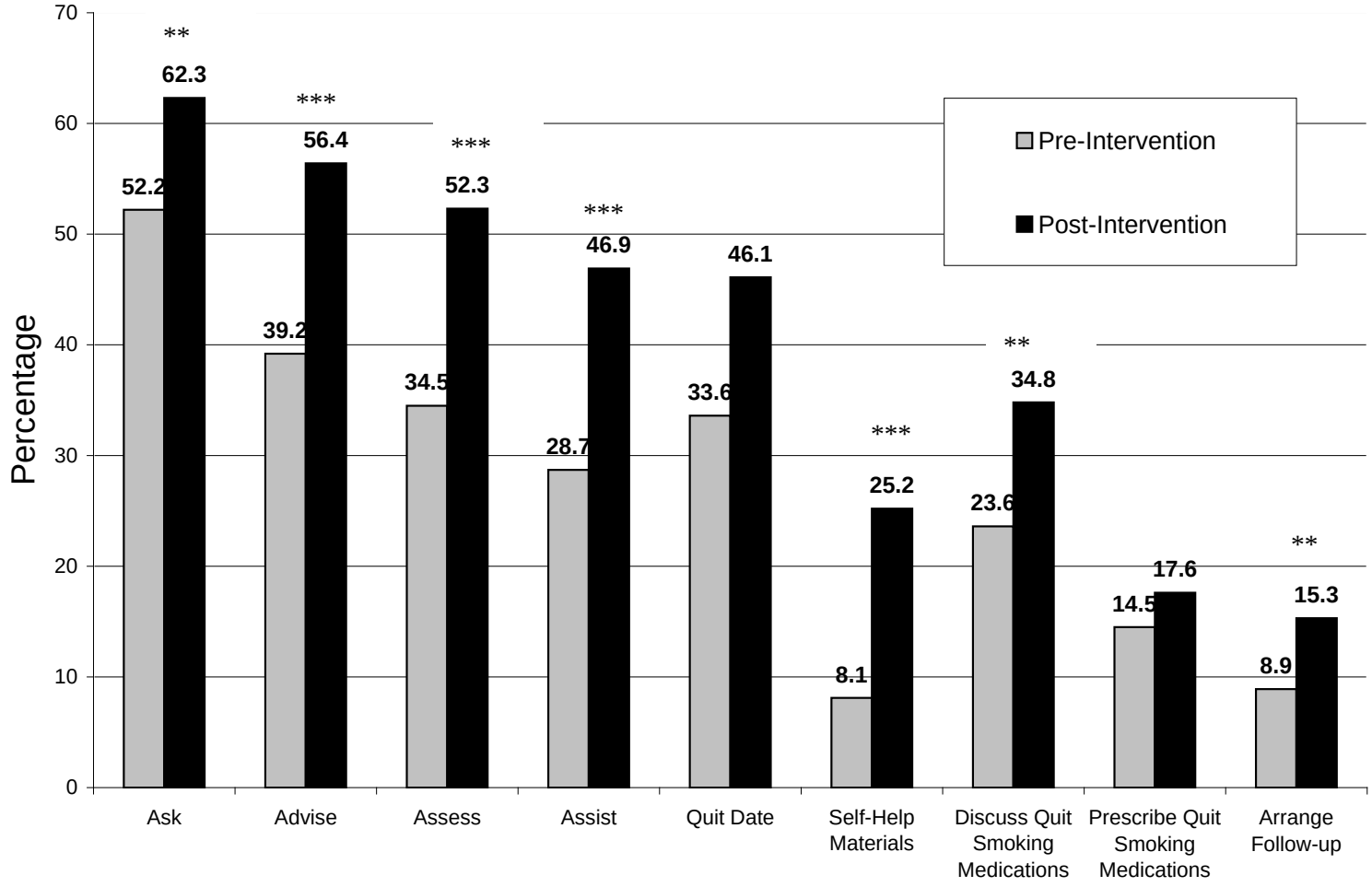


Table 22: Provider performance in 5As delivery pre- and post-intervention

Parameter	% Pre	% Post	Delta	Odds Ratio	Lower 95% CI	Upper 95% CI	P=	Coeff.	SE	Wald Test	Intra-Clinic ICC	Intra-Provider ICC
Ask	52.2	62.3	10.1	1.50	1.12	2.00	**	0.41	0.15	7.6	0.00	0.04
Advise	39.2	56.4	17.2	2.02	1.53	2.67	***	0.70	0.14	24.2	0.00	0.04
Assess	34.5	52.3	17.8	2.13	1.59	2.85	***	0.76	0.15	25.8	0.00	0.04
Assist	28.7	46.9	18.2	2.30	1.70	3.12	***	0.84	0.16	29.0	0.00	0.05
Assist – Quit Date	33.6	46.1	12.5	1.23	0.77	1.95		0.21	0.24	0.8	0.00	0.13
Assist – Self-help	8.1	25.2	17.1	4.02	2.56	6.33	***	1.39	0.23	36.3	0.00	0.11
Assist – Discuss Medications	23.6	34.8	11.2	1.78	1.29	2.46	**	0.58	0.17	12.2	0.01	0.07
Assist – Prescribe Medications	14.5	17.6	3.1	1.25	0.86	1.83		0.23	0.19	1.4	0.05	0.05
Arrange	8.9	15.3	6.4	1.94	1.23	3.04	**	0.66	0.23	8.3	0.01	0.12

Controlling for clinic and provider level variance between clusters.
CI = confidence interval.
ICC = Intra-class correlation coefficient.
[a]Based on self-report data. All patients lost to follow-up were categorized as smokers.
*p < .05. **p < .01. ***p <.001.

5.3.2 Other clinic staff

Data on the rates at which other clinic staff (i.e., nurse, pharmacist, reception) delivered 5As is presented as Table 23. A large (19.6%) increase in the involvement of staff in screening for smoking status (i.e., “ask”) was documented. Small but statistically significant increases were also observed for the involvement of other clinic staff members in the “advise”, “assess”, and “assist” domains of 5As delivery on the day of the patient’s clinic appointment.

5.3.3 Assistance with quitting reported at the 4-month follow-up assessment

Table 24 presents responses collected at the 4-month follow-up telephone interview regarding the delivery of supplemental smoking cessation advice, counselling and pharmacotherapies. A statistically significant increase in both the rates of advice and recommendations regarding pharmacotherapy were documented. No differences were observed in the number of patients who reported receiving smoking cessation counselling from their primary care physician’s office between the pre- and post-assessment.

5.3.4 Comparison of pre- and post-assessment data by study clinic

Table 25 provides a summary of provider performance in 5As delivery across intervention clinics. Change scores for performance in 5As delivery by intervention clinic between the pre- and post-assessment are presented in Table 26. Significant variability was observed in provider performance for 5As delivery between clinics with change scores ranging from a reduction of 12.7% to an improvement of 43%.

Table 23: Performance of Other Staff[a] in the Delivery of Tobacco Treatment Strategies (5As)

Parameter	*Pre*	*Post*	Δ
Ask			
Today's Visit	42/350 (12.0)	128/405 (31.6)	+19.6
Last 12 months	-	157/395 (39.7)	-
Advise			
Today's Visit	25/349 (7.2)	46/404 (11.4)	+4.2
Last 12 months	60/349 (17.2)	100/397 (25.2)	+8.0
Assess			
Today's Visit	18/345 (5.2)	44/396 (11.1)	+5.9*
Last 12 months	-	106/404 (26.2)	-
Assist			
Today's Visit	15/347 (4.3)	32/397 (8.1)	+3.7
Last 12 months	-	78/405 (19.3)	-

[a]Other Staff refers to non-physician members of the clinic staff (nurse practitioners, nurses, pharmacists, reception).

Table 24: Smoking cessation support reported at 4-month assessment pre- and post-intervention

Parameter	Pre	Post	Δ	P=
Has your family doctor or another member of the clinic staff advised you to quit smoking in the last 12 months?	218/311 (70.1)	202/258 (78.3)	+8.2	.027
Have you sought/received counselling for smoking cessation from your primary care physician office?	128/416 (30.5)	126/419 (30.1)	-0.4	.596
In the last 12 months has your doctor or another member of the clinic staff recommended you use one of the available quit smoking medication?	149/309 (48.2)	158/255 (62.0)	+13.8	.001

Table 25: Provider performance in 5As delivery pre- and post-intervention by clinic

Clinic	Ask	Advise	Advise 12 Months	Assess	Assist	Assist Discuss Quit Smoking Medications	Assist Prescribe Quit Smoking Medications	Assist Set Quit Date	Assist Provide Self-Help Materials	Arrange Follow-up
Clinic 1										
Pre	20/56 (36)	13/54 (24)	32/56 (57)	13/54 (24)	9/54 (16)	8/55 (15)	3/55 (6)	9/56 (16)	5/55 (9)	0/56 (0)
Post	37/52 (71)	30/51 (59)	34/49 (69)	32/50 (64)	25/50 (50)	16/51 (31)	8/52 (15)	4/52 (8)	10/52 (19)	7/53 (13)
Clinic 2										
Pre	27/57 (47)	22/57 (39)	41/58 (71)	18/57 (32)	18/57 (31)	14/57 (25)	5/57 (9)	2/58 (3)	7/56 (13)	5/58 (9)
Post	29/59 (49)	31/57 (54)	50/57 (88)	24/57 (42)	21/57 (36)	14/57 (25)	7/57 (12)	5/60 (8)	4/60 (7)	6/60 (10)
Clinic 3										
Pre	32/52 (62)	23/53 (43)	41/55 (75)	22/53 (42)	17/53 (32)	8/53 (15)	5/53 (9)	8/55 (15)	3/53 (6)	4/55 (7)
Post	42/62 (68)	36/62 (58)	48/62 (77)	29/61 (48)	26/61 (42)	17/61 (28)	5/61 (8)	9/64 (14)	15/62 (24)	11/64 (17)
Clinic 4										
Pre	38/64 (59)	28/64 (44)	52/67 (78)	26/66 (39)	28/66 (42)	20/65 (31)	14/65 (22)	8/70 (11)	6/65 (9)	13/69 (19)
Post	28/60 (47)	27/61 (44)	53/61 (87)	25/59 (42)	23/58 (40)	15/58 (26)	11/59 (19)	6/61 (10)	15/60 (25)	15/63 (24)
Clinic 5										
Pre	29/56 (52)	29/55 (53)	45/55 (82)	25/56 (45)	22/56 (39)	17/56 (30)	13/56 (23)	6/56 (11)	7/55 (13)	5/56 (9)
Post	34/50 (68)	32/49 (65)	47/52 (90)	27/49 (55)	27/49 (55)	25/47 (53)	16/46 (35)	11/52 (21)	13/46 (28)	5/52 (10)
Clinic 6										
Pre	31/57 (54)	19/57 (33)	36/57 (63)	21/57 (37)	16/57 (28)	18/57 (32)	11/57 (19)	6/57 (11)	5/57 (9)	7/57 (12)
Post	39/60 (65)	34/59 (58)	48/59 (81)	35/59 (59)	30/59 (51)	22/58 (38)	11/59 (19)	8/60 (13)	20/59 (34)	7/60 (12)
Clinic 7										
Pre	35/64 (55)	24/63 (38)	41/64 (64)	15/63 (24)	7/64 (11)	11/64 (17)	8/64 (13)	2/64 (3)	0/64 (0)	3/64 (5)
Post	45/66 (68)	38/65 (59)	43/62 (69)	37/65 (57)	35/65 (54)	29/65 (45)	12/63 (19)	5/63 (8)	25/65 (39)	13/65 (20)

Reported as n/N (%)

Table 26: Percent (%) change in provider performance in 5As delivery from pre-intervention to post-intervention by clinic

Clinic	Ask	Advise Today's Visit	Advise Last 12 Months	Assess	Assist	Assist Discuss Quit Smoking Medications	Assist Prescribe Quit Smoking Medications	Assist Set Quit Date	Assist Provide Self-Help Materials	Arrange Follow-up
Clinic 1	35.8	34.7	12.3	39.9	33.3	16.9	9.9	-8.4	10.1	13.2
Clinic 2	1.8	15.8	17.0	10.5	5.2	0.0	3.5	4.9	-5.8	1.4
Clinic 3	6.2	14.7	2.9	6.0	10.5	12.8	-1.2	-0.4	18.5	9.9
Clinic 4	-12.7	0.5	9.3	3.0	-2.7	-4.9	-2.9	-1.6	15.8	5.0
Clinic 5	16.2	12.6	8.6	10.5	15.8	22.8	11.6	10.5	15.6	0.7
Clinic 6	10.6	24.3	18.2	22.5	22.7	6.3	-0.7	2.8	25.1	-0.6
Clinic 7	13.5	20.4	5.3	33.1	42.9	27.4	6.5	4.8	38.5	15.2

All values reported are percentages calculated as % Change = post-assessment rate – pre-assessment rate.

5.3.5 Patient quit attempts

Table 27 presents data for the number of patients who made a quit attempt between the exit interview and 4-month follow-up interview at the pre- and post-assessment. Table 28 presents the outcome estimates generated from the multi-level analysis comparing smoking outcomes for the pre- and post-assessments. A statistically significant increase was documented for the number of patient quit attempts between the pre- and post-assessment (31% to 37%, $p<0.001$; OR 1.42, 95% CI 1.04-1.94).

5.3.6 Smoking abstinence

A small increase was documented in the 7-day point prevalence abstinence at the post-assessment (7.7% vs. 11.5%; OR 1.5, 95% CI 0.94-2.5); however, observed differences were not statistically different (Table 27 and Table 28). No significant increase was documented between assessment points for continuous abstinence. Bio-chemically validated smoking abstinence was 3.6% vs. 5.5% at the pre- and post-assessments, respectively. Observed differences were not statistically significant. All biochemical samples returned confirmed smoke-free status of patients. The differential between the self-reported and bio-chemically validated rates reflects the large number (45%) of patients who did not return the biochemical sample and were coded as active smokers. The intra-clinic ICC for 7-day point prevalence abstinence was also consistent with *a priori* estimates. However, ICCs for both quit attempts and continuous abstinence were larger than the *a priori* estimates, indicating a greater degree of clustering. Intra-provider ICC values ranged between 0.04 to 0.13 indicating most of the variation observed was between individual providers within a clinic. Smoking outcomes by study clinics are presented as Table 29). Clinics 3 and 5 documented the largest increases in smoking abstinence between the pre- and post-assessment (~+15%). Clinic 7 documented an increase of 5%, and no changes were documented in the remaining clinics. This data should be interpreted with caution given the small sample size at each clinic.

Table 27: Smoking abstinence and quit attempts reported at the 4-month follow-up pre- and post-intervention for all smokers and smokers ready to quit in next 30 days

Parameter	All Smokers			Smokers Ready to Quit		
	Pre	Post	Δ	Pre	Post	Δ
Participants Reached – Self-reported						
Continuous Abstinence	15/369 (4.1)	17/373 (4.6)	+0.5	11/126 (8.7)	12/121 (9.9)	+1.2
7-day ppa Abstinence	32/370 (8.6)	48/373 (12.9)	+4.3	15/127 (11.8)	24/120 (20.0)	+8.2
Full Sample – Self-reported[a]						
Continuous Abstinence	15/416 (3.6)	17/419 (4.1)	+0.5	11/141 (7.8)	12/131 (9.2)	+1.4
7-day ppa Abstinence	32/416 (7.7)	48/419 (11.5)	+3.8	15/141 (10.6)	24/131 (18.3)	+7.7
Full Sample - Bio-chemically validated						
7-day ppa Abstinence	15/416 (3.6)	23/419 (5.5)	+2.3	6/141 (4.3)	10/131 (7.6)	+3.3
Quit Attempt, n (%)	113/370 (30.5)	136/370 (36.8)	+6.3	58/126 (46.0)	71/120 (59.2)	+13.2

[a]All patients lost to follow-up were categorized as smokers.

Table 28: Quit attempts and smoking abstinence reported at the pre- and post-intervention assessments

Parameter	% Pre	% Post	Delta	Odds Ratio	Lower 95% CI	Upper 95% CI	P=	Coeff.	SE	Wald Test	Clinic ICC	Provider ICC
7-day point prevalence[a]	7.7	11.5	3.8	1.52	0.94	2.46		0.42	0.25	2.9	0.01	0.14
Continuous abstinence[a]	3.6	4.1	0.5	1.23	0.61	2.49		0.21	0.36	0.3	0.05	0.05
Quit attempts	30.5	36.8	6.3	1.42	1.04	1.94	**	0.35	0.16	5.0	0.02	0.04

Controlling for clinic and provider level variance between clusters.
CI = confidence interval.
ICC = Intra-class correlation coefficient.
[a]Based on self-report data. All patients lost to follow-up were categorized as smokers.
*p < .05. **p < .01. ***p <.001.

Table 29: Smoking outcomes measured at 4-month follow-up interview pre- and post-intervention by study clinic

Clinic	Continuous Abstinence[a]	7-day Point Prevalence Abstinence[a]	Quit Attempts
Clinic 1			
Pre	4/56 (7.1)	11/56 (19.6)	20/49 (40.8)
Post	4/54 (7.4)	7/54 (13.0)	24/45 (53.3)
Clinic 2			
Pre	1/58 (1.7)	2/58 (3.4)	8/52 (15.4)
Post	2/60 (3.3)	2/60 (3.3)	15/53 (28.3)
Clinic 3			
Pre	0/55 (0)	2/55 (3.6)	16/50 (32.0)
Post	4/64 (6.3)	11/64 (17.2)	28/59 (47.5)
Clinic 4			
Pre	6/70 (8.6)	7/70 (10.0)	22/67 (32.8)
Post	3/63 (4.8)	8/63 (12.7)	20/54 (37.0)
Clinic 5			
Pre	0/55 (0)	0/55 (0.0)	18/43 (41.9)
Post	1/52 (1.9)	8/52 (15.4)	16/45 (35.6)
Clinic 6			
Pre	4/57 (7.0)	8/57 (14.0)	18/49 (36.7)
Post	2/59 (3.4)	5/60 (8.3)	18/47 (38.3)
Clinic 7			
Pre	0/63 (0)	1/63 (1.6)	11/54 (20.4)
Post	2/65 (3.1)	4/65 (6.2)	15/49 (30.6)

Reported as n/N (%).
[a]Based on self-reported data for full study sample. Patients lost to follow-up were categorized as smokers.

5.3.7 Reasons for returning to smoking

The reason for returning to active smoking was recorded for patients who reported having made a quit attempt between the exit interview and 16-week follow-up interview (Table 30). The most commonly reported factor that contributed to relapse was stress (39.4%), death or illness in the family (15.6%), and habit (12.5%).

Table 30: Patients self-reported reason for returning to smoking following unsuccessful quit attempt

Reason	n	%
Stress	63	39.4
Death or illness in the family	25	15.6
Habit	20	12.5
Social environment/gathering	12	7.5
Cravings	9	5.6
Nerves/Emotional problems	8	5.0
Enjoyment/Relaxation	6	3.8
Boredom	4	2.5
Spouse	4	2.5
Drinking	3	1.9
Medication side effect	3	1.9
Lack of motivation/willpower	3	1.9
Other	8	5.0
No reason	5	3.1
Don't know	13	8.1

5.4 Fidelity of intervention implementation

5.4.1 Implementation of intervention components

Implementation results are shown in Table 31 for the pre- and post-assessment periods. At baseline, most clinics had very few supports in place to assist with the delivery of evidence-based smoking cessation services. The majority of study clinics formed a multi-disciplinary task force, and all of the study clinics developed their own clinic-specific tobacco use protocol and received a training workshop on smoking cessation; however, the proportion of the overall physician providers who attended the training session varied by clinic. Two of the study clinics were no longer using the tobacco use survey at the post-assessment consistently (i.e., used in modified manner with subset of patients).

Table 32 presents information on the proportion of providers in each clinic that completed the training as well as the model used to deliver the quit plan visits. Sixty-three percent of all providers attended the 3-hour continuing medical education workshop on smoking cessation best practices that was offered to both intervention groups as part of the study. Significantly more providers in the PS group attended the training workshop ($p=0.039$). Providers in clinics 1 and 7 who were not able to attend the workshop met one-on-one with a representative from the clinic task force to review the clinic tobacco control protocol.

Three of the seven clinics had an existing staff member to whom physicians could refer patients who smoke for support with quitting and follow-up. At post-intervention, all seven clinics had identified staff trained in smoking cessation and available to be referred to for smoking cessation consults. Half of the clinics used front-line staff to deliver all program elements including the quit plan visit at the end of the patient appointment or via appointment. One clinic was not able to identify any non-physician staff to complete these consults and physicians delivered all program elements. The

other half of clinics chose to identify a dedicated staff member(s) who served as the clinic's smoking cessation counsellor by appointment. These staff received smoking cessation referrals from all clinic physicians and conducted 10- to 30-minute visits to develop a personalized quit plan with patients ready to quit smoking in the next 30 days. The majority of clinics used nursing staff (RN or NP) to conduct the quit plan visits. The remaining clinics used pharmacists (n=2) or physicians (n=1) in this role.

Table 31: Implementation of intervention program activities pre- and post-intervention

Practice Implementation Activities		Time	Clinic							Overall
			PS Group				FC Group			
			2	3	5	7	1	4	6	
1.	Clinic task force formed	*Pre*	-	-	-	-	-	X	-	1/7
		Post	X	X	X	X	X	-	X	6/7
2.	Clinic tobacco control protocol developed	*Pre*	-	-	-	-	-	-	-	0/7
		Post	X	X	X	X	X	X	X	7/7
3.	Tobacco use queried and documented for all clinic patients	*Pre*	-	-	-	-	-	-	-	0/7
		Post	-	X	X	X	X	-	X	5/7
4.	Training tobacco dependence treatment offered to health care providers in last year	*Pre*	-	-	-	-	-	-	-	0/7
		Post	X	X	X	X	X	X	X	7/7
5.	Dedicated staff to provide tobacco dependence treatment	*Pre*	X	X	-	-	-	X	-	3/7
		Post	X	X	X	X	X	X	X	7/7
6.	Tobacco use survey in use	*Pre*	-	-	-	-	-	-	-	0/7
		Post	-	X	X	X	X	-	X	5/7
7.	Consult form in use	*Pre*	-	-	-	-	-	-	-	0/7
		Post	X	X	X	X	X	-	X	6/7
8.	Process to follow-up tobacco users for at least one month after clinic visit in place	*Pre*	X	-	-	-	-	X	-	2/7
		Post	X	X	-	X	X	X	X	6/7
9.	Process to evaluate quality or program implementation in place	*Pre*	-	-	-	-	-	-	-	0/7
		Post	X	-	-	X	X	-	X	4/7
10.	Process to provide feedback to clinicians about performance in place	*Pre*	-	-	-	-	-	-	-	0/7
		Post	X	X	X	X	X	X	X	7/7
Total Pre-Assessment			2/10	1/10	0/10	0/10	0/10	3/10	0/10	
Total Post-Assessment			8/10	9/10	8/10	10/10	10/10	6/10	10/10	

Table 32: Attendance at training workshop and service delivery model used by study clinics, study group, and overall

Parameter	1	2	3	4	5	6	7	PS Group %	FC Group %	Overall %	p=
Participated in CME in training, %	36.0[a]	87.5	79.2	69.2	77.8	77.8	33.3[a]	72.9	53.2	63.2	.039
Service Delivery Model											
Front-line staff	0	0	1	0	1	1	0	50.0	33.3	43.0	.659
Specialized staff	1	1	0	1	0	0	1	50.0	66.6	57.0	

[a]Providers from clinic 1 and 7 who were not able to participate in the CME training had a brief orientation to the clinic's tobacco control protocol conducted one-on-one by a member of the clinic staff prior to the launch of the program.

5.4.2 Patient participation in telephone follow-up program

A total of 1140 referrals were received to the telephone-based follow-up system between the launch of the pilot program and the end of the data collection period in December 2009, including 425 patients who were embarking upon a quit attempt. The 60-day quit rate among the patients referred for follow-up was 41.6%. In the calculation of quit rates, patients who could not be reached were coded as active smokers.

Among patients in the FC group who took part in the study assessments 31/175 (17.7%) at the post-assessment agreed to be enrolled in the telephone follow-up program (see Table 33). Among patients who reported they were ready to quit in the next 30-days, 32.6% were referred to the telephone follow-up program and 31.2% were abstinent at the end of 4 months.

Table 33: Patients who agreed to receive the adjunct telephone follow-up support

Population	Overall		Quit Rate	
	Pre	Post	Pre	Post
All Patients	16/183 (8.7)	31/175 (17.7)	4/16 (25.0)	8/31 (25.8)
Ready to Quit in Next 30 days	7/62 (11.3)	16/49 (32.6)	2/7 (28.5)	5/16 (31.2)

Sixteen patients from the FC pre-intervention assessment sample who had received a quit plan session were referred to the telephone-based smoking cessation program. This data indicates that patients were seen in the clinic again after the smoking cessation intervention was instituted at the clinic and were exposed to the intervention. Data was re-analyzed to remove those participants who were referred to the telephone-based follow-up program for whom exposure to the intervention

condition was known to have occurred (see Table 34). Removing these participants partially explained the higher quit rates observed in the FC group at baseline relative to the PS group; however, significant differences still remained between groups even after these cases were removed. It should be noted that three patients in the PS group who did not have access to the telephone follow-up program were referred for IVR follow-up (2/233 at baseline and 1/241 at the follow-up) indicating some cross-over between groups.

Table 34: Smoking abstinence rates overall and by study group at the pre- and post-intervention assessment when patients who were exposed to intervention were removed from the analysis

Time	PS Group n/N (%)	FC Group n/N (%)	Overall n/N (%)
Pre	5/233 (2.1)	23/167 (13.8)	28/399 (7.0)
Post	25/242 (10.3)	23/177 (13.0)	48/419 (11.5)
Δ	8.1%	-0.8%	4.5%

5.5 Examination of mediating and moderating variables

Multi-level modelling was used to examine the influence of clinic, provider, and patient characteristics on study outcomes.

5.5.1 Smoking abstinence and quit attempts

Table 35 presents the final models for smoking abstinence and quit attempts. There were no clinic- or provider-level characteristics that were found to be significantly associated with patient smoking abstinence or quit attempts. Assignment to the PS group remained a significant factor in predicting smoking abstinence at the post-assessment. At the level of the patient, self-reported readiness to quit in the next 30 days was associated with higher rates of continuous abstinence (OR

3.09, 95% CI 1.49-6.40). High self-efficacy defined as confidence of 7 or greater on a 10-point scale was found to be a modest, however statistically significant, predictor of 7-day point prevalence abstinence. It should be noted that both readiness to quit and self-efficacy were moderately correlated in models for both continuous and point prevalence abstinence and could potentially be used interchangeably as predictors of smoking abstinence (r=.334, p=0.01). Not having made a previous quit attempt in the past year was significantly associated with reporting a quit attempt at the 16-week follow-up.

5.5.2 Provider performance in 5As delivery

Tables 36 and 37 present the final models for provider performance in each of the 5As strategies. No significant relationship between clinic characteristics and provider performance in 5As delivery was documented. At the level of the provider, provider age was found to have a small but statistically significant association with the rates at which self-help materials were provided to patients and medications discussed. Female providers and non-physician staff members (i.e., residents or nurse practitioners) were more likely to arrange follow-up appointments for patients to discuss smoking cessation. No other relationship between provider characteristics and outcomes was found.

Table 35: Final model for the multi-level analysis of clinic, provider, and patient characteristics related to smoking cessation outcomes

Parameter	Response	OR (95% CI)		
		Continuous Abstinence	7-day Point Prevalence Abstinence	Quit Attempt
Patient Characteristics				
Confidence	1= greater than 7/10		1.10 (1.01, 1.20)*	
Ready to quit in next 30 days	1=yes	3.09 (1.49, 6.40)**		
Previous quit attempt in last year	1=yes			0.43 (0.31, 0.60)***
Provider Characteristics				
-				
Clinic characteristics				
-				
Intervention				
Group	1= FC Group	0.06 (0.01, 0.45)**	0.16 (0.06, 0.41)***	0.71 (0.52, 0.98)*
Time	1=Post Assessment			
Interaction Effects				
Group x Time		9.19 (1.17, 72.4)*	4.95 (1.85, 13.25)**	

CI = confidence interval.
*p < .05. **p < .01. ***p <.001.
Note: Continuous Abstinence (1=32, 0=803), 7-Day Point Prevalence Abstinence (1=80, 0=755), Quit Attempt (1=249, 0=491).

At the level of the patient, having fewer years of formal education was associated with higher rates of being asked about smoking status, advised to quit, prescribed quit smoking medications, and receiving follow-up. The presence of a smoking-related illness was associated with increased rates of asking and advising but not with any of the other 5As strategies. One of the most significant factors associated with 5As delivery was the nature of the clinic encounter on the day of the assessment. Patients who were seen in clinic for an annual exam were more likely to be asked about smoking status (OR 8.2, 95% CI 4.6-14.6), advised to quit (OR 4.7, 95% CI 3.0-7.5), assessed for readiness to quit (OR 5.3, 95% CI 3.4-8.3), receive assistance with quitting (OR 4.8, 95% CI 3.1-7.4), receive self-help materials (OR 2.1, 95% CI 1.2-3.6), discuss medications (OR 3.0, 95% CI 1.8-4.9), and receive a prescription for a quit smoking medication (OR 1.9, 95% CI 1.1-3.5) compared to patients who were seen for a follow-up appointment or other appointment. As would be expected, patients who were ready to quit in the next 30 days reported receiving self-help material, setting a quit date, discussing medication, and receiving a prescription for a quit smoking medication statistically more often than patients who were not ready to quit. A small relationship between time to first cigarette in the morning (a predictor of nicotine addiction) and rates of advising, assessing, and prescribing medications was documented. Having had at least one unsuccessful quit attempt in the last year was also associated with receiving a prescription for a quit smoking medication. Patients were more likely to have had set a quit date on the day of their visit if they were ready to quit in the next 30 days and had high levels of self-efficacy as well as those patients who ranked importance of quitting as high (7 or more on a scale of 1 to 10). Within the final models, the time variable (post-intervention period) remained a significant factor, predicting rates of asking, advising, assisting, providing self-help materials, discussing medications, and arranging follow-up. As was documented in the main multi-level model, the time (pre vs. post) variable was not significantly associated with setting a quit date or prescribing medications in the final models.

Table 36: Final model for the multi-level analysis of clinic, provider, and patient characteristics related to rates of provider delivery for ask, advise, assess and assist

Parameter	Response	OR (95% CI)			
		Asking	Advising	Assessing	Assisting
Patient Characteristics					
Education	1% for every year	0.93 (0.88, 0.98)**	0.94 (0.88 . 0.99)*		
Smoking-related illness	1=yes	1.70 (1.22, 2.37)**	1.64 (1.18, 2.29)**		
Purpose of Clinic Visit	1=annual exam	8.18 (4.6, 14.6)***	4.74 (3.01, 7.47)***	5.3 (3.4, 8.3)***	4.78 (3.09, 7.40)***
Time to first cigarette	1=within 30 mins		1.64 (1.17, 2.30)**	1.87 (1.33, 2.64)***	
Readiness to Quit	1=Ready		1.65 (1.18, 2.32)**		
Cigarettes/day	1% for every cigarette				1.03 (1.01, 1.05)**
Years smoking	1% for every year				1.01 (1.00, 1.03)*
Quit Attempt in Last Year	1=Yes				
Other smokers in home	1=yes	1.60 (1.16, 2.22)**			
Confidence	1=greater than 7/10			1.07 (1.01, 1.14)*	1.09 (1.02, 1.16)**
Importance	1= greater than 7/10	1.10 (1.04, 1.15)**		1.09 (1.03, 1.15)**	1.12 (1.1, 1.2)**
Intervention					
Time	1=Post Assessment	1.4 (1.01, 1.95)*	2.22 (1.60, 3.09)***	1.90 (1.38, 2.62)***	2.20 (1.55, 3.12)***
Group					
Interaction Effects					
Group x Time					
Random	**variance (SE)**				
Clinic					
Provider					

OR = Odds Ratio; CI = confidence interval; SE = Standard error.
*p < .05. **p < .01. ***p <.001.
Note : Ask (1=465,0=348), Advise (1=386,0=420), Assess (1=349,0=456), Assist (1=304,0=501).

Table 37: Final model for the multi-level analysis of clinic, provider, and patient characteristics related to rates of delivery for the provision of self-help materials, setting quit date, discussing and prescribing medications, and arranging follow-up

Parameter	Response	OR (95% CI)				
		Self-Help Material	Set Quit Date	Discuss Medication	Prescribe Medications	Arrange
Patient Characteristics						
Education	1% for every year				0.88 (0.81, 0.96)**	0.90 (0.83, 0.98)*
Smoking-related illness	1=yes					
Purpose of Clinic Visit	1=annual exam	2.06 (1.17, 3.63)**		2.98 (1.8, 4.9)***	1.91 (1.06, 3.45)*	
Time to first cigarette	1=within 30 mins				2.11 (1.21, 3.68)**	
Readiness to Quit	1=ready	2.41 (1.47, 3.94)**	4.10 (2.20, 764)***	2.45 (1.6, 3.7)***	1.91 (1.12, 3.27)*	
Cigs/day	1% for every cigarette			1.03 (1.0, 1.1)*		
Years smoking	1% for every year					
Quit Attempt in Last Year	1=yes				2.01 (1.17, 3.44)**	
Other smokers in home	1=yes					
Confidence	1=greater than 7/10		1.17 (1.05, 1.29)**		1.20 (1.09, 1.33)***	
Importance	1= greater than 7/10		1.32 (1.12, 1.55)**			1.48 (1.30, 1.68)***
Provider Characteristics						
Provider Age	1% for every year	1.03 (1.0, 1.07)*		1.03 (1.01, 1.06)*		
Provider Gender	1=male					0.37 (0.16, 0.87)*
Health Professional	1=physician					0.53 (0.30, 0.93)*
Intervention						
Time	1=post-assessment	5.46 (3.1, 9.7)***		1.94 (1.27, 2.96)**		1.81 (1.10, 2.99)*
Group						
Interaction Effects						
Group x Time						
Random	**variance (SE)**					
Provider		0.21 (0.187)	0.526 (0.284)	0.135 (0.128)		0.215 (0.204)

OR = Odds Ratio; CI = confidence interval; SE = Standard error.
*p < .05. **p < .01. ***p <.001.
Note: Self-help material (1=135, 0=673), Set Quit Date (1=88, 0=739), Discuss Medication (1=234, 0=569), Prescribe Medication (1=129, 0=674), Arrange (1=101, 0=729).

5.5.3 Patients ready to quit smoking in the next 30 days

Participants who reported they were ready to quit smoking in the next 30 days on the exit survey were more likely to receive "assistance" with quitting and be "prescribed a quit smoking medication" than the overall study sample (see Table 38). However, only about half of participants ready to quit smoking reported receiving assistance with quitting at the exit survey. It should be noted as per above that several of the 5As areas assessed (i.e., "set quit date", "prescribe medications") would likely have been delivered at a separate clinic appointment (quit plan visit) and, as such, not captured as part of the exit survey. At the post-assessment, participants were twice as likely to have a follow-up appointment arranged to discuss smoking cessation than at the pre-assessment.

Among patients ready to quit smoking in the next 30 days, a significant increase in the number of quit attempts was documented between the pre- and post-assessment (46% to 59%, p=0.04; OR 1.7, 95% CI 1.03, 2.8). This is a greater increase than that observed in the overall sample. A 7% increase was documented in the 7-day point prevalence abstinence at the post-assessment (11% vs. 18%, p=.074; OR 1.9, 95% CI 0.94, 3.8); however, observed differences were not statistically different. There were no changes documented between assessment points for continuous abstinence.

5.5.4 Type of clinic visit

The evaluation found patients at both the pre- and post-assessment were significantly more likely to be "asked" about smoking status if they were scheduled for an annual physical compared to other types of clinic appointments. A similar pattern was observed for each of the 5As at both the pre- and post-assessment (see Figure 8), with the exception or "quit date", and "prescribe medication", for which a small decline was documented between the pre- and post-assessment. Interestingly, patients who were surveyed following their annual exam did not report as many quit attempts at the 16-week follow-up assessment.

Table 38: Provider performance in 5As delivery and smoking outcomes pre- and post-intervention for participants who are ready to quit in next 30 days

Parameter	Pre n/N	Post n/N	Pre %	Post %	Delta	Odds Ratio	Lower 95% CI	Upper 95% CI	P =	Coeff.	SE	Wald Test
Provider Performance												
Ask	73/138	86/130	52.9	66.2	13.3	1.74	1.06	2.85	**	0.554	0.25	4.8
Advise	61/136	81/128	44.9	63.3	18.4	2.11	1.29	3.47	***	0.751	0.25	8.9
Assess	51/136	76/126	37.5	60.3	22.8	2.53	1.54	4.17	***	0.930	0.25	13.4
Assist	51/137	68/125	37.2	54.4	17.2	2.01	1.28	3.30	***	0.699	0.25	7.7
Assist – Quit Date	31/141	37/128	22.0	28.9	6.9	1.44	0.83	2.51		0.367	0.28	1.7
Assist – Self-help	19/137	40/129	13.9	31.0	17.1	2.79	1.51	5.14	***	1.026	0.31	10.8
Assist – Discuss Medications	46/137	58/125	33.6	46.4	12.8	1.71	1.04	2.82	*	0.538	0.26	4.46
Assist – Prescribe Medications	33/138	40/126	23.9	31.7	7.8	1.48	0.86	2.54		0.392	0.28	2.0
Arrange	20/141	38/131	14.2	29.0	14.8	2.47	1.35	4.53	**	0.905	0.31	8.6
Smoking Outcomes, 16 weeks[a]												
7-day point prevalence	15/141	24/131	10.6	18.3	7.7	1.88	0.94	3.77		0.633	0.35	3.2
Continuous abstinence	11/141	12/131	7.8	9.2	1.4	1.19	0.51	2.80		0.175	0.44	0.2
Quit attempts	58/126	71/120	46.0	59.2	13.1	1.70	1.03	2.82	*	0.530	0.26	4.2

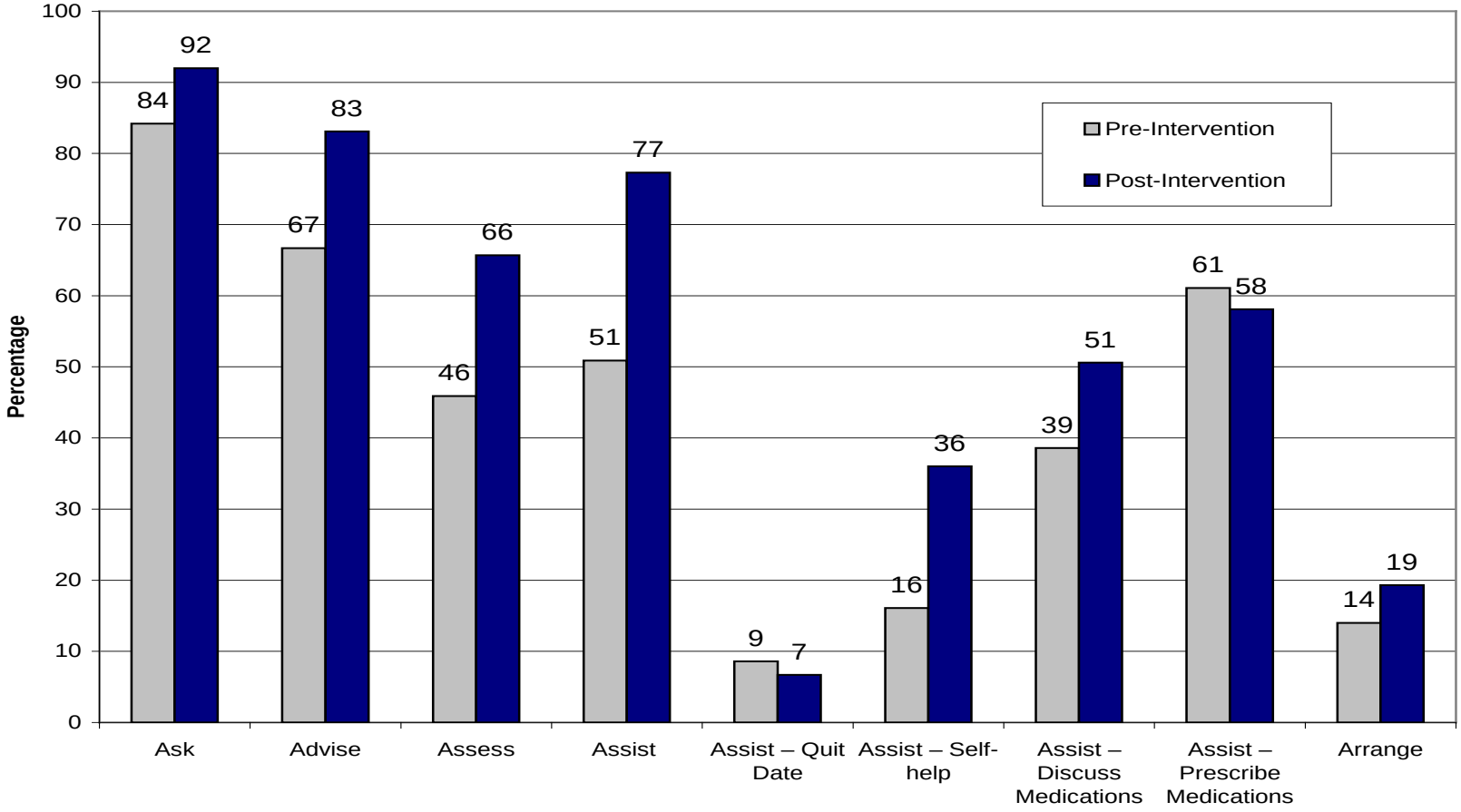
Controlling for clinic and provider level factors.

CI = confidence interval.

*p < .05. **p < .01. ***p <.001.

[a] Smoking abstinence based on self-reported data for full sample with missing data considered active smoker.

Figure 8: Comparison of provider delivery of 5As at the pre- and post-intervention for those patients screened at an appointment for an annual exam



Chapter 6 Discussion

6.1 Summary and interpretation of the findings

6.1.1 Incremental value of extended adjunct telephone-based smoking cessation counselling

The primary objective of this study was to compare the incremental impact of delivering adjunct telephone-based follow-up counselling as part of a multi-component intervention in primary care practice. As hypothesized, improvements in provider delivery of evidence-based smoking cessation treatments were documented in both study intervention groups at the post-intervention assessment with no differences between groups. Contrary to the study hypothesis, FC clinics that had the ability to refer patients to a telephone-based smoking cessation counselling program did not document greater improvement in patient smoking abstinence at the 4-month follow-up compared to baseline. Moreover, a higher and statistically significant increase in 7-day point prevalence abstinence (OR 6.8, 95% CI 2.1, 21.7; p= <0.01) and continuous abstinence (OR 13.7, 95% CI 2.1, 128.3; p= <0.05) was observed in the PS group compared to the FC group at the 4-month follow-up. These data should be interpreted in light of the large confidence intervals surrounding this point estimate, which indicates significant uncertainty.

The results of the present study are in contrast to a study by Borland and colleagues (2008), who found that the referral of primary care patients who smoke to a quit line doubled quit rates compared to the standard in-clinic primary care treatment (Borland et al. 2008, 382-389). A 2006 study by An et al. also found that telephone-based behavioural counselling delivered over a 2-month period was effective in increasing smoking abstinence at the 12-month follow-up [OR 3.50; 95% CI 1.99, 6.15] (An et al. 2006, 536-542). These studies compared adjunct counselling delivered in isolation to no intervention in a primary care setting. In the present trial, a multi-component intervention program providing

practice and provider-level supports was used as the comparator. Five previous studies of multi-component interventions have included extended adjunct counselling in addition to practice and provider-level intervention strategies; each trial was able to document a positive impact on smoking abstinence (Grandes, Cortada, and Arrazola 2000, 803-807; Pieterse et al. 2001, 182-190; Katz et al. 2002, 293-301; Young, D'Este, and Ward 2002, 572-583; Katz et al. 2004, 594-603). However, this data is confounded by the fact that cost-free pharmacotherapies were also provided to patients in four of the five trials. A recent study by Rothemich and colleagues (2010) found that an expanded tobacco use vital sign combined with fax referral to a quitline, and provider feedback on quitline referrals increased the number of patients who reported receiving cessation support compared to a traditional tobacco use vital sign (Rothemich et al. 2010, 367-374). This study did not report on the subsequent impact on patient smoking abstinence. To my knowledge, the current study is the first randomized control trial that attempts to isolate the value of patient-level follow-up counselling in the primary care setting when delivered as part of a multi-component intervention on patient smoking abstinence.

The study hypothesis that adjunct telephone-based counselling would increase smoking abstinence was based on previous work that has documented a relationship between extended counselling and improved patient smoking outcomes (Fiore et al. 2008; Stead, Bergson, and Lancaster 2008b, CD000165; Papadakis et al. 2010, 199-213). Given the time and resource constraints reported in the primary care setting for delivering such follow-up support, it was hypothesized that linking patients to adjunct follow-up counselling conducted by individuals external to the practice could serve as a feasible method to “extend treatment” when delivered in conjunction with initial intervention provided by primary care providers (Zhu et al. 2002, 1087-1093; Smith et al. 2009, 47-53). A crude assessment of the study data would lead one to conclude that the multi-component intervention program tested, which included practice and provider-level supports, was more likely, to increase smoking abstinence than providing access to a telephone-based smoking

cessation follow-up program for patients. However, a closer examination of the data suggests that factors related to program implementation may have confounded study outcomes. The lack of a significant increase in smoking abstinence at the 4-month follow-up needs to be examined in light of the significant differences in rates of smoking abstinence documented between intervention groups at the pre-assessment: 2.1% vs. 14.8% in the PS and FC group, respectively. Data indicates that 16 patients from the FC group pre-intervention assessment were seen at the clinic again after the smoking cessation intervention was instituted at the clinic and were exposed to the intervention. It appears likely that exposure to the intervention may in part explain the larger quit rate observed among patients in the FC group prior to the program being implemented. Removing these participants partially explained the higher quit rates observed in the FC group at baseline relative to the PS group; however, significant differences still remained between groups even after these cases were removed. It is not possible to determine if patients from the pre-intervention sample, other than those referred to the telephone follow-up system, received support from the clinic as a result of the intervention program, which may have affected study outcomes.

Patients sampled at the PS group post-assessment reported receiving both prescriptions for first-line quit smoking medications and follow-up support more frequently than participants in the FC group. For example, a 16% increase in the number of patients who were recommended pharmacotherapy was documented in the PS group compared to a 10% increase observed in the FC group. The higher rates at which assistance and follow-up were provided to patients may explain the observed improvement in smoking abstinence in the PS group relative to the FC group. This data also suggests that it may be feasible for some primary care clinics to deliver follow-up support to patients with existing resources, at least as part of a research study.

Other factors that may have contributed to the larger increase in quit rate observed in the PS group following implementation of the program may include differences in the characteristics of

patients sampled between groups. Significantly more patients in the PS group compared to the FC group reported being depressed at both the pre- and post-intervention assessment periods. Although the presence of anxiety or depression was not found to be significantly associated with smoking abstinence in the final study models, the known association between anxiety and depression and smoking abstinence may offer insight into the observed differences documented at baseline in quit rates between groups.

Another factor to be considered in the interpretation of outcomes related to smoking abstinence is the possibility that the implementation of the telephone follow-up program was not executed as planned. Data suggests that not all patients who were ready to quit in the FC group were referred to the telephone follow-up program. Among all patients screened at FC clinics at the post-assessment, only 17.7% agreed to be enrolled in the telephone follow-up program. The proportion of patients who were referred to the telephone follow-up program increased to 33% when only the subset of patients who were ready to quit in the next 30-days was examined. Patients who were referred for telephone follow-up were more likely to be ready to quit smoking and to have been seen by a provider who reported lower self-efficacy to deliver smoking cessation counselling. Among those patients who were referred to the telephone follow-up program, the rate of 7-day point prevalence abstinence at the 4-month follow-up was 31.2%.

It is also possible that the mode of delivery and/or schedule of contacts used in the telephone-based counselling program tested in the present study was not acceptable to some patients identified in the clinic setting and contributed to lower levels of uptake by patients. Other authors have reported that patient attitudes towards smoking cessation program supports are poor, and that these attitudes may impede patient interest in these services (Vogt, Hall, and Marteau 2010, 160-166). Given that the follow-up counselling intervention tested in the present study used an IVR system to deliver follow-up telephone calls to patients, the system was able to triage people who were in need of smoking

cessation counselling to a smoking cessation specialist for more specialized counselling and support. The IVR system has the potential to be a cost-effective method for intervening with large volumes of patients who smoke. There has been limited research on the acceptability of IVR-mediated telephone follow-up supports among patients who smoke. Only one study in the primary care setting has looked at the use of IVR for smoking cessation; in this study, IVR was used solely to assess the smoking status and readiness to quit of clinic patients prior to their quit appointment (McDaniel et al. 2005, S57-66). Outside of the primary care setting, IVR-mediated telephone follow-up counselling for smoking cessation has been evaluated in a pilot study of hospitalized patients who smoke with coronary artery disease (Reid et al. 2007, 319-326). The study found the system was an acceptable modality for delivering smoking cessation follow-up support to smokers. Due to the sample size, the increase in 12-month smoking abstinence favouring the IVR group that was documented was not statistically significant. A second study, which combined IVR-mediated calls with web and text message communication to deliver smoking cessation interventions to smokers recruited via the Internet in Norway, found a statistically significant increase for the IVR intervention compared to controls (Brendryen and Kraft 2008, 478-84). Data regarding personal preferences of patients in regard to the mode of delivery of follow-up support was not examined in the present study.

6.1.2 Comparison of pre- versus post-intervention data

The secondary objective of this study was to examine whether the introduction of a multi-component intervention in primary care clinics is associated with higher rates at which evidence-based smoking cessation treatments (5As) are delivered to patients and, subsequently, to increased quit attempts and smoking abstinence among patients.

In regard to 5As delivery, although the present study lacks an untreated control group, the results of the pre vs. post assessment provides evidence that the implementation of the multi-

component intervention program, which combined outreach visits with practice supports, provider training, and performance feedback, was associated with a significant increase in the rates at which most evidence-based cessation treatments are delivered by primary care practitioners. These findings are consistent with previous research, which has shown multi-component intervention programs to be effective in improving primary care provider performance in 5As delivery (Kottke et al. 1992, 701-708; Grandes, Cortada, and Arrazola 2000, 803-807; Grimshaw et al. 2001, II2-45; Pieterse et al. 2001, 182-190; Young, D'Este, and Ward 2002, 572-583; Anderson and Jane-Llopis 2004, 299-312; Katz et al. 2004, 594-603; Unrod et al. 2007, 478-484; Fiore et al. 2008; Papadakis et al. 2010, 199-213;). Table 39 provides a comparison of the odds ratios (OR) documented in the present study for the pre- and post-intervention assessments and the pooled OR for previously published multi-component interventions conducted in the primary care setting (Papadakis et al. 2010, 199-213). Observed increases in the present study for “ask”, “advise”, and “assess” are of a comparable magnitude to that of published research studies. However, increases observed following the introduction of the multi-component intervention in the present study for “setting a quit date” and “prescribing medications” were lower rates than had been previously reported in the literature. Only one previous study has reported on the impact of a multi-component intervention on the rates at which follow-up support was arranged in primary care settings (Unrod et al. 2007, 478-484). Unrod and colleagues (2007) reported a large effect estimate, which was not achieved in the present study.

Data gathered in the present study should, however, be interpreted with caution, given that many study clinics scheduled a separate quit plan appointment for patients who were ready to quit in the next 30 days. At this quit plan visit, clinicians would set a quit date, discuss medications, and arrange for supplemental follow-up support. The exit survey was limited to capturing information regarding activities that occurred on the day the patient was originally seen in the clinic. As such, it

may only be appropriate to compare data from the exit survey to rates at which patients were “asked”, “advised”, and “assessed” from previous trials.

Table 39: Comparison of odds ratio for the pilot study and published trials of multi-component interventions in primary care setting

Outcome	Pilot Study Pre vs. Post	Published Multi-component Interventions	
	OR [95% CI}	# Trials	Pooled OR [95% CI]
Ask	1.50 [1.12, 2.00]	6	1.79 [1.6, 2.1]
Advise	2.02 [1.53, 2.67]	7	1.60 [1.4, 1.8]
Assess	2.13 [1.59, 2.85]	3	1.92 [1.4, 2.7]
Assist	2.30 [1.70, 3.12]	1	1.22 [0.8, 1.9]
Assist – Set Quit Date	1.23 [0.77, 1.96]	5	3.45 [2.8, 4.2]
Assist – Prescribe Medications	1.25 [0.86, 1.83]	4	9.29 [6.8, 12.8]
Arrange	1.94 [1.23, 3.04]	1	8.53 [5.1, 14.2]
Smoking Abstinence	1.52 [0.94,2.46]	7	2.19 [1.7, 2.8]

In regard to the impact of the multi-component intervention program on the number of patients who made a quit attempt, patients from the post-intervention assessment sample reported making a quit attempt more often than the baseline sample, with an overall increase in quit attempts of 7% documented. Among patients who reported they were ready to quit smoking in the next 30 days, there was a 13% increase in the number of quit attempts made by patients between the pre- and post-assessment samples. Patients who received advice to quit at the time of their visits were more likely to report making a quit attempt at the 4-month follow-up. These data lend support to the hypothesis that the intervention program was associated with increased patient motivation to quit as well as with accelerating a quit attempt among patients who had been contemplating quitting. A significant increase in patient self-efficacy was documented at the post-assessment compared to pre-intervention.

There was a 3.8% improvement in self-reported 7-day point prevalence smoking abstinence between patients sampled at the pre- and post-assessment; however, observed differences were not statistically significant. For the respondents who reported a readiness to quit in the next 30 days, a 7.7% increase in 4-month point prevalence smoking abstinence was documented following the implementation of the intervention program. Previous evaluations of multi-component interventions reported increases in smoking abstinence that ranged between 3.8% and 15%. For example, in a randomized controlled trial conducted by Katz et al. (2004) that involved eight primary care clinics and 2163 patients, an adjusted OR of 1.7 [95% CI 1.2, 2.6] was reported for smoking abstinence measured at 6 months of follow-up, representing a 5% increase in patient quit rates between the intervention and control group (15.4% vs. 9.8%) (Katz et al. 2004, 594-603). The intervention program tested by Katz and colleagues (2004) involved: (1) physician tutorial in delivery of 5As; (2) real-time provider reminders using a modified vital signs stamp applied to progress notes with questions to stratify a

patient's stage of readiness; (3) an 8-week supply of NRT patches and self-help material; (4) telephone counselling for eligible patients, which involved telephone counselling via a centralized cessation counselling service prior to and one week following the patient's quit date; and (5) feedback to intake clinicians on performance of guideline recommended activities delivered at baseline and interim. A second, by Grandes, Cortada and Arrazolla (2000), tested a multi-component intervention program using a before-after controlled trial design involving 10 primary care clinics and over 1700 patients, reporting a 5% increase in smoking abstinence compared to control group [2.1% vs. 7.1%; OR 3.50, 95% CI 1.90, 6.47] at 12 months of follow-up. The multi-component intervention program tested included development of a therapeutic plan for patients (i.e., setting quit date and prescribing NRT), follow-up calls placed by physicians on the quit day and 15 days following the patient's quit day, and in-person follow-up consultation at 4 and 8 weeks (Grandes, Cortada, and Arrazola 2000, 803-807).

Given that smoking abstinence in the present trial was assessed at the end of 4 months, the increases documented are slightly lower than that reported in previously published studies, which report outcomes after at least 6 months of follow-up (see Table 39).

There are several conclusions that can be drawn regarding the non-significant increases in smoking abstinence observed between the pre- and post-assessments in the present study. The first is that the documented 4% increase in smoking abstinence is an important population-level association; however, limitations related to the sample size were not sufficient to appropriately power the study. It was known *a priori* that the study was not powered to detect differences of less than 10%. A larger trial would therefore be required to provide more conclusive evidence regarding the value of the program in improving patient smoking abstinence. Another possibility is that the changes observed in provider behaviours do not consistently translate into changes in patient smoking abstinence. The so-called "hardening" hypothesis has been previously discussed in the literature (Warner and Burns 2003, 37-48). The hypothesis suggests that relative to earlier generations of smokers many individuals who smoke today may have specific needs and challenges that make them less willing to make a quit attempt as well as make it more difficult to modify long-term smoking behaviours. A recent Canadian study estimated that the prevalence of "hardcore smokers" in Ontario ranges from 0.03% to 13.77% (Costa et al. 2010, 860-864). This suggests that people who are considered to be "hardcore smokers" constitute a relatively small fraction of the population (Augustson and Marcus 2004, 621-629). The present study had limited ability to evaluate social variables and their role in predicting outcomes. It is possible that social context and other factors play a larger role than the intervention itself in determining smoking outcomes and may assist with explaining the observed impacts on smoking abstinence in the present trial. Stress was the most common reason patients reported relapse to active smoking in the present trial.

6.1.3 Multi-level modelling of patient, provider and clinic-level variables in predicting study outcomes

Although several published studies of multi-component interventions in primary care settings have controlled for clinic-level variation in outcome estimates using hierarchical modelling, few have reported on clinic and provider characteristics that are associated with outcomes of interest (Quinn et al. 2005, 77-84; Ulbricht et al. 2006, 232-238; Bentz et al. 2007, 341-349). The present study was able to examine a sub-set of provider and patient-level factors that were hypothesized to mediate and/or moderate the association between intervention and outcomes of interest. As has been reported in the literature, the presence of smoking-related illness was predictive of patients being asked and advised to quit; however, having a smoking-related illness did not increase the likelihood that patients would receive assistance with quitting or follow-up support to address smoking (Wynn et al. 2002, 997-999; Martinson et al. 2003, 125-132; Steinberg et al. 2006, 405-412; Azuri et al. 2009, 710-717). In contrast to previous research (Lucan and Katz 2006, 16-23; Browning et al. 2008, 55-61), which has reported that patients with higher education are more likely to be advised to quit, the present study found that participants with fewer years of formal education were more likely to be asked about their smoking status, advised to quit, prescribed a quit smoking medication, and have a follow-up appointment arranged. Further research is required to understand the possible explanation of this previously unreported finding.

The type of patient visit had a significant influence on the rate at which smoking cessation treatment was delivered to patients. Patients were eight times more likely to be asked about smoking status, five times more likely to be advised to quit or report receiving assistance with quitting, and twice as likely to receive self-help materials and discuss medications if the purpose of their visit was for an annual exam compared to other types of appointments. The higher rates at which smoking cessation treatments are delivered at appointments for annual exams is likely related to the fact that

these visits are typically longer in duration, therefore making intervention more feasible. Annual health exams are also typically the time during which preventative health issues are raised with patients in primary care, and higher rates of cessation interventions at the annual health exam have been previously documented in the literature (Litaker et al. 2005, 556-563).

Participants who reported they were ready to quit in the next 30 days were three times more likely to be abstinent at the follow-up after controlling for other variables. Being ready to quit in the next 30 days made it more likely that a patient received advice to quit, "assistance" with quitting, and were "prescribed a quit smoking medication" on the day of his or her visit to the clinic when compared to those not ready to quit in the next 30 days. However, only about half of patients who were ready to quit smoking reported receiving assistance with quitting at the exit survey. Moreover, although a two-fold increase was observed in the number of patients ready to quit smoking with whom a follow-up appointment was arranged, two thirds of participants who were ready to quit were not scheduled for a follow-up appointment at the post-assessment, thereby indicating a missed opportunity to provide evidence-based care to patients interested in quitting.

Interestingly, study participants who had not made a quit attempt in the last year were more likely to report making a quit attempt between the exit survey and telephone follow-up assessment four months later. This finding is contrary to a study by Browning and colleagues (2008) that reported higher quit rates among individuals who made at least one prior quit attempt in the last year (Browning et al. 2008, 55-61).

The present study found moderate provider-level variation in the rates at which asking, advising, and assessing was delivered to patients with ICCs values ranging between 0.04-0.05. However, the study did document larger intra-provider variability (ICC between 0.07 to 0.14) in the rates at which patients received self-help materials, set a quit date, discussed medications, and had follow-up support arranged, as well as for 7-day point prevalence abstinence. In all cases, intra-

provider variability was larger than the intra-clinic variability observed. In the final models, female providers were significantly more likely to refer patients for follow-up support, a finding that has been previously reported in the literature (O'Loughlin et al. 2001, 627-638; Schnoll et al. 2006, 233-239). In addition, nurse practitioners were more likely to arrange follow-up support than physicians, with no other differences observed between providers and nurse practitioners or medical residents in 5As delivery. These provider-level factors, however, only partially explain the observed differences between providers; further investigation is required to better understand important factors associated with intra-provider variation in 5As delivery.

The multi-level analysis documented minimal clinic-level variance in 5As delivery, and in some cases, no variance was found between clinics. It is likely that the lack of documented variance is a result of the limited number of clinics involved in the pilot study. The present study did, however, document trends that may be used to generate hypotheses regarding possible clinic-level factors that influence outcomes. A large range was documented for change scores between study clinics for 5As delivery between the pre- and post-intervention assessments, with change scores ranging from a reduction of 12.7% to an improvement of 43%. Clinics can be categorized into three groups according to documented increases in 5As delivery: high performers, moderate performers, and poor performers. The largest improvements in 5As delivery were noted in clinics 1, 6, and 7. Clinics 2, 3, and 5 showed moderate improvements at the post-assessment. The poorest performance was documented in clinic 4, for which performance declined from the pre- to post-assessment in several domains of the 5As. Examination of the data related to program implementation suggests that factors such as baseline rate of 5As delivery were low and that having both a nurse and physician champion may be associated with greater improvements in 5As delivery.

The fidelity of the intervention’s implementation among participating clinics was also examined as part of this study. There was variation between clinics in the implementation of the

intervention program. Trends were observed between the number of intervention activities in place at the post-assessment and the overall improvements in 5As delivery documented among study clinics. The failure of some clinics to implement intervention activities may explain the lack of observed changes in study outcomes. For example, clinic 4, which had the fewest number of intervention activities implemented at the follow-up, also had the lowest overall changes in study outcomes at the post-assessment. This finding emphasizes the importance of high quality implementation of future programs.

6.1.4 Who did the intervention reach?

The rationale for intervening in primary care settings is that this setting offers the opportunity to interact with large numbers of smokers during a potentially teachable moment; intervention should result in more smokers making a quit attempt. It may be useful as such to examine the potential reach of smoking cessation programs delivered in primary care and any potential biases in the population of smokers reached. Thirteen per cent of patients screened in the study smoked daily and consumed an average of 15.6 cigarettes per day, which is consistent with the overall population of smokers in both Ontario and Canada (CTUMS 2010; Ontario Tobacco Research Unit 2010). Smoking prevalence rates varied significantly between study clinics, ranging from 12% to 29%. The highest rate of smoking was documented in the single rural clinic. This pattern is consistent with previously reported rates of smoking for sub-regions within the Champlain District, which range from 14.1% in the City of Ottawa to 26% in surrounding public health regions (Statistics Canada 2009). Data from the present study suggests that the primary care setting is well suited to supporting interactions with patients 45 to 64 years old which represents the largest group of smokers in Canada. However, relative to the known population of people who smoke in Canada, fewer younger men (aged 20 to 34) participated in the present study. This finding supports previous reports that primary care settings may not be well suited to reaching the young males who smoke (Jaakkimainen et al. 2006). It would be important to note that

a significant proportion of patients from the pre-post assessment samples reported the presence of anxiety (29%) or depression (27.5%). While these rates are large, they are lower than the rates of anxiety and depression that have been reported for the general population of people who smoke in the United States (Lasser et al. 2000, 2606-2610). Only limited comparable data is available for smokers in Canada. The single paper to report rates of major clinical depression in Canada suggests the overall rate is 10% and 19% for high-dependence smokers (Khaled et al. 2009, 204-208).

In regards to the ability of a primary care visit to serve as a teachable moment for patients, almost 60% of respondents indicated the advice of their primary care physician was either an "extremely important" or "important" factor in motivating them to quit smoking at the baseline assessment. In the present study, almost 70% of participants who smoke reported they were interested in quitting smoking in the next 6 months, and one third of all participants reported they were ready to quit in the next 30 days. Readiness to quit in the next 30 days was higher among study participants than that which has been reported nationally, and patients were also more likely to have made a quit attempt in the last year. These data suggest that respondents may represent a sub-set of patients with greater readiness to quit than the overall population of smokers in Canada.

A comparison of participants in the present study to those in a recent evaluation of the Ottawa Model for Smoking Cessation in the hospital setting indicates overall prevalence of smoking is similar in both clinical settings (15% vs. 19.8%) (Reid et al. 2010, 11-18). Participants sampled were almost 10 years younger (45.8 ± 14.6 years vs. 55.6 ± 17.4 years) than the hospital sample with a smaller proportion of men sampled (41% vs. 60%). Patients from the present study reported similar levels of nicotine dependence with 54% smoking within 30 minutes of waking versus 58% in the sample of hospitalized smokers.

Comparison of the characteristics of smokers from the present study with that reported in a large trial of a multi-component intervention conducted in primary care settings showed the samples

were similar. The mean age of participants in a study by Katz et al. (2004) was 42 years and 45% of participants were male who smoked an average of 17 cigarettes per day (Katz et al. 2004, 594-603). The mean years of formal education for participants in the present study was higher than in the study by Katz et. al..

6.2 Study limitations and generalizability

The study findings should be interpreted in the context of the study's limitations. There are several factors that may undermine the study's internal validity; that is, the ability to make correct inferences about the relationship between the independent variable and the outcome of interest as well as the ability to generalize the study findings to other populations, settings, and treatments. Potential threats to the study's internal and external validity are examined here (Shadish, Cook, and Campbell 2002).

6.2.1 Threats to statistical conclusion validity

The most obvious threat to validity was the limitations imposed by the study's sample size. Given that the number of intervention practices was fixed at seven, the study was not adequately powered to examine differences in the rates of delivery of evidence-based smoking cessation treatments and quit-smoking rates of less than 10%. Based on the observed increase in self-reported 7-day point prevalence abstinence (7.7% pre-assessment, 11.5% post-assessment) and ICC value observed (0.01) documented in the present study, a total of 20 practices (10 practices per group) and 70 patients per practice would have been required to detect a difference of 4% in the rate of smoking abstinence. The number of clinics involved in the present study meant there was also limited power to examine clinic-level variables, which may be predictive of 5As delivery or smoking outcomes as part of the multi-level analysis. A larger pool of clinics would be required to allow for adequate statistical examination of clinic-level variability.

The broader context in which data collection activities occurred is also important to consider when reporting on the gaps in 5As delivery by providers. Post-assessments took place during H1N1 influenza outbreak in the fall of 2009. The outbreak was declared a pandemic by the World Health Organization (World Health Organization 2009b). Six of the seven clinics involved in the study had post-intervention assessment activities taking place during the peak of the H1N1 pandemic. Many of these clinics reported significant disruptions to normal clinic routines and the need to alter in-take processes to manage patient volumes and patient exposure. In addition, patients seen in clinic during the H1N1 outbreak may have been more likely to present with acute symptoms, which may have resulted in smoking cessation being made a lesser priority at the visit for both patient and provider. Although the study protocol aimed to exclude urgent care visits, it is possible that the H1N1 influenza negatively affected the rates of 5As delivery documented at study clinics during the post-assessment data collection period. The largest increases in provider delivery of smoking treatments was observed in clinic 1, which was also the only clinic in which post-assessment activities were completed prior to fall 2009. It is possible that the H1N1 influenza pandemic limited the ability to accurately document increases in 5As delivery resulting from the intervention program. Reports from participating clinics also suggest that some clinics were affected to a larger extent than others by the H1N1 outbreak. Clinic 4 informed study investigators that workload related to H1N1 had required the clinic to temporarily discontinue tobacco use screening and distribution of the tobacco use survey. Clinic 4 is the only clinic to document at the post-assessment rates of 5As delivery that were lower than those documented at the pre-assessment. Although it seems likely that H1N1 negatively affected study outcomes, it is not possible to quantify the magnitude of this impact.

Multiple outcome measures were examined in the present study that may introduce error rate problems. No correction was made to p-values to adjust for the multiple ends points and, as such, it may be argued that there is a possibility that statistical significance may be artificially inflated.

Concern regarding the lack of corrected p-values should be considered in light of the fact that study outcomes were reported as odds ratios bounded by confidence intervals so that the magnitude of the co-variation and precision of the point estimate could be used to better reflect uncertainty versus an emphasis on significance testing based on p-values alone.

6.2.2 Threats to internal validity

The lack of a control-group comparison arm limits the study's ability to exclude maturation as a threat to internal validity. Given the robust literature regarding multi-component interventions, it was felt that a comparison of two active intervention groups would make a larger contribution to addressing knowledge gaps in the field. It is possible that secular trends towards increasing rates of preventative service delivery during the study timeframe could explain the increase observed in 5As delivery during the pre- and post-assessment periods. However, the likelihood of secular trends explaining outcomes is considered minimal given the relatively short time period (less than 6 months) between the pre- and post-intervention assessments.

Another limitation of this study is the use of a cross-sectional sample of patients versus within-participant design. The cross-sectional sample design introduces the possibility of patient level-factors affecting study outcomes. There were differences documented between treatment groups at baseline, as well as differences in the pre-post intervention samples, which may have affected study outcomes. Adjustment for the covariation observed in the present trial was addressed in the multi-level analyses techniques employed.

6.2.3 Threats to construct validity

Treatment diffusion, or exposure to the intervention, was documented among the pre-intervention sample in the FC group, thereby making differentiation between the pre- and post-assessment samples challenging. In addition, it appears possible that compensatory equalization may

have occurred in the PS group, in which providers may have delivered compensatory services to support patient follow-up that they might not have otherwise provided if they had not participated in the present study.

The possibility of reporting bias should also be considered given that patient self-report is used to assess rates at which smoking cessation services were delivered by providers. Although patients were instructed at both the exit survey and telephone interview to be honest with their responses, it is possible that patients were over-reporting rates of provider delivery of smoking so as not to have their physician rated unfavourably. Previous research has shown patient exit survey data regarding 5As delivery to be reliable; however, when a discrepancy occurred it was generally a patient over-reporting of intervention (Pbert et al. 1999, 183-188). In addition, both readiness to quit and smoking abstinence are subject to social desirability bias in that patients are more likely to report being ready to quit and being successful in a quit attempt because they perceive this to be a more socially favourable response. The proportion of patients who report a readiness to quit in the pilot study at the pre-intervention assessment was higher than other national survey data, which may support the possibility that patients are over-reporting their readiness to quit smoking. Although bio-chemical validation was used to validate self-report smoking abstinence, the biochemical samples were completed by only 53% of patients, therefore making the possibility of self-report bias a potentially important threat to study validity. Numerous studies have reported poor return rates with respect to biochemical samples such as that observed in the present study (Etter, Perneger, and Ronchi 1998, 141-146; SRNT 2002, 149-159; Katz et al. 2004, 594-603). The Society for Research on Nicotine and Tobacco (SRNT) subcommittee on Biochemical Validation recommends that self-reported abstinence be used in the evaluation for low to moderate intensity interventions such as that delivered in the present trial (SRNT 2002, 149-159).

In the present study, it was not feasible to blind investigators or clinic staff to the outcome assessment or intervention group assignment, nor to when data collection activities were occurring. It is possible that clinics and individual providers engaged in behaviours that they would not have normally as a result of their knowledge that their performance was being measured. The ability of providers to maintain such behaviours over the duration of the four- to eight-week data collection period seems unlikely. It should be noted that the study investigator was involved in the delivery of the intervention, which may have biased the intervention support provided to clinics to favour the hypothesized study outcome. Experimenter expectancies may have also introduced biases in the questionnaire design. Given the study findings did not support the study hypothesis, it seems unlikely that this occurred.

There is also a possibility that the measurement tools used in the present study did not adequately capture rates of "assist" and "arrange" that were delivered to patients at the post-assessment. As noted previously, several study clinics developed protocols that involved the scheduling of a separate appointment in which a physician or non-physician staff member met with patients to develop a quit plan. As such, the exit survey may not have adequately captured activities that would occur at this follow-up visit, including providing self-help materials, setting a quit date, and discussing and prescribing medications. Although it is very likely that such a measurement error occurred, it seems unlikely that this measurement bias would have occurred disproportionately in one of the two intervention groups. It is more likely that the post-assessment data may underestimate rates at which the "assist" outcomes were documented by limiting the measurement to a fixed date when the actual delivery of these intervention components would occur over a wider window of time.

Another limitation of the present study was the timeframe over which outcome data was collected. Due to constraints with study funding, a limited timeframe was available to complete the study; smoking abstinence was assessed 4 months after a patient's visit to the clinic. The gold-standard

measure of long-term smoking abstinence is a minimum of 6 months, and ideally the assessment of smoking abstinence would be measured at 12-months follow-up (West et al. 2005, 299-303).

6.2.4 Threats to external validity

An effort was made to maximize generalizability of the study findings by including clinics from both urban, suburban, and rural settings, including several types of primary care practices models (e.g., family health groups, teams, and networks), as well as including all patients who consume greater than one cigarette per day, rather than simply those who are ready to quit, as is often the case in clinical trials. Despite efforts made to increase the study's generalizability, the ability to generalize findings from the present study to a broader population of people who smoke should be examined in light of potential threats to the study's external validity.

The method of recruitment may potentially be a significant threat to the study's generalizability. In the present study, the recruitment of clinics was limited to practices with five or more physicians from three sub-regions in the Champlain District. The response rate among invited clinics was 54% (7/13 clinics). It is possible that the eligibility criteria as well as the enrollment rate achieved in the present study would limit the ability to generalize findings to a broader group of primary care clinics. Clinics that chose to participate in the study might have been more motivated compared to those that declined participation in the study, which may bias results towards greater improvements than what might otherwise be expected if the intervention program was disseminated to all primary care clinics. Clinics which choose to participate in the present study may have also been higher performing clinics and as such reduced the ability to detect differences between the pre and post assessment. The pre-intervention rate at which physician advice to quit was delivered in the last 12 months was similar to reported rates of advice in Ontario and 15% higher than rates reported nationally based on data gathered from the Canadian Tobacco Monitoring Survey (CTUMS 2006). This may suggest that clinics sampled as part of the present study are similar to the broader primary

care community in Ontario with respect to the delivery of smoking cessation treatments, but may be higher performers than primary care clinics nationally.

Perhaps the most serious limitation to generalizability was the rate of participation amongst eligible smokers in the clinic setting. Fifty-four percent of eligible patients screened agreed to participate in the study and completed the exit survey. This recruitment rate is lower than that reported by previously published studies (Katz et al. 2004, 594-603). It is possible that the sample recruited may be biased and, as such, limit generalizability to the broader population of patients who smoke seen in primary care settings. Limited information was available on the demographic profile of non-respondents to assess the potential impact of such biases. As such, the study is limited in regards to reporting on how the study sample may differ from the overall population of patients who smoke in primary care settings. The loss to follow-up rate in the present study was very low at less than 11%, therefore minimizing concern that sample attrition may have biased study findings.

Another potential threat to the study's generalizability is that the recruitment of practices was limited to clinics from one geographic region in Eastern Ontario. It will be important, as such, to replicate the study findings in other practice types and geographic settings in order to address this limitation. Finally, the present study tested a multi-component intervention program that included four intervention components to intervene at the level of the provider and practice. It is possible that another combination of sub-components may yield different results. Moreover, the telephone-based follow-up support program offered to patients in the FC group was one potential format to deliver extended follow-up support to patients identified in primary care. Other follow-up programs may produce different results than those observed in the present trial. A recent study found a dose response effect in the delivery of behavioural counselling to patients who smoke identified in the primary care settings (Secades-Villa et al. 2009, 747-758). The present study also recommended an intra-disciplinary model to support the diffusion of the 5As model in which members of the clinic staff

(physicians, nurses, allied health) shared the responsibility of delivering components of the 5As. It is possible that a different type of intervention model, which for example emphasized physician delivery of 5As, may yield different results.

6.3 Implications to policy and practice

The decline in the overall prevalence of smoking in Canada has been the result of progressive policies and programs such as smoke-free spaces legislation, taxation of tobacco products, warning labels on cigarette packaging, and social marketing campaigns (McIvor 2009, 21-26). Today in Canada, the majority of people who smoke want to quit, and many are actively making quit attempts (CTUMS 2005; Ismailov and Leatherdale 2010, 282-285). Unfortunately, the vast majority of people who smoke are not accessing evidence-based supports that may increase the likelihood of long-term abstinence (Hammond et al. 2004, 1042-1048; McIvor 2009, 21-26; Ismailov and Leatherdale 2010, 282-285). Our ability to motivate a cessation attempt among the remaining population of residents who smoke, as well as increase the use of evidence-based cessation treatments, will be important if we are to further impact on smoking outcomes in Canada.

Health care delivery systems may be a potentially important component of a comprehensive tobacco control system. Several authors have reported encouraging improvements in the rates at which primary care providers are documenting smoking status and providing cessation advice over the last decade (CTUMS 2006; Curry et al. 2006, 269-272; Schnoll et al. 2006, 233-239; Curry et al. 2008, 411-428; McIvor 2009, 21-26; CTUMS 2010; Szatkowski 2010). In the present study, prior to the introduction of the intervention program, 70% of patients reported they were advised to quit by their physician in the last 12 months at the baseline assessment. However, on the day of their last visit to the clinic, only 39% of patients reported receiving advice to quit. Given that clinical practice guidelines recommend that all patients be asked about their smoking status and advised to quit at every clinic visit, data from the pilot study suggests that despite the observed improvements following the

intervention program there continues to be a large number of patients who are not regularly advised to quit smoking (Fiore et al. 2008).

In the present study, it was rare for non-physician health providers working in primary care settings to deliver any of the 5As at the pre-intervention. This observation has been previously reported in the literature (Dosh et al. 2005, S50-2). The present study found a multi-component intervention that seeks to involve an inter-disciplinary team and simplify the role of physician providers increased the likelihood that 5As treatments were delivered to patients.

Although there is clear evidence regarding the cost-effectiveness of smoking cessation interventions, there is a lack of implementation knowledge to inform the design and delivery of these interventions into routine clinical practice. In this pilot study, best available evidence from the world of tobacco control, health systems, and health behaviour change was used to design an intervention program aimed at increasing the likelihood family doctors deliver evidence-based treatments. The intervention program aimed to address many of the barriers that are hypothesized to have limited widespread delivery of cessation intervention to date.

This pilot study offers policy-makers evidence to support the feasibility and efficacy of multi-component intervention programs to support the delivery of smoking cessation services within busy primary care practices in Canada. Given that ministries of health in Ontario, Alberta, British Columbia, and Quebec have made significant investments to support the delivery of preventative interventions in primary care settings, this information would seem particularly important. It will be important for system-level supports to be introduced to support the delivery of smoking cessation treatments in primary care. This would include ensuring adequate supports such as those provided in the present multi-component program are available to primary care providers and are delivered as part of a comprehensive quality improvement program rather than in isolation (i.e., training, provider prompts) which has typically been the case in Canada. The multi-component intervention program

tested is scalable for implementation in primary care settings across Canada. Examples of similar programs for other disease prevention and management areas such as diabetes, asthma, and hypertension can be found in Canada (Ontario Ministry of Health and Long-Term Care). Most provinces have not included smoking cessation as a key preventative target and, as such, a significant opportunity to impact a major risk factor for chronic disease is being missed. Many provinces, like Ontario, have the necessary infrastructure in primary care settings to allow intra-disciplinary teams to deliver cessation interventions to large numbers of patients who smoke using similar approaches to the one tested in this pilot study.

This study offers several insights for primary care practitioners who are interested in implementing smoking cessation programs within their clinical settings. In the present study, the well-known 5As model was modified for use in a multi-disciplinary clinic environment by defining roles and responsibilities for reception, nursing, allied health professionals, and physician providers based on time available and access to patients, which may assist with addressing the feasibility of intervention delivery when physician time is limited. Although the present study was not specifically designed to test the value of specific implementation factors, the following activities were undertaken as part of this study to support the implementation of a smoking cessation program in primary care settings: formation of a multi-disciplinary task force at the clinic; developing a detailed tobacco control protocol for the clinic; using a multi-disciplinary team to deliver the intervention program with clear roles and responsibilities assigned for each of the 5As strategies; frequent screening of patient smoking status and readiness to quit; real time provider prompts created and embedded into existing clinic routines; and performance metrics collected and reported regularly. Given that many primary care clinics use electronic medical records, attention should also be given to strengthening the design of electronic medical records to cue providers in the assessment of smoking status, delivery of strong advice, and the simplification of the referral process to designated staff within the clinic who will

provide supplemental support to patients (Cantrell and Shelley 2009, 81). The experience developed as part of the present study supports the need for practitioners to pay careful attention to issues related to program implementation as the quality of implementation appears to be associated with larger improvements in 5As delivery.

In the present study, a higher rate of 5As delivery was documented for visits scheduled for annual health exams. However, only 16.2% of appointments in the present study were for annual exams. Evidence-based guidelines emphasize the importance of assessing smoking status at every visit. A study by Jaén et al. (2001) suggested that tobacco-specific discussion is appropriate in approximately three fourths of primary care visits by patients who smoke (Jaén et al. 2001, 859-863). It will be important for clinicians to ensure patients are asked, advised, and offered assistance with making a quit attempt regularly, and that trained staff are available to support patients with making a quit attempt using evidence-based supports. If proven efficacious in a larger trial, the telephone-based counselling intervention evaluated within the present study could potentially be delivered by existing quit lines (e.g., smoker's helpline), therefore making the larger scale rollout of the intervention model feasible within Ontario and Canada. Creating stronger links to cessation interventions outside of the primary care setting, as part of a systems approach to cessation, may serve to increase the reach of evidence-based cessation interventions and address barriers faced by busy primary care practitioners.

6.4 Implications for future research

The results of the present study also have implications for future research. Given the limitations related to sample size, a larger trial involving a greater number of primary care clinics is recommended to strengthen the evidence base regarding the effectiveness of the multi-component intervention program in primary care settings. A larger trial would assist with addressing two significant areas of research that were not addressed in the pilot study. The first is the ability to

adequately examine the impact of the multi-component intervention on patient quit rates between the pre- and post-assessments periods as well as between group differences. The second relates to the ability to examine clinic-level factors that are associated with high and low performance with respect to the delivery of evidence-based smoking cessation treatments.

Replicating the study would also enable the opportunity to re-examine outcome estimates that would be expected for 5As delivery in the absence of the disruptions encountered in the present trial as a result of the H1N1 pandemic. It is recommended that future trials strengthen the intervention design so as to: 1) measure smoking abstinence at 6 months of follow-up or longer; 2) limit the potential of intervention diffusion in the pre-assessment sample; and 3) ensure measurement of 5As accounts for the possibility that intervention may be delivered over multiple clinic appointments. It may be important for future research to also consider intra-provider variability when calculating sample size. In the present study, intra-provider ICC values were found to be larger than that observed for intra-clinic variability. Finally, the inclusion of a no-intervention control group may be valuable to provide gold standard evidence regarding the multi-component interventions efficacy.

Additional research is also required to better understand important clinic-level factors that are associated with improved program implementation, 5As delivery, and smoking outcomes. For example, it would be important to know precisely what types of clinic environments are most conducive to the successful delivery of multi-component programs such as that tested in the present study. In addition, given provider-level variability observed in the present trial, it may be important to pay more attention to provider-level variation. Mixed methods approaches may offer value in further understanding the clinic and provider-level factors influencing outcomes, variation in program implementation activities, and program sustainability.

It would also seem important to develop and test new instruments for assessing variables hypothesized to mediate 5As delivery at both the level of the clinic and the provider. At present, tools

available to meaure changes in attitudes, knowledge, and self-efficacy, as well as other variables that may mediate the relationship between the intervention and study outcomes, are rudamentary and have not been well validated. A recent study by Delucchi, Tajima, and Guydish (2009) used exploratory factor analysis to identify five factors that are associated with provider delivery of smoking cessation services including a single "knowledge" factor, three "attitude" factors ("treatment barriers", "counsellor self-efficacy", and "counsellor attitudes") and a single "practices" factor (Delucchi, Tajima, and Guydish 2009, 347-364). Supplemental work to refine our knowledge and ability to measure these underlining factors is required.

Many providers continue to report modest levels of self-efficacy in setting a quit date, recommending medications, and providing extended counselling even after training. The highest scores for provider self-efficacy were documented for: advising patients to quit, the provision of brief counselling, and prescribing of medications (all mean scores were greater than 8 on a 10-point scale). These are arguably the simplest intervention strategies to deliver. Slightly lower levels of self-efficacy were documented for other activities, such as setting a quit date with patients, the provision of extended smoking cessation counselling, and arranging follow-up. This data suggests that providers continue to lack confidence in their ability to adequately counsel patients who smoke in more complicated aspects of 5As delivery. Additional research is required to understand how best to address provider self-efficacy for the delivery of smoking cessation treatments. Intervention strategies that are hypothesized to modify provider self-efficacy, such as performance feedback, may be a practical area of future research. The present study offered a fairly low intensity intervention related to performance feedback with data provided to the clinic's smoking cessation task force at three different time-points during the study. Previous research has reported that the more intensive the feedback, the greater its effect on outcomes (Jamtvedt et al. 2006, CD000259). A recent study found a one-time individualized audit and feedback session with providers resulted in an increase in the documentation of tobacco

dependence counselling from 7.5% to 46.5% ($p<0.0001$) and the appropriateness of NRT dosing from 26% to 64% ($p<0.001$) following the intervention in hospital settings (McKay-Brown et al. 2008, 4). Gaining a better understanding of the value of a more intensive performance feedback protocol on provider self-efficacy and 5As delivery would also seem to be an important area for additional research.

The present study tested one possible patient-level intervention strategy (i.e., extended adjunct telephone counselling). Future research should examine other possible patient-level intervention strategies for supporting long-term abstinence among patients identified in primary care settings when delivered as part of multi-component interventions. One such strategy is the provision of cost-free quit smoking medications to patients. Cost-free pharmacotherapy was included in 50% of the multi-component interventions that were included in the meta-analysis of primary care intervention strategies (Papadakis et al. 2010, 199-213). The most impressive increases in smoking abstinence were reported by Twardella and Brenner (2007), in which practice-level supports were combined with the provision of cost-free pharmacotherapy (Twardella and Brenner 2007, 15-21; Salize et al. 2009, 230-5). Supplemental research would assist with understanding the incremental impact of cost-free medications when delivered in combination with multi-component interventions, as well as the effectiveness of combining both adjunct counselling and cost-free medications.

The pilot study examined 5As delivery two months following implementation of the multi-component intervention program. The ability of clinics and providers to maintain rates at which 5As treatments are delivered over an extended period of time was not examined. Previous authors have reported that intervention programs that result in improved outcomes may revert to baseline after the intervention stimulus ends. Moreover, it has been shown that initial implementation success does not predict institutionalization of outcome changes (Stange et al. 2003, 296-300). Future research should

aim to examine the rate at which interventions are maintained over the long term as well as factors predictive of long-term maintenance of such programs in real-world settings.

Investment in intervention strategies designed to reach the population of hard-to-reach patients may also be required if we are to continue to have an impact on smoking prevalence in the population. Possible segmentation strategies for motivating and supporting quit attempts in sub-populations of people who smoke would also appear to be an important area for future research.

Finally, it will also be important to continue to monitor current practice trends and practice gaps in the delivery of cessation services in primary care settings. Several studies have noted improvements in the last five years in the rates at which patients are asked and advised to quit; however, much lower rates are reported for the delivery of the remaining 5As (CTUMS 2006; Schnoll et al. 2006, 233-239; CTUMS 2010). Changes in practice behaviours over time would affect the relative benefit derived from some interventions strategies. As such, having adequate information to monitor trends in provider behaviours will be important.

6.5 Conclusions

This is the first study to evaluate a multi-component intervention program in primary care practices within the Canadian health care system. It is also the first study to examine the incremental value of adjunct telephone-based smoking cessation counselling when delivered as part of a multi-component intervention program. The strengths of the present study include the use of a cluster-randomized control trial design, the evaluation of both rates of evidence-based smoking cessation treatment delivery and smoking abstinence, and low rate of patient loss to follow-up. The study builds on existing knowledge regarding the value of interventions that combine practitioner-, practice-, and patient-level intervention components.

This study documents three new pieces of information. First, a multi-component intervention tested in primary care clinics in Canada is associated with enhanced provider performance in the delivery of evidence-based smoking cessation treatments to patients, as well as a higher proportion of patients who make a quit attempt 4 months following their visit to clinic. Second, making adjunct telephone-based follow-up support available to patients identified in primary care clinics who have implemented a multi-component program does not necessarily lead to improved patient smoking outcomes; however, smoking abstinence tended to be greater among those patients who are referred to the telephone follow-up support program. Third, patient, provider, and possibly clinic-level factors may influence the rates at which smoking cessation treatments are delivered to patients in primary care settings. These findings will assist with informing future policy, practice, and research in regards to the design, implementation, and evaluation of intervention programs for improving the delivery of smoking cessation treatments to patients identified in primary care settings.

Study data suggests that both clinic and implementation factors have significant influence on the improvements achieved following implementation of a multi-component smoking cessation program in primary care. However, due to the number of clinics involved in the present trial, it was not possible to adequately examine clinic-level factors, which may influence success achieved using multi-level modelling techniques. It was also not possible to adequately explain the observed differences in provider and clinic level variation. Finally, this study does not rule out the possibility that a different type of telephone counselling program may have yielded different results. A larger trial is recommended to conclusively determine the impact of the intervention program on rates at which providers are delivering cessation treatments, long-term smoking abstinence, and the characteristics of clinics, which are required to support successful implementation of the intervention.

Bibliography

An, L. C., et al. 2006. Benefits of telephone care over primary care for smoking cessation: a randomized trial. *Archives of Internal Medicine* 166, no. 5:536-542.

An, L. C., et al. 2008. A randomized trial of a pay-for-performance program targeting clinician referral to a state tobacco quitline. *Archives of Internal Medicine* 168, no. 18:1993-1999.

Anderson, P., and E. Jane-Llopis. 2004. How can we increase the involvement of primary health care in the treatment of tobacco dependence? A meta-analysis. *Addiction (Abingdon, England)* 99, no. 3:299-312.

Andrews, J. O., M. S. Tingen, J. L. Waller, and R. J. Harper. 2001. Provider feedback improves adherence with AHCPR Smoking Cessation Guideline. *Preventive medicine* 33, no. 5:415-421.

Augustson, E., and S. Marcus. 2004. Use of the current population survey to characterize subpopulations of continued smokers: a national perspective on the "hardcore" smoker phenomenon. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 6, no. 4:621-629.

Azuri, J., S. Peled, E. Kitai, and S. Vinker. 2009. Smoking prevention and primary physician's and patient's characteristics. *American Journal of Health Behavior* 33, no. 6:710-717.

Bandura, A. 1986. *Social foundations of thought and action: A social cognitive theory*. Englewood Cliffs, N.J.: Prentice-Hall.

Bandura, A. 2004. *Health promotion by social cognitive means*. *Health Education and Behaviour.* 31, no. 2:143-64.

Baskerville, N. B., W. Hogg, and J. Lemelin. 2001. The effect of cluster randomization on sample size in prevention research. *The Journal of family practice* 50, no. 3:W241-6.

Benowitz, N. L. 2003. Cigarette smoking and cardiovascular disease: pathophysiology and implications for treatment. *Progress in cardiovascular diseases* 46, no. 1:91-111.

Bentz, C. J., et al. 2007. Provider feedback to improve 5A's tobacco cessation in primary care: a cluster randomized clinical trial. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 9, no. 3:341-349.

Boily, K., Lavato, C., and Murphy, C. 2006. *Training in tobacco cessation counselling for medical, nursing, dentistry and pharmacy students: Environmental scan and recommendations. Report prepared for the Canadian Public Health Association, December, 29, 2006.*

Bonevski, B., et al. 1999. Randomized controlled trial of a computer strategy to increase general practitioner preventive care. *Preventive medicine* 29, no. 6 Pt 1:478-486.

Borland, R., et al. 2008. In-practice management versus quitline referral for enhancing smoking cessation in general practice: a cluster randomized trial. *Family practice* 25, no. 5:382-389.

Brendryen, H., and P. Kraft. 2008. Happy ending: a randomized controlled trial of a digital multi-media smoking cessation intervention. *Addiction (Abingdon, England)* 103, no. 3:478-84; discussion 485-6.

Breslau, N., and E. O. Johnson. 2000. Predicting smoking cessation and major depression in nicotine-dependent smokers. *American Journal of Public Health* 90, no. 7:1122-1127.

Bronfenbrenner, U. 1976. *The ecology of human development: experiments by nature and design.* Cambridge, Mass.: Harvard University Press.

Browning, K. K., A. K. Ferketich, P. J. Salsberry, and M. E. Wewers. 2008. Socioeconomic disparity in provider-delivered assistance to quit smoking. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 10, no. 1:55-61.

Burgess, D. J., et al. 2009. Employment, gender, and smoking cessation outcomes in low-income smokers using nicotine replacement therapy. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 11, no. 12:1439-1447.

Cahill, K., L. F. Stead, and T. Lancaster. 2008. Nicotine receptor partial agonists for smoking cessation. *Cochrane database of systematic reviews (Online)* (3), no. 3:CD006103.

Campbell, M. K., et al. 2004. Sample size calculator for cluster randomized trials. *Computers in biology and medicine* 34, no. 2:113-125.

Canadian Lung Association. 2003. *Making Quit Happen – Canada's Challenges to Smoking Cessation.*

Cantrell, J., and D. Shelley. 2009. Implementing a fax referral program for quitline smoking cessation services in urban health centers: a qualitative study. *BMC family practice* 10, 81.

Cepeda-Benito, A., J. T. Reynoso, and S. Erath. 2004. Meta-analysis of the efficacy of nicotine replacement therapy for smoking cessation: differences between men and women. *Journal of consulting and clinical psychology* 72, no. 4:712-722.

Coambs, R. B., S. Li, and L. T. Kozlowski. 1992. Age interacts with heaviness of smoking in predicting success in cessation of smoking. *American Journal of Epidemiology* 135, no. 3:240-246.

Coleman, R. 2000. *The cost of tobacco in Nova Scotia.* Edited by Cancer Care Nova Scotia.

Coleman, T., and A. Wilson. 2000. Anti-smoking advice from general practitioners: is a population-based approach to advice-giving feasible? *The British journal of general practice : the journal of the Royal College of General Practitioners* 50, no. 461:1001-1004.

Coleman, T., et al. 2001. Intervention study to evaluate pilot health promotion payment aimed at increasing general practitioners' antismoking advice to smokers. *British Medical Journal (Clinical research ed.)* 323, no. 7310:435-436.

Coleman, T., F. Cheater, and E. Murphy. 2004. Qualitative study investigating the process of giving anti-smoking advice in general practice. *Patient education and counseling* 52, no. 2:159-163.

Coleman, T., et al. 2007. Distributing questionnaires about smoking to patients: impact on general practitioners' recording of smoking advice. *BMC health services research* 7, 153.

Coleman, T. 2010. Do financial incentives for delivering health promotion counselling work? Analysis of smoking cessation activities stimulated by the quality and outcomes framework. *BMC public health* 10, 167.

Cooke, F., et al. 2008. Diagnostic accuracy of NicAlert cotinine test strips in saliva for verifying smoking status. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 10, no. 4:607-612.

Costa, M. L., et al. 2010. "Hardcore" definitions and their application to a population-based sample of smokers. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 12, no. 8:860-864.

Cromwell, J., et al. 1997. Cost-effectiveness of the clinical practice recommendations in the AHCPR guideline for smoking cessation. Agency for Health Care Policy and Research. *JAMA : the journal of the American Medical Association* 278, no. 21:1759-1766.

CTUMS. 2005. *Canadian Tobacco Use Monitoring Survey (CTUMS) 2005.*Health Canada.

CTUMS. 2006. *Canadian Tobacco Use Monitoring Survey (CTUMS) 2006.*Health Canada.

CTUMS. 2010. *Canadian Tobacco Use Monitoring Survey (CTUMS) 2010.*Health Canada.

Curry, S. J., P. A. Keller, C. T. Orleans, and M. C. Fiore. 2008. The role of health care systems in increased tobacco cessation. *Annual Review of Public Health* 29, 411-428.

Curry, S. J., C. T. Orleans, P. Keller, and M. Fiore. 2006. Promoting smoking cessation in the healthcare environment: 10 years later. *American Journal of Preventive Medicine* 31, no. 3:269-272.

D'Angelo, M. E., R. D. Reid, K. S. Brown, and A. L. Pipe. 2001. Gender differences in predictors for long-term smoking cessation following physician advice and nicotine replacement therapy. *Canadian journal of public health* 92, no. 6:418-422.

Delucchi, K. L., B. Tajima, and J. Guydish. 2009. Development of the Smoking Knowledge, Attitudes, and Practices (S-KAP) Instrument. *Journal of Drug Issues* 39, no. 2:347-364.

Doll, R., R. Peto, J. Boreham, and I. Sutherland. 2004. Mortality in relation to smoking: 50 years' observations on male British doctors. *British Medical Journal (Clinical research ed.)* 328, no. 7455:1519.

Donner, A., and N. Klar, eds. 2000. *Design and Analysis of Cluster Randomization Trials in Health Research.* London: Arnold.

Dosh, S. A., et al. 2005. Changing organizational constructs into functional tools: an assessment of the 5 A's in primary care practices. *Annals of family medicine* 3 Suppl 2, S50-2.

Dubey, V., et al. 2006. Improving preventive service delivery at adult complete health check-ups: the Preventive health Evidence-based Recommendation Form (PERFORM) cluster randomized controlled trial. *BMC family practice* 7, 44.

Eckert, T., and C. Junker. 2001. Motivation for smoking cessation: what role do doctors play? *Swiss medical weekly : official journal of the Swiss Society of Infectious Diseases, the Swiss Society of Internal Medicine, the Swiss Society of Pneumology* 131, no. 35-36:521-526.

Eddy, D. M., et al. 2009. Effect of smoking cessation advice on cardiovascular disease. *American Journal of Medical Quality : The Official Journal of the American College of Medical Quality* 24, no. 3:241-249.

Emmons, K. 2000. Health behaviors in a social context. In *Social Epidemiology*, edited by Berkman L. and I. Kawachi. Oxford: Oxford University Press.

Etter, J. F., T. V. Perneger, and A. Ronchi. 1998. Collecting saliva samples by mail. *American Journal of Epidemiology* 147, no. 2:141-146.

Fiore, M. C., C. R. Jaén, T. B. Baker, et al. 2008. *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Edited by Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.

Forsetlund, L., et al. 2009. Continuing education meetings and workshops: effects on professional practice and health care outcomes. *Cochrane database of systematic reviews (Online)* (2), no. 2:CD003030.

Franco, O. H., et al. 2007. Primary prevention of cardiovascular disease: cost-effectiveness comparison. *International Journal of Technology Assessment in Health Care* 23, no. 1:71-79.

Frank, O., J. Litt, and J. Beilby. 2004. Opportunistic electronic reminders. Improving performance of preventive care in general practice. *Australian Family Physician* 33, no. 1-2:87-90.

Garvey, A. J., et al. 2000. Effects of nicotine gum dose by level of nicotine dependence. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 2, no. 1:53-63.

Gaziano, T. A., G. Galea, and K. S. Reddy. 2007. Scaling up interventions for chronic disease prevention: the evidence. *Lancet* 370, no. 9603:1939-1946.

Glanz, K., B. K. Rimer, and F. M. Lewis. 2002. *Health Behavior and Health Education:Theory, Research, and Practice, 3rd Ed.* San Francisco: Jossey-Bass.

Glassman, A. H., et al. 1990. Smoking, smoking cessation, and major depression. *JAMA : the journal of the American Medical Association* 264, no. 12:1546-1549.

Goldstein, M. G., et al. 1997. Physicians counseling smokers. A population-based survey of patients' perceptions of health care provider-delivered smoking cessation interventions. *Archives of Internal Medicine* 157, no. 12:1313-1319.

Goldstein, M. G., et al. 2003. An academic detailing intervention to disseminate physician-delivered smoking cessation counseling: smoking cessation outcomes of the Physicians Counseling Smokers Project. *Preventive medicine* 36, no. 2:185-196.

Goodwin, M. A., et al. 2001. A clinical trial of tailored office systems for preventive service delivery. The Study to Enhance Prevention by Understanding Practice (STEP-UP). *American Journal of Preventive Medicine* 21, no. 1:20-28.

Gottlieb, N. H., J. L. Guo, S. A. Blozis, and P. P. Huang. 2001. Individual and contextual factors related to family practice residents' assessment and counseling for tobacco cessation. *The Journal of the American Board of Family Practice / American Board of Family Practice* 14, no. 5:343-351.

Grandes, G., J. M. Cortada, and A. Arrazola. 2000. An evidence-based programme for smoking cessation: effectiveness in routine general practice. *The British journal of general practice : the journal of the Royal College of General Practitioners* 50, no. 459:803-807.

Grandes, G., J. M. Cortada, A. Arrazola, and J. P. Laka. 2003. Predictors of long-term outcome of a smoking cessation programme in primary care. *The British journal of general practice : the journal of the Royal College of General Practitioners* 53, no. 487:101-107.

Grant, B. F., et al. 2004. Nicotine dependence and psychiatric disorders in the United States: results from the national epidemiologic survey on alcohol and related conditions. *Archives of General Psychiatry* 61, no. 11:1107-1115.

Grimshaw, J. M., et al. 2001. Changing provider behavior: an overview of systematic reviews of interventions. *Medical care* 39, no. 8 Suppl 2:II2-45.

Hammond, D., P. W. McDonald, G. T. Fong, and R. Borland. 2004. Do smokers know how to quit? Knowledge and perceived effectiveness of cessation assistance as predictors of cessation behaviour. *Addiction (Abingdon, England)* 99, no. 8:1042-1048.

Haug, S., et al. 2010. Predictors and moderators of outcome in different brief interventions for smoking cessation in general medical practice. *Patient education and counseling* 78, no. 1:57-64.

Hawe, P., A. Shiell, and T. Riley. 2004. Complex interventions: how "out of control" can a randomised controlled trial be? *British Medical Journal (Clinical research ed.)* 328, no. 7455:1561-1563.

Health Canada. 1999. *Statistical Report on the Health of Canadians.* Ottawa: Health Canada.

Helgason, A. R., and K. E. Lund. 2002. General practitioners' perceived barriers to smoking cessation-results from four Nordic countries. *Scandinavian journal of public health* 30, no. 2:141-147.

Hogg, W., et al. 2008. Improving prevention in primary care: evaluating the effectiveness of outreach facilitation. *Family practice* 25, no. 1:40-48.

Hughes, J. R., L. F. Stead, and T. Lancaster. 2007. Antidepressants for smoking cessation. *Cochrane database of systematic reviews (Online)* (1), no. 1:CD000031.

Hyland, A., et al. 2004. Predictors of cessation in a cohort of current and former smokers followed over 13 years. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 6 Suppl 3, S363-9.

Hyland, A., et al. 2006. Individual-level predictors of cessation behaviours among participants in the International Tobacco Control (ITC) Four Country Survey. *Tobacco control* 15 Suppl 3, iii83-94.

Institute of Education. *MLwiN version 2.02.* London, UK.

Ismailov, R. M., and S. T. Leatherdale. 2010. Smoking cessation aids and strategies among former smokers in Canada. *Addictive Behaviors* 35, no. 3:282-285.

Jaakkimainen, L., et al. 2006. *Primary care in Ontario: Ambulatory Physician Care for Adults.*Institute for Clinical and Evaluative Sciences.

Jaén, C. R., et al. 2001. Tailoring tobacco counseling to the competing demands in the clinical encounter. *The Journal of family practice* 50, no. 10:859-863.

Jamtvedt, G., et al. 2006. Audit and feedback: effects on professional practice and health care outcomes. *Cochrane database of systematic reviews (Online)* (2), no. 2:CD000259.

Jarvis, M. J., et al. 1987. Comparison of tests used to distinguish smokers from nonsmokers. *American Journal of Public Health* 77, no. 11:1435-1438.

Kahn, R., R. M. Robertson, R. Smith, and D. Eddy. 2008. The impact of prevention on reducing the burden of cardiovascular disease. *Diabetes care* 31, no. 8:1686-1696.

Katz, D. A., et al. 2002. Effectiveness of a clinic-based strategy for implementing the AHRQ Smoking Cessation Guideline in primary care. *Preventive medicine* 35, no. 3:293-301.

Katz, D. A., et al. 2004. Effectiveness of implementing the agency for healthcare research and quality smoking cessation clinical practice guideline: a randomized, controlled trial. *Journal of the National Cancer Institute* 96, no. 8:594-603.

Kenfield, S. A., M. J. Stampfer, B. A. Rosner, and G. A. Colditz. 2008. Smoking and smoking cessation in relation to mortality in women. *JAMA : the journal of the American Medical Association* 299, no. 17:2037-2047.

Khaled, S. M., A. Bulloch, D. V. Exner, and S. B. Patten. 2009. Cigarette smoking, stages of change, and major depression in the Canadian population. *Canadian journal of psychiatry* 54, no. 3:204-208.

Kottke, T. E., M. L. Brekke, L. I. Solberg, and J. R. Hughes. 1989. A randomized trial to increase smoking intervention by physicians. Doctors Helping Smokers, Round I. *JAMA : the journal of the American Medical Association* 261, no. 14:2101-2106.

Kottke, T. E., et al. 1992. A controlled trial to integrate smoking cessation advice into primary care practice: Doctors Helping Smokers, Round III. *The Journal of family practice* 34, no. 6:701-708.

Kreuter, M. W., S. G. Chheda, and F. C. Bull. 2000. How does physician advice influence patient behavior? Evidence for a priming effect. *Archives of Family Medicine* 9, no. 5:426-433.

Kunzel, C., et al. 2005. On the primary care frontlines: the role of the general practitioner in smoking-cessation activities and diabetes management. *Journal of the American Dental Association (1939)* 136, no. 8:1144-53; quiz 1167.

Lancaster, T., C. Silagy, and G. Fowler. 2000. Training health professionals in smoking cessation. *Cochrane database of systematic reviews (Online)* (3), no. 3:CD000214.

Lasser, K., et al. 2000. Smoking and mental illness: A population-based prevalence study. *JAMA : the journal of the American Medical Association* 284, no. 20:2606-2610.

Lee, C. W., and J. Kahende. 2007. Factors associated with successful smoking cessation in the United States, 2000. *American Journal of Public Health* 97, no. 8:1503-1509.

Lemelin, J., W. Hogg, and N. Baskerville. 2001. Evidence to action: a tailored multifaceted approach to changing family physician practice patterns and improving preventive care. *CMAJ : Canadian Medical Association Journal* 164, no. 6:757-763.

Lennox, A. S., et al. 1998. Stages of change training for opportunistic smoking intervention by the primary health care team. Part 1: randomized controlled trial of the effect of training on patient smoking outcomes and health professional behaviour as recalled by patients. *Health Education Journal* 57, no. 140:140.

Litaker, D., S. A. Flocke, J. P. Frolkis, and K. C. Stange. 2005. Physicians' attitudes and preventive care delivery: insights from the DOPC study. *Preventive medicine* 40, no. 5:556-563.

Litaker, D., et al. 2006. Using complexity theory to build interventions that improve health care delivery in primary care. *Journal of general internal medicine* 21 Suppl 2, S30-4.

Longo, D. R., et al. 2006. Characteristics of smoking cessation guideline use by primary care physicians. *Missouri medicine* 103, no. 2:180-184.

Lucan, S. C., and D. L. Katz. 2006. Factors associated with smoking cessation counseling at clinical encounters: the Behavioral Risk Factor Surveillance System (BRFSS) 2000. *American Journal of Health promotion : AJHP* 21, no. 1:16-23.

Makomaski Illing, E. M., and M. J. Kaiserman. 2004. Mortality attributable to tobacco use in Canada and its regions, 1998. *Canadian journal of public health* 95, no. 1:38-44.

Marcy, T. W., J. Skelly, R. N. Shiffman, and B. S. Flynn. 2005. Facilitating adherence to the tobacco use treatment guideline with computer-mediated decision support systems: physician and clinic office manager perspectives. *Preventive medicine* 41, no. 2:479-487.

Martinson, B. C., P. J. O'Connor, N. P. Pronk, and S. J. Rolnick. 2003. Smoking cessation attempts in relation to prior health care charges: the effect of antecedent smoking-related symptoms? *American Journal of Health promotion : AJHP* 18, no. 2:125-132.

McDaniel, A. M., P. L. Benson, G. H. Roesener, and J. Martindale. 2005. An integrated computer-based system to support nicotine dependence treatment in primary care. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 7 Suppl 1, S57-66.

McIlvain, H. E., E. L. Backer, B. F. Crabtree, and N. Lacy. 2002. Physician attitudes and the use of office-based activities for tobacco control. *Family medicine* 34, no. 2:114-119.

McIvor, A. 2009. Tobacco control and nicotine addiction in Canada: current trends, management and challenges. *Canadian respiratory journal : journal of the Canadian Thoracic Society* 16, no. 1:21-26.

McKay-Brown, L., et al. 2008. The impact of a GP clinical audit on the provision of smoking cessation advice. *Asia Pacific family medicine* 7, no. 1:4.

McLeroy, K. R., D. Bibeau, A. Steckler, and K. Glanz. 1988. An ecological perspective on health promotion programs. *Health education quarterly* 15, no. 4:351-377.

Meredith, L. S., E. M. Yano, S. C. Hickey, and S. E. Sherman. 2005. Primary care provider attitudes are associated with smoking cessation counseling and referral. *Medical care* 43, no. 9:929-934.

Milch, C. E., et al. 2004. Smoking cessation in primary care: a clinical effectiveness trial of two simple interventions. *Preventive medicine* 38, no. 3:284-294.

Miller, W. L., R. R. McDaniel Jr, B. F. Crabtree, and K. C. Stange. 2001. Practice jazz: understanding variation in family practices using complexity science. *The Journal of family practice* 50, no. 10:872-878.

Monso, E., et al. 2001. Sociodemographic predictors of success in smoking intervention. *Tobacco control* 10, no. 2:165-169.

National Cancer Institute. 2005. *Theory at a glance: a guide for health promotion practice (second edition).*U.S. Department of Health and Human Services. National Institute of Health.

National Center for Chronic Disease Prevention and Health Promotion. Office on Smoking and Health. 2001. *Women and Smoking: A Report of the Surgeon General.*United States. Public Health Service. Office of the Surgeon General.

NCSS. 2008. *PASS.* Kaysville, Utah: .

O'Brien, M. A., et al. 2007. Educational outreach visits: effects on professional practice and health care outcomes. *Cochrane database of systematic reviews (Online)* (4), no. 4:CD000409.

Okene, J. K., D. W. Hosmer, J. W. Williams, et al. 1987. The relationship of patient characteristics to physician delivery of advice to stop smoking. *J Gen Intern Med* 2, 237-340.

Oldenburg, B., and G. Parcel. 2002. *Diffusion of Innovations*. In *Health Behavior and Health Education: Theory, Research, and Practice*, edited by K. Glanz, F. M. Lewis and B. K. Rimer. San Francisco: Jossey-Bass.

O'Loughlin, J., et al. 2001. Smoking cessation counseling practices of general practitioners in Montreal. *Preventive medicine* 33, no. 6:627-638.

Ontario Ministry of Health and Long-Term Care. *Ontario Health Insurance Plan (OHIP) Billing Codes.* Ontario Ministry of Health and Long Term Care (OMOHLTC), 2009.

Ontario Ministry of Health and Long-Term Care. Quality Improvement and Innovation Partnership, accessed October 2010. Available from http://www.qiip.ca/.

Ontario Tobacco Research Unit. *Indicators of Smoke-Free Ontario Progress.* Monitoring and Evaluation Series, Vol. 14/15, No. 2. Toronto: Ontario Tobacco Research Unit, Special Report, January 2010.

Ossip-Klein, D. J., et al. 2000. Smokers ages 50+: who gets physician advice to quit? *Preventive medicine* 31, no. 4:364-369.

Papadakis, S., et al. 2010. Strategies to increase the delivery of smoking cessation treatments in primary care settings: A systematic review and meta-analysis. *Preventive medicine* 51, no. 3-4:199-213.

Pbert, L., et al. 1999. The patient exit interview as an assessment of physician-delivered smoking intervention: a validation study. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association* 18, no. 2:183-188.

Pederson, L. L. 1982. Compliance with physician advice to quit smoking: a review of the literature. *Preventive medicine* 11, no. 1:71-84.

Peto, R., et al. 2000. Smoking, smoking cessation, and lung cancer in the UK since 1950: combination of national statistics with two case-control studies. *British Medical Journal (Clinical research ed.)* 321, no. 7257:323-329.

Pieterse, M. E., et al. 2001. Effectiveness of a minimal contact smoking cessation program for Dutch general practitioners: a randomized controlled trial. *Preventive medicine* 32, no. 2:182-190.

Piper, M. E., D. E. McCarthy, and T. B. Baker. 2006. Assessing tobacco dependence: a guide to measure evaluation and selection. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 8, no. 3:339-351.

Piper, M. E., et al. 2008a. Using mediational models to explore the nature of tobacco motivation and tobacco treatment effects. *Journal of abnormal psychology* 117, no. 1:94-105.

Piper, M. E., et al. 2008b. Refining the tobacco dependence phenotype using the Wisconsin Inventory of Smoking Dependence Motives. *Journal of abnormal psychology* 117, no. 4:747-761.

Piper, M. E., et al. 2010. Psychiatric disorders in smokers seeking treatment for tobacco dependence: relations with tobacco dependence and cessation. *Journal of consulting and clinical psychology* 78, no. 1:13-23.

Plek, P. 2000. Redesigning health care with insights from the science of complex adaptive systems. In *Crossing the quality chasm: a new health system for the 21st century*. Washington: The National Academy Press.

Quinn, V. P., et al. 2005. Tobacco-cessation services and patient satisfaction in nine nonprofit HMOs. *American Journal of Preventive Medicine* 29, no. 2:77-84.

Rehm, J., et al. 2006. *The Costs of Substance Abuse in Canada 2002*.Canadian Centre on Substance Abuse.

Reid, R. D., A. L. Pipe, and B. Quinlan. 2006. Promoting smoking cessation during hospitalization for coronary artery disease. *The Canadian journal of cardiology* 22, no. 9:775-780.

Reid, R. D., A. L. Pipe, B. Quinlan, and J. Oda. 2007a. Interactive voice response telephony to promote smoking cessation in patients with heart disease: a pilot study. *Patient education and counseling* 66, no. 3:319-326.

Reid, R. D., et al. 2010. Smoking cessation for hospitalized smokers: an evaluation of the "Ottawa Model". *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 12, no. 1:11-18.

Rigotti, N. A., M. R. Munafo, and L. F. Stead. 2007. Interventions for smoking cessation in hospitalised patients. *Cochrane database of systematic reviews (Online)* (3), no. 3:CD001837.

Rogers, E. 2003. *Diffusion of Innovations.* New York, NY: Free Press.

Roski, J., et al. 2003. The impact of financial incentives and a patient registry on preventive care quality: increasing provider adherence to evidence-based smoking cessation practice guidelines. *Preventive medicine* 36, no. 3:291-299.

Rothemich, S. F., et al. 2008. Effect on cessation counseling of documenting smoking status as a routine vital sign: an ACORN study. *Annals of family medicine* 6, no. 1:60-68.

Rothemich, S. F., et al. 2010. Promoting primary care smoking-cessation support with quitlines: the QuitLink Randomized Controlled Trial. *American Journal of Preventive Medicine* 38, no. 4:367-374.

Salize, H. J., et al. 2009. Cost-effective primary care-based strategies to improve smoking cessation: more value for money. *Archives of Internal Medicine* 169, no. 3:230-5; discussion 235-6.

Sallis, J., and N. Owen, N. 1999. Ecological models. In *Health Behavior and Health Education: Theory, Research, and Practice*, edited by K. Glanz, F. M. Lewis and B. K. Rimer. San Francisco: Jossey-Bass.

Schnoll, R. A., M. Rukstalis, E. P. Wileyto, and A. E. Shields. 2006. Smoking cessation treatment by primary care physicians: An update and call for training. *American Journal of Preventive Medicine* 31, no. 3:233-239.

Schnoll, R. A., et al. 2010. Increased self-efficacy to quit and perceived control over withdrawal symptoms predict smoking cessation following nicotine dependence treatment. *Addictive Behaviors*.

Schorr, G., et al. 2009. Mental health and readiness to change smoking behavior in daily smoking primary care patients. *International Journal of Behavioral Medicine* 16, no. 4:347-354.

Seale, J. P., et al. 2010. Impact of vital signs screening & clinician prompting on alcohol and tobacco screening and intervention rates: a pre-post intervention comparison. *BMC family practice* 11, 18.

Secades-Villa, R., F. Alonso-Perez, O. Garcia-Rodriguez, and J. R. Fernandez-Hermida. 2009. Effectiveness of three intensities of smoking cessation treatment in primary care. *Psychological reports* 105, no. 3 Pt 1:747-758.

Senore, C., et al. 1998. Predictors of smoking cessation following physicians' counseling. *Preventive medicine* 27, no. 3:412-421.

Shadish, W. R., T. D. Cook, and D. T. Campbell. 2002. *Experimental and quasi-experimental designs for generalized causal inference.* Boston, MA: Houghton Mifflin Company.

Shaohua, H., A. L. McAlister, A. F. Meshack, and J. A. Margois. 2003. Physician's views and practices of smoking cessation. *Texas Medicine*.

Shiffman, S., C. M. Dresler, and J. M. Rohay. 2004. Successful treatment with a nicotine lozenge of smokers with prior failure in pharmacological therapy. *Addiction (Abingdon, England)* 99, no. 1:83-92.

Shinton, R., and G. Beevers. 1989. Meta-analysis of relation between cigarette smoking and stroke. *British Medical Journal (Clinical research ed.)* 298, no. 6676:789-794.

Smith, P. M., S. M. Sellick, P. Brink, and A. D. Edwardson. 2009. Brief smoking cessation interventions by family physicians in northwestern Ontario rural hospitals. *Canadian journal of rural medicine : the official journal of the Society of Rural Physicians of Canada* 14, no. 2:47-53.

Snijders, T. A. B., and R. J. Bosker. 1999. *Multilevel analysis.* Newbury Park, California: Sage.

SPSS Inc. *SPSS 17.0* Chicago, IL: .

SRNT. 2002. SRNT Subcommittee on Biochemical Verification. Biochemical verification of tobacco use and cessation. *Nicotine Tob Res.* 4, 149-159.

Stange, K. C., M. A. Goodwin, S. J. Zyzanski, and A. J. Dietrich. 2003. Sustainability of a practice-individualized preventive service delivery intervention. *American Journal of Preventive Medicine* 25, no. 4:296-300.

Statistics Canada. 2009. *Canadian Community Health Survey.*

Stead, L. F., et al. 2008a. Nicotine replacement therapy for smoking cessation. *Cochrane database of systematic reviews (Online)* (1), no. 1:CD000146.

Stead, L., G. Bergson, and T. Lancaster. 2008b. Physician advice for smoking cessation. *Cochrane database of systematic reviews (Online)* (2), no. 2:CD000165.

Steinberg, M. B., et al. 2006. Gender and age disparities for smoking-cessation treatment. *American Journal of Preventive Medicine* 30, no. 5:405-412.

Swartz, S. H., T. M. Cowan, J. DePue, and M. G. Goldstein. 2002. Academic profiling of tobacco-related performance measures in primary care. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 4 Suppl 1, S38-44.

Szatkowski, L., S. Lewis, A. McNeill, and T. Coleman. 2010. Is smoking status routinely recorded when patients register with a new GP? *Family practice*.

Szpunar, S. M., et al. 2006. Effects of the tobacco use cessation automated clinical practice guideline. *The American Journal of Managed Care* 12, no. 11:665-673.

Tallia, A. F., et al. 2003. Understanding organizational designs of primary care practices. *Journal of healthcare management / American College of Healthcare Executives* 48, no. 1:45-59; discussion 60-1.

Tengs, T. O., et al. 1995. Five-hundred life-saving interventions and their cost-effectiveness. *Risk analysis : an official publication of the Society for Risk Analysis* 15, no. 3:369-390.

Tong, E. K., et al. 2010. National survey of U.S. health professionals' smoking prevalence, cessation practices, and beliefs. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 12, no. 7:724-733.

Twardella, D., and H. Brenner. 2005. Lack of training as a central barrier to the promotion of smoking cessation: a survey among general practitioners in Germany. *European journal of public health* 15, no. 2:140-145.

Twardella, D., and H. Brenner. 2007. Effects of practitioner education, practitioner payment and reimbursement of patients' drug costs on smoking cessation in primary care: a cluster randomised trial. *Tobacco control* 16, no. 1:15-21.

Ulbricht, S., et al. 2006. Provision of smoking cessation counseling by general practitioners assisted by training and screening procedure. *Patient education and counseling* 63, no. 1-2:232-238.

Unrod, M., et al. 2007. Randomized controlled trial of a computer-based, tailored intervention to increase smoking cessation counseling by primary care physicians. *Journal of general internal medicine : official journal of the Society for Research and Education in Primary Care Internal Medicine* 22, no. 4:478-484.

USDHHS. 1984. *The Health Consequences of Smoking: Cardiovascular Disease. A Report of the Surgeon General.* Edited by Rockville, Maryland: U.S. Department of Health and Human Services, Public Health Service, Office on Smoking and Health, 1984. D.H.H.S. Publication No. (P.H.S.) 84-50204.

USDHHS. 2004. *The Health Consequences of Smoking: A Report of the Surgeon General.* Atlanta, Georgia: Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

Vaughn, T. E., et al. 2002. Organizational and provider characteristics fostering smoking cessation practice guideline adherence: an empirical look. *The Journal of ambulatory care management* 25, no. 2:17-31.

Vogt, F., S. Hall, and T. M. Marteau. 2005. General practitioners' and family physicians' negative beliefs and attitudes towards discussing smoking cessation with patients: a systematic review. *Addiction (Abingdon, England)* 100, no. 10:1423-1431.

Vogt, F., S. Hall, and T. M. Marteau. 2010. Examining why smokers do not want behavioral support with stopping smoking. *Patient education and counseling* 79, no. 2:160-166.

Warner, K. E., and D. M. Burns. 2003. Hardening and the hard-core smoker: concepts, evidence, and implications. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 5, no. 1:37-48.

Weingarten, M. A., D. Bazel, and H. S. Shannon. 1989. Computerized protocol for preventive medicine: a controlled self-audit in family practice. *Family practice* 6, no. 2:120-124.

West, R., P. Hajek, L. Stead, and J. Stapleton. 2005. Outcome criteria in smoking cessation trials: proposal for a common standard. *Addiction (Abingdon, England)* 100, no. 3:299-303.

Woolf, S. H. 1999. The need for perspective in evidence-based medicine. *JAMA : the journal of the American Medical Association* 282, no. 24:2358-2365.

World Health Organization. 2009a. WHO Report on the Global Tobacco Epidemic, 2009.

World Health Organization. 2009b. World now at the start of 2009 influenza pandemic. Statement to the press by WHO Director-General Dr Margaret Chan 11 June 2009. Available from http://www.who.int/mediacentre/news/statements/2009/h1n1_pandemic_phase6_20090611/en/index.html.

Wynn, A., T. Coleman, S. Barrett, and A. Wilson. 2002. Factors associated with the provision of anti-smoking advice in general practice consultations. *The British journal of general practice : the journal of the Royal College of General Practitioners* 52, no. 485:997-999.

Yano, E. M., et al. 2008. Targeting Primary Care Referrals to Smoking Cessation Clinics Does Not Improve Quit Rates: Implementing Evidence-Based Interventions into Practice. *Health services research*.

Yarnall, K. S., et al. 2003. Primary care: is there enough time for prevention? *American Journal of Public Health* 93, no. 4:635-641.

Young, J. M., and J. E. Ward. 2001. Implementing guidelines for smoking cessation advice in Australian general practice: opinions, current practices, readiness to change and perceived barriers. *Family practice* 18, no. 1:14-20.

Young, J. M., C. D'Este, and J. E. Ward. 2002. Improving family physicians' use of evidence-based smoking cessation strategies: a cluster randomization trial. *Preventive medicine* 35, no. 6:572-583.

Zhu, S.H., et al. 2000. Smoking cessation with and without assistance: a population-based analysis. *American Journal of Preventive Medicine* 18, no. 4:305-311.

Zhu, S. H., et al. 2002. Evidence of real-world effectiveness of a telephone quitline for smokers. *The New England journal of medicine* 347, no. 14:1087-1093.

Appendix A– Systematic review and meta-analysis of strategies to increase the delivery of smoking cessation treatments in primary care setting

Preventive Medicine 51 (2010) 199–213

Contents lists available at ScienceDirect

Preventive Medicine

journal homepage: www.elsevier.com/locate/ypmed

Review

Strategies to increase the delivery of smoking cessation treatments in primary care settings: A systematic review and meta-analysis

Sophia Papadakis [a,b,*], Paul McDonald [a], Kerri-Anne Mullen [b], Robert Reid [a,b], Kimberly Skulsky [b], Andrew Pipe [b]

[a] Department of Health Studies and Gerontology, Faculty of Applied Health Sciences, University of Waterloo, 200 University Ave. West, Waterloo, Ontario, Canada
[b] Minto Prevention and Rehabilitation Centre, University of Ottawa Heart Institute, 40 Ruskin Street, Ottawa, Ontario, Canada

ARTICLE INFO

Available online 17 June 2010

Keywords:
Smoking cessation
Primary health care
Physicians
Family practice
Prevention

ABSTRACT

Objectives. A systematic review and meta-analysis was conducted to evaluate evidence-based strategies for increasing the delivery of smoking cessation treatments in primary care clinics.

Methods. The review included studies published before January 1, 2009. The pooled odds-ratio (OR) was calculated for intervention group versus control group for practitioner performance for "5As" (Ask, Advise, Assess, Assist and Arrange) delivery and smoking abstinence. Multi-component interventions were defined as interventions which combined two or more intervention strategies.

Results. Thirty-seven trials met eligibility criteria. Evidence from multiple large-scale trials was found to support the efficacy of multi-component interventions in increasing "5As" delivery. The pooled OR for multi-component interventions compared to control was 1.79 [95% CI 1.6–2.1] for "ask", 1.6 [95% CI 1.4–1.8] for "advice", 9.3 [95% CI 6.8–12.8] for "assist" (quit date) and 3.5 [95% CI 2.8–4.2] for "assist" (prescribe medications). Evidence was also found to support the value of practice-level interventions in increasing 5As delivery. Adjunct counseling [OR 1.7; 95% CI 1.5–2.0] and multi-component interventions [OR 2.2; 95% CI 1.7–2.8] were found to significantly increase smoking abstinence.

Conclusion. Multi-component interventions improve smoking outcomes in primary care settings. Future trials should attempt to isolate which components of multi-component interventions are required to optimize cost-effectiveness.

Contents

Abbreviations: "5As", refers to the five strategies for smoking cessation treatments in clinical settings and includes Ask, Advise, Assess, Assist and Arrange.

* Corresponding author. Minto Prevention and Rehabilitation Centre, University of Ottawa Heart Institute, H2358, 40 Ruskin Street, Ottawa, Canada K1Y 4W7. Fax: +1 613 761 5309.
E-mail addresses: SPapadakis@Ottawaheart.ca (S. Papadakis), pwmcdona@uwaterloo.ca (P. McDonald), Kmullen@ottawaheart.ca (K.-A. Mullen), BReid@ottawaheart.ca (R. Reid), KSkulsky@ottawaheart.ca (K. Skulsky), APipe@ottawaheart.ca (A. Pipe).

0091-7435/$ – see front matter. Crown Copyright © 2010 Published by Elsevier Inc. All rights reserved.
doi:10.1016/j.ypmed.2010.06.007

Introduction

Tobacco use remains the leading cause of premature morbidity and mortality worldwide (World Health Organization, 2002). Smoking cessation treatment is considered the 'gold standard' intervention in the prevention of chronic diseases (Eddy, 1992; Gaziano et al., 2007; Kahn et al., 2008). The cost per life-year-saved for smoking cessation is estimated to be between $2000 and $4000; it is the most cost-effective preventive intervention available to clinicians (Tengs et al., 1995; Benowitz, 2003; Kahn et al., 2008).

Most smokers will visit their primary care physician annually (Jaakkimainen et al., 2006; Health Canada, 1999; Zwar and Richmond, 2006; Centers for Disease Control and Prevention, 1993). A family doctor's advice to quit has been shown to increase a smoker's motivation to quit (Fiore et al., 2008; Eckert and Junker, 2001; Kreuter et al., 2000; Ossip-Klein et al., 2000; Pederson, 1982; Stead et al., 2008). Smoking cessation is more likely to occur when practitioners offer advice and support compared to no advice, and the effect appears greater as frequency and duration of the support increases. The pooled odds ratio (OR) of cessation is 1.3 [95% CI 1.01, 1.6] for brief counseling (<3 min), 1.6 [95% CI 1.2–2.0] for low intensity counseling (3–10 min), and 2.3 [95% CI 2.0–2.7] for higher intensity counseling (>10 min) (Fiore et al., 2008; Stead et al., 2008).

The United States Department of Health and Human Services (USDHHS) Clinical Practice Guideline for Treating Tobacco-Use and Dependence is a highly regarded and frequently cited reference manual concerning smoking cessation treatment in clinical settings (Fiore et al., 2008). The guideline specifically recommends five strategies as the basis for brief smoking cessation interventions in clinical settings. The "five As" (5As) strategies are: ask and record the smoking status of all patients at each visit; advise all smokers to quit; assess smokers' readiness to make a quit attempt; assist smokers in making a quit-attempt (e.g. provide self-help materials, set quit date, recommend and prescribe smoking cessation medications); and arrange follow-up.

Despite evidence supporting the importance of smoking cessation, there is a well-documented 'practice gap' in the rates at which smoking cessation is addressed by practitioners in clinical settings. International studies have documented that between 40 and 70% of smokers report having received cessation advice from their physicians (Longo et al., 2006; Young and Ward, 2001; Hu et al., 2003; CTUMS, 2006). While practitioners tend to deliver advice to quit at moderate rates, studies have shown that the rates of providing specific assistance with quitting (i.e. counseling, self-help materials, quit-smoking medications, or follow-up support) are below 20% (Longo et al., 2006; Young and Ward, 2001; Hu et al., 2003; Gottlieb et al., 2001; Curry, 2000; DePue et al., 2002; Piper et al., 2003). Several barriers to optimal cessation

practice have been identified at the level of the patient, practitioner, practice, and system; all have been suggested to limit the delivery and uptake of cessation treatments in the primary care setting (Vogt et al., 2005).

While several published meta-analyses have examined the effect of physician advice and other provider interventions on smoking cessation, these reviews have not been specific to the primary care setting (Fiore et al., 2008; Stead et al., 2008; Lancaster et al., 2000).

Moreover, previously published reviews have been limited to reporting on smoking abstinence and have not examined the impact of these interventions on provider performance in the delivery of evidence-based smoking cessation treatments. The only published analysis of strategies to influence provider behaviour in the primary care setting reviewed literature published up to 2001 (Anderson and Jane-Llopis, 2004).

The aim of the present study was to conduct an up-to-date systematic review and meta-analysis of trials evaluating the effectiveness of strategies that increase the delivery of evidence-based cessation interventions as well as increase the rate of smoking cessation among patients in primary care settings.

Review methods

Search strategy

The MEDLINE electronic database was used to identify studies published prior to January 1, 2009 using the MeSH headings "smoking" or "smoking cessation" and "primary health care" or "physicians" or "family practice". Search limits were used to exclude non-English language publications ($n=811$) and trials which were not indexed within MEDLINE as a randomized controlled trial, controlled clinical trial, or evaluation study ($n=5550$). This was supplemented with hand searches of the bibliographies of screened articles.

Selection criteria

Two reviewers independently screened the results of the search. A two-phase review process was used to assess the eligibility of publications. In phase 1, abstracts for all publications identified in the search strategy were screened. In phase 2 the full text manuscripts for all abstracts which were identified for further assessment were screened for eligibility. To be eligible for inclusion in the present review, studies must have: (i) been reported in English; (ii) delivered the intervention in the primary care setting; (iii) been directed at patients 18 years or older; (iv) evaluated one or more smoking cessation interventions compared to control; (v) used a randomized controlled trial or controlled before–after trial design; and (vi) reported on practitioner performance in one or more of the 5As and/or smoking abstinence.

Trials were excluded if they: reported on medical residents rather than primary care practitioners; reported on cessation among physicians versus patients; evaluated simple physician advice or counseling; evaluated the efficacy of pharmacotherapy without evaluation of any other smoking cessation intervention; based the assessment on self-reported data by physician regarding 5As delivery; reported on smoking abstinence measured less than 6 months following the end of the intervention; involved both primary care and specialist settings for which outcome data could not be extracted exclusively for primary care settings; limited study inclusion criteria to specific high risk sub-populations of patients (i.e. COPD, cancer and coronary heart disease) versus the practice at large; measured impact of intervention at level of the community versus practice, practitioner or patient; or, did not include sufficient data for the calculation of odds ratios required for the meta-analysis. A single trial which reported on smoking abstinence determined less than 6 months following the end of the intervention also reported on 5As delivery. (Puschel et al., 2008) Only data on 5As delivery from this trial was considered eligible for inclusion in the meta-analysis.

Data extraction

The reviewers independently extracted data from all eligible studies. Differences between reviewers were resolved through discussion. For each trial, the following data was extracted from published reports: (i) country in which the trial was conducted; (ii) details of study methods (design, duration of follow-up, recruitment methods, data collection method); (iii) outcome measures; (iv) description of the intervention comparators; (v) sample size; (vi) intervention effects; and (vii) loss to follow-up rate. Authors were contacted, as required, to collect information not included in the original publication. For the purpose of the present review, duration of follow-up was defined as the time between the delivery of the intervention and post-intervention data collection.

Interventions were categorized into one of five groups according to the level the intervention was designed to influence: patient-level, practitioner-level, practice-level, system-level, and multi-component. For the purpose of this review, single-component interventions were defined as interventions which include only one intervention strategy. Multi-component interventions were defined as interventions which included two or more intervention strategies; these strategies could target the same or multiple levels.

From the published results of each study, data was extracted to reflect the number of participants abstinent from smoking at follow-up and total sample size (quits/*N*) for both control and intervention groups. As suggested by the Cochrane collaboration's Tobacco Addiction Group, the most rigorous definition of abstinence reported in each trial was used in the pooled analysis (Stead et al., 2008). In addition, the proportion of patients (# patients received strategy/ total # smokers) receiving each of the 5As (Ask, Advise, Assess, Assist and Arrange) strategies was extracted for the intervention group versus control group. For the "assist" strategy, data was collected for the provision of self-help materials, setting of a quit date, recommending/prescribing smoking cessation medications, as well as overall assistance with quitting.

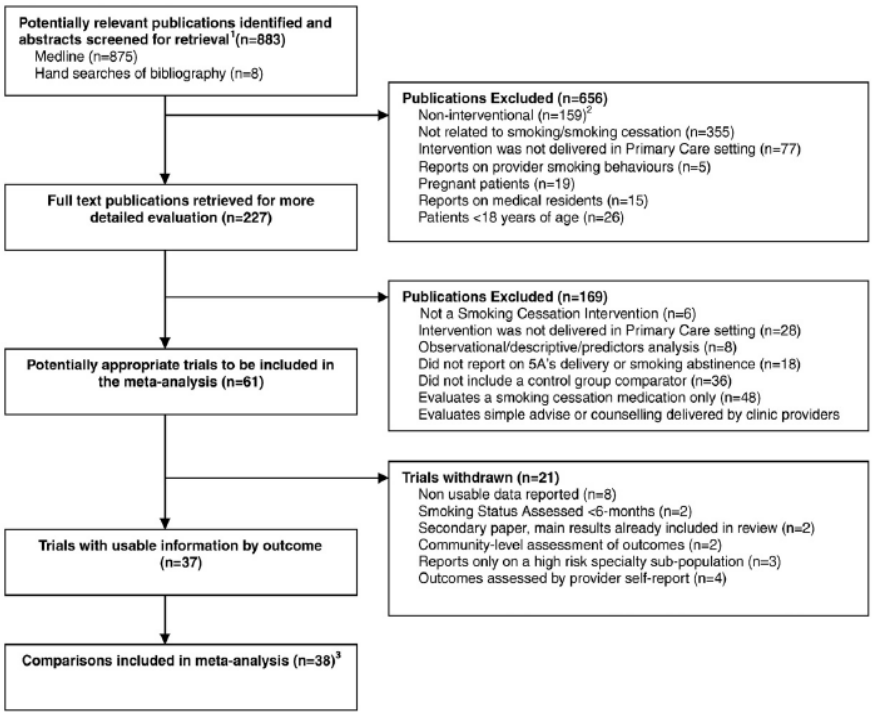
Effect size calculation

Results were expressed for each outcome of interest as the odds ratio (OR) [intervention:control], together with the 95% confidence interval (CI). The pooled treatment effects were reported using a Mantel–Haenszel fixed effect model. Heterogeneity was reported using the I^2 statistic, which describes the percentage of the variability in effect estimates that is due to heterogeneity rather than to sampling error. An I^2 value greater than 50% was evidence of substantial heterogeneity. Studies using cluster randomization were included in the meta-analysis using the patient-level data and adjusted using the intra-class correlation coefficient (ICC) reported in the paper. When the ICC was not reported, sensitivity analysis was used to test the impact of low and high ICC estimates on outcomes. Based on previously published data for primary care practices, we assumed for purposes of the sensitivity analysis, that the minimum and maximum ICC value for smoking abstinence was 0.01 and 0.05 respectively, and 0.05 and 0.15 for the delivery of the 5As strategies (Baskerville et al., 2001). Sensitivity analysis was also used to examine the effect of non-randomized study design on outcomes. A quality assessment for each trial included in the review was conducted using a subset of the criteria outlined by the CONSORT group, along with two additional criteria which addressed the use of biochemical validation of smoking abstinence and loss to follow-up rate being greater than 80% (Moher et al., 2001; Campbell et al., 2004).

Results

Study selection

Fig. 1 presents a flow chart of the selection process. A total of 38 comparisons from 37 published studies met the eligibility criteria



[1]Articles excluded using search limits [Non-English Language (n=811); Design was not listed as randomized controlled trial, controlled clinical trial, or evaluation study (n=5550)]
[2]Non-interventional studies included three review articles and 156 observational or descriptive papers identified during abstract review process.
[3]Two separate comparisons of active interventions versus control are reported by Szpunar 2006 which were included in the review

Fig. 1. Review flow diagram (review includes studies published before January 1, 2009).

and were included in the present review. A summary of the excluded studies can be accessed from the online version of this publication.

Description of studies

Table 1 summarizes the characteristics of the studies included in the present review. Table 2 provides an overview of the study design, description of comparator groups and outcomes of the 38 trials included within the review. A more detailed summary of trial characteristics, follow-up rates, and outcomes has been published as Supplemental material in the online version of this publication only. Table 3 provides a summary of the pooled OR for smoking abstinence and improved performance in each of the 5As by intervention level.

Patient-level interventions

Patient-level interventions were designed to take place directly with patients identified in the primary care setting and included both counseling that was provided by non-physician staff as well as computer-tailored patient materials. In all trials, counseling was provided to smokers outside of the standard primary care clinic visit by a counselor who was not a physician.

Adjunct counseling

Smoking abstinence

The pooled odds ratio for adjunct counseling on smoking abstinence was 1.7 [95% CI 1.5–2.0]. The intervention effects remained significant in the sensitivity analysis.

Fig. 2 presents a forest plot for the seven RCTs that reported on the efficacy of adjunct counseling on smoking abstinence. It is worth noting that several of these trials did not document a significant effect. There was also variability in the pool of patients reported within the trials assessing adjunct counseling. For example, some authors limited analysis to patients who received adjunct counseling; others used an intention to treat analysis. Despite the mixed findings among the trials identified within the review the variability in effect estimates was in the acceptable range ($I^2 = 37\%$).

Provider 5As performance

Adjunct counseling was also found to have a significant influence on provider performance in "assisting" with prescribing smoking cessation medications and "arranging" follow-up.

Tailored print materials

Smoking abstinence

Two trials evaluated the impact of providing patients with computer-tailored print intervention (self-help materials customized

Table 1
Summary of study characteristics and research designs of eligible studies (review includes studies published before January 1, 2009).

Study characteristic	N (%)
Design[a]	
RCT (patient-level)	12 (32)
Cluster RCT (physician-level)	3 (8)
Cluster RCT (practice-level)	13 (35)
Before–after controlled study	9 (24)
Country of origin[a]	
USA	19 (51)
Australia	5 (14)
United Kingdom	4 (11)
Germany	2 (5)
Scotland	2 (5)
Canada	1 (3)
Netherlands	1 (3)
Spain	1 (3)
Chile	1 (3)
Israel	1 (3)
Intervention type[b]	
Patient-level	10 (26)
Adjunct counselling	8 (21)
Tailored print materials	2 (5)
Practitioner-level	4 (11)
Training	2 (5)
Performance feedback	2 (5)
Practice-level	12 (32)
Screener	3 (8)
Automated screeners	1 (3)
Checklist	1 (3)
EMR and decision supports	5 (13)
Academic detailing	1 (3)
Increased duration of visit	1 (3)
System-level	2 (5)
Provider incentives	2 (5)
Multi-component	10 (26)
Outcome[a]	
Performance in delivery of 5As	
Ask	18 (49)
Advise	17 (46)
Assess	16 (43)
Assist	7 (19)
Assist (Meds)	7 (19)
Assist (Quit date)	6 (16)
Assist (Self-help)	2 (5)
Arrange	9 (24)
Smoking abstinence	23 (62)
Duration of follow-up for outcome assessment[a]	
<12 weeks	5 (14)
3–<6 months	3 (8)
6–<12 months	9 (24)
12 months	14 (38)
>12 months	6 (16)

RCT = randomized controlled trial.
[a] Based on $N = 37$ trials.
[b] Based on 38 comparisons.

based on patient's own personal smoking profile) compared to a control condition on smoking abstinence (Lennox et al., 2001; Meyer et al., 2008). The pooled OR for computer-tailored interventions versus controls for smoking abstinence was 1.50 [95% CI 1.06, 2.11], however the results did not remain significant in the sensitivity analysis.

Provider 5As performance

None of these trials reported on provider performance in 5As delivery.

Practitioner-level interventions

Practitioner-level interventions are directed at a physician or another member of the clinical team and include training and provider performance feedback.

Training

Smoking abstinence/provider 5As performance

No significant impact was observed in the two identified trials that evaluated the efficacy of physician training on the delivery of smoking cessation treatments for either smoking abstinence or provider performance (Lennox et al., 1998; Kottke et al., 1989). These trials involved the delivery of an intervention that was based solely on training; however, a number of trials have involved training as one component of a multi-component intervention and their results are reported under multi-component interventions.

Practitioner performance feedback

Smoking abstinence

None of the trials identified within this review evaluated the effect of performance feedback on smoking abstinence.

Provider 5As performance

Two trials evaluated the efficacy of audits and practitioner feedback on performance in the delivery of smoking cessation treatments as compared to peer-established benchmarks (Bentz et al., 2007; Andrews et al., 2001). Performance feedback was found to significantly increase rates of "assisting" compared to controls. However the variability in the effects was large with an I^2 of 87% and should be interpreted with caution. No significant differences were found for rates of "asking" or "advising" compared to controls.

Practice-level interventions

Practice-level interventions involve changes to protocols or systems within the primary care practice environment.

Screeners/vital stamp (smoker identification)

Smoking abstinence

No impact was seen on patient smoking abstinence as a result of the screener or vital stamp interventions. Milch found that an expanded screener, which included 5 questions for assessing patient smoking status, readiness to quit, and counseling prompts, outperformed both control group and vital stamp group in increasing smoking abstinence (Milch et al., 2004).

Provider 5As performance

Three trials observed that the addition of smoking to the clinic 'vital sign stamp' (i.e. standard set of patient data collected at each clinic encounter) on clinic medical records significantly increased rates of "asking" patients about smoking status; however, no impact was seen in the delivery of other 5As strategies (Piper et al., 2003; Milch et al., 2004; Rothemich et al., 2008). Only one study identified in the present review compared a control group to practitioners who used an electronic check-in screener (Szpunar et al., 2006). Rates of "asking" about smoking status were higher in the check-in screener group as compared to controls.

Checklists

Smoking abstinence

No trials were identified within this review which assessed the impact of checklists on smoking abstinence.

Table 2
Description of studies included in review of strategies to support the delivery of smoking cessation treatments in primary care settings.

Author (year) Country	Design	Duration of follow-up	Comparators	Smoking abstinence OR [95% CI]	5As Delivery OR [95% CI]
Adjunct counselling (patient-level)					
Murray et al. (2008) *United Kingdom*	Cluster RCT (practice-level)	6 months	CG: no intervention In: proactive identification of smokers by letter offering smoking cessation support through the national health smoking cessation service.	1.62 [1.22, 2.15]	–
Young et al. (2008) *Australia*	RCT (patient-level)	12 months	CG: no intervention In: ability to refer smokers to a telephone-based smoking cessation program comprising assessment and stage based behavioural advice, written information and follow-up delivered by a nurse.	1.30 [0.54, 3.31]	Advise: 1.57 [0.88, 2.82] Assist – Quit date: 1.47 [0.55, 3.92] Assist – self-help: 1.00 [0.55, 1.79] Arrange: 1.40 [0.31, 6.02]
Sherman et al. (2007) *USA*	Cluster RCT (practice-level)	18 months	CG: no intervention In: access to an on-call counsellor who provided counselling and care coordination. Social marketing efforts included educational outreach, provider feedback and financial incentives. $25 gift certificate given to provider with most patients each month.*	0.85 [0.4, 1.9]	Assist – counsel: 1.7 [1.0, 2.9] Assist – meds: 2.35 [1.08, 5.13] Arrange: 2.08 [1.2, 3.6]
An et al. (2006) *USA*	RCT (patient-level)	12 months	CG: mailed self-help materials In: received behavioural counselling via telephone (7 calls over 2 months) with mailing of smoking cessation medications as clinically indicated. Additional calls were placed over a 12 month period at the discretion of the counsellor.	3.45 [1.96, 6.06]	Assist-meds: 7.85 [5.34, 11.53] Arrange: 104 [56,194]
Aveyard et al. (2003) *United Kingdom*	RCT (patient-level)	12 months	CG: no intervention In 1: self help workbook and three questionnaires at three monthly intervals; In 2: self-help workbook + three tailored newsletters, and three telephone calls; In 3: self-help workbook + three tailored newsletters, and three visits to nurse practitioner	1.50 [0.74, 3.03]	–
Hollis et al. (1993) *USA*	RCT (patient-level)	12 months	CG: usual care In: Brief physician advise and referral to onsite nurse smoking counsellor who provided a self-quit training, carbon monoxide sample, 10 minute video, written materials, and a follow-up phone call	1.73 [1.4, 2.2]	–
Vetter and Ford (1990) *United Kingdom*	RCT (patient-level)	6 months	CG: Physician advise In: Physician advise + backed up by nurse	1.79 [1.0, 3.22]	–
Robson et al. (1989) *United Kingdom*	RCT (patient-level)	5 years	CG: general practitioner intervention alone In: computerized system used by health promotion nurse counsellor to identify and follow-up with patients with risk factors	–	Ask: 2.01 [1.73, 2.33]
Tailored print materials (patient-level)					
Meyer et al. (2008) *Germany*	Quasi-RCT (patient-level)	24 months	CG: assessment only In 1: computer-generated tailored letters	1.58 [1.03, 2.43]	–
Lennox et al. (2001) *Scotland*	RCT (patient-level)	6 months	CG: no intervention In 2: tailored letter on smoking cessation	1.37 [0.78, 2.39]	–
Training (provider-level)					
Lennox et al. (1998) *Scotland*	Cluster RCT Matched pair design (practice-level)	14 months	CG: no training In: 1-day stages of change approach to smoking cessation training workshop	0.76 [0.47, 1.23]	Ask: 1.29 [0.96, 1.74]
Kottke et al. (1989) *USA*	RCT (physician-level)	12 months	CG: no assistance In: 6-hour training intervention.	1.10 [0.63, 1.92]	Insufficient data
Performance feedback (provider-level)					
Bentz et al. (2007) *USA*	Cluster RCT (practice-level)	12 months	CG: EMR In: EMR + feedback report. Provider specific monthly feedback reports generated from EMR data. The reports rated provider performance in asking, advising, assessing, and assisting with tobacco cessation compared with a clinic average and an achievable benchmark of care.	–	Ask: 2.91 [2.21, 2.43] Advise: 2.36 [2.12, 4.95] Assess: 2.86 [1.38, 5.90] Assist: 2.42 [0.76, 7.69]

Table 2 (*continued*)

Author (year) Country	Design	Duration of follow-up	Comparators	Smoking abstinence OR [95% CI]	5As Delivery OR [95% CI]
Performance feedback (provider-level)					
Andrews et al. (2001) *USA*	Before–after controlled time series design (cross-sectional)	8 weeks	CG: no additional intervention. In: A vital stamp + single educational intervention on AHCPR guideline, 4As and tobacco dependence treatment was delivered + individual and team feedback on 4As performance was provided as well as booster education.	–	Ask: 3.09 [0.12, 76.62] Advise: 0.86 [0.43, 1.72] Assist: 16.29 [7.9, 33.6] Arrange: 47.37 [2.82, 796]
Screener/vital sign stamp (practice-level)					
Rothemich et al. (2008) *USA*	Cluster RCT (practice-level)	6 months	CG: did not use any systematic tobacco screening or identification system. In: nurses and medical assistants were instructed to assess the tobacco use status of every adult patient and record it with the traditional vital signs.	–	Ask: 5.34 [3.32, 8.58] Advise: 3.94 [2.19, 7.06]
Milch et al. (2004) *USA*	Before–after controlled study (cross-sectional)	12 months	CG: no intervention In: a 5-question form that assessed patient level cessation readiness and provided counselling prompts for clinicians	3.21 [1.53, 6.74]	Ask: 10.86 [5.04, 23.42] Advise: 2.06 [1.26, 3.39]
Piper et al. (2003) *USA*	Before–after controlled study (cross sectional)	12 months	CG: no intervention In: use of progress notes stamped with the expanded vital signs that included smoking status, blood pressure, temperature, pulse, respiratory rate1	0.85 [0.75, 0.96]	Ask: 1.32 [1.22,1.44] Advise: 0.54 [0.50,0.59] Assist–Meds: 0.60 [0.46, 0.79] Assist–Quit Date: 0.57 [0.44, 0.74] Arrange: 0.25 [0.17,0.37]
Szpunar et al. (2006) *USA*	Before–after controlled study (cross sectional)	14-weeks	CG: no intervention In: EMR based check-in screener regarding smoking status	–	Ask: 1.38 [1.09, 1.75] Advise: 1.24 [1.06, 1.46] Assist: 0.73 [0.63, 0.85] Assess: 1.28 [1.10, 1.50] Arrange: 1.25 [1.02, 1.54]
Checklist (practice-level)					
Dubey et al. (2006) *Canada*	Cluster RCT (practice-level)	5 months	CG: no checklist In: a single checklist reminder which incorporate sex specific evidence-based recommendations on 13 preventative interventions including smoking	–	Assist: 6.94 [3.81, 12.64]
Electronic medical record prompts (practice-level)					
Szpunar et al. (2006) *USA*	Before–after controlled study (cross sectional)	14-weeks	CG: no intervention In: automated electronic medical record based clinical practice guideline with prompts	–	Ask: 2.45 [1.9, 3.15] Advise: 1.40 [1.19, 1.64] Assess: 1.28 [1.10, 1.50] Assist: 1.0 [0.86, 1.16] Arrange: 2.32 [1.92, 2.81]
Frank et al. (2004) *Australia*	Quasi RCT (patient-level)	Not reported	CG: no reminder In: Automatic electronic record of preventative care reminder for 12 preventative care activities including smoking.	–	Ask:1.12 (0.90, 1.39)
Bonevski et al. (1999) *Australia*	Cluster RCT (physician-level)	3 months	CG: no intervention In: continuing medical education program delivered by a touch screen computer with reminder and feedback to providers	–	Ask: 1.63 [1.09, 2.44]
McPhee et al. (1991) *USA*	RCT (patient-level)	12 months	CG: no intervention In: computerized reminder system for screening and self help materials for patients	–	Assess: 1.71 [1.44, 2.02] Assist: 2.00 [1.51, 2.64]
Weingarten et al. (1989) *Isreal*	RCT (patient-level)	30 months	CG: manual records In: computerized reminder system	–	Ask: 3.78 [1.99, 7.17]
Academic detailing (practice-level)					
Yano et al. (2008) *USA*	Cluster RCT (practice-level)	12 months	CG: mailed guidelines and VA audit-feedback reports. In: Evidence-based Quality Improvement Plan structured evidence review, local priority setting, quality improvement plan development, practice facilitation, expert feedback.	0.96 [0.63, 1.47]	Advise: 1.08 [0.84, 1.40] Arrange: 0.72 [0.56, 0.92]
Increase length of clinic appointments (practice-level)					
Wilson et al. (1992) *United Kingdom*	Before−after controlled study (cross-sectional)	Exit	CG: no intervention In: prolong length of each GP visit by 3 min to address health behaviours including smoking	–	Advise: 1.78 [1.21, 2.62]

(*continued on next page*)

Table 2 (*continued*)

Author (year) Country	Design	Duration of follow-up	Comparators	Smoking abstinence OR [95% CI]	5As Delivery OR [95% CI]
Provider incentives (system-level)					
An et al. (2008) *USA*	Cluster RCT (practice-level)	Na	CG: no intervention In: pay for performance program in which clinics were offered $5000 for 50 quit line referrals.	–	Arrange: 2.93 [2.63, 3.27]
Roski et al. (2003) *USA*	Cluster RCT (practice-level)	6 months	CG: no intervention In : financial incentive for meeting preset performance targets	1.21 [0.98, 1.49]	Ask: 1.38 [1.20, 1.58] Advise: 1.08 [0.80, 1.46]
Multi-component					
Puschel et al. (2008) *Chile*	Before after controlled trial	Exit.	CG: standard care was provided to women smokers participating in the study. In: Clinic staff received four × 3 h training session on smoking cessation. All women patients had their smoking status and readiness to quit assessed as part a vital signs screening process. A nurse practitioner provided advise and assisted and arranged follow-up for smokers ready to quit.	Smoking assessed less than 6-month post-intervention. Data not included in meta-analysis.	Advise: 0.90 [0.64, 1.26]
Twardella and Brenner (2007) *Germany*	Cluster RCT (practice-level)	12 months	CG: no intervention In: 2-hour group training + incentive ($130 for every patient quit at 12 months) + free NRT	In 3: 6.16 [1.44, 26.4]	–
Unrod et al. (2007) *USA*	Cluster RCT (physician-level)	6 months	CG: no intervention In: physician training + physicians and patients received a one-page report that characterized patients smoking habit and history and offered tailored recommendations.	1.56 [0.84, 2.91]	Ask: 1.75 [1.21, 2.53] Advise: 2.93 [1.96, 4.36] Assess: 5.41 [3.62, 8.09] Assist-Quit Date: 5.06 [3.4, 7.7] Assist-Selfhelp: 6.38 [3.6, 11.4] Assist-Meds: 4.93 [3.31, 7.35] Arrange: 8.53 [5.13, 14.18]
Katz et al. (2004) *USA*	Cluster RCT (practice-level)	6 months	CG: general information about smoking cessation guidelines In: (1) physician tutorial in delivery of 5As; (2) real time reminder using a modified vital signs stamp applied to progress notes with question to stratify smokers stage of readiness; (3) 8-week supply of NRT patches and self-help material; (4) telephone counselling: patients deemed eligible for counselling (prior to and 1-week following quit date) were referred via fax to a centralized cessation counselling service; (5) feedback to intake clinician on performance of guideline recommended activities delivered at baseline and interim.	3.09 [1.84, 5.21]	Ask: 3.28 [2.44, 4.41] Advise: 1.44 [1.14, 1.83] Assess: 6.31 [4.87, 8.17] Assist-Quit Date: 36.4 [14.9, 89.5] Assist-Meds: 3.91[2.90, 5.27]
Joseph et al. (2004) *USA*	Cluster RCT (practice-level)	12 months	CG: usual care In: 2-day training meeting which encouraged the use of EMRs for screening, and use of quit smoking medications, + 2 to 3 day site visit to communicate with prime movers in the practice using an academic detailing model.	0.85 [0.51, 1.4]	Ask: 1.09 [0.86, 1.40] Advice: 1.11 [0.7, 1.8] Assist: 1.22 [0.79, 1.87] Assist Meds: 0.78 [0.44, 1.39]
Young et al. (2002) *Australia*	Cluster RCT (practice-level)	6 months	CG: intervention on cervical cancer screening In: three academic detail visits which combined: (1) audit and feedback; (2) skills training (video, workbook, clinical practice guideline, prompt sheet); (3) patient mediated prompts and reminders for medical records; (4) resources for patients (eg, starter packs of NRT)	–	Ask: 1.46 [0.81, 2.62] Advise: 1.69 [0.94, 3.04] Assist-Quit Date: 2.43 [1.12, 5.29] Assist-Meds: 11.07 [5.11, 24.01]
Katz et al. (2002) *USA*	Before–after controlled study (cross-sectional)	6 months	Same as Katz et al. (2004). See description above.	3.44 [0.75, 15.75]	Ask: 6.56 [2.58, 16.68] Advise: 1.66 [0.91, 3.03] Assess: 9.38 [4.67, 18.3] Assist-Quit Date: 80 [4.85,1321] Assist-Meds: 2.41 [1.27, 4.57]
Pieterse et al. (2001) *Netherlands*	RCT (patient-level)	12 months	CG: no intervention In: 2-hour training session focused on counselling, nicotine addiction, and required changes to practice processes with physicians. Medical assistant assesses smoking status and physician delivers brief (10-min) counselling.	2.82 [1.23, 6.45]	–
Grandes et al. (2000) *Spain*	Before–after controlled study	12 months	CG: no intervention In: 5As including focused on developing therapeutic plan (quit date, NRT), follow-up calls placed by physician on quit day and 15 days, and in person follow-up consultation at 4 and 8 weeks.	3.50 [1.90, 6.47]	–
Kottke (1992) *USA*	Before–after controlled study	18 months	CG: no intervention In: outreach educational training, facilitation support, revision of professional roles, feedback	–	Ask: 1.89 [1.44, 2.48] Advise: 1.93 [1.48, 2.54]

CG = control group, In = intervention group, RCT = randomized controlled trial, F/U = follow up, OR = odds ratio.
Crude odds ratios are presented were calculated in RevMan based on data reported in publications.

Table 3
Pooled odds ratio of 5As (Ask, Advise, Assess, Assist and Arrange) delivery for patient-level, physician-level, practice-level, system-level and multi-component intervention strategies delivered in primary care settings (review includes studies published before January 1, 2009).

Intervention	Smoking abstinence		Ask		Advise		Assess		Assist meds		Assist quit date		Assist		Arrange	
	k	OR [95%CI]	*k*	OR [95%CI]	*k*	OR [95%CI]	*k*	OR [95%CI]	*k*	OR [95%CI]	*k*	OR [95%CI]	*k*	OR [95%CI]	*K*	*OR [95%CI]*
Patient-level																
Adjunct counselling	7	1.73 [1.5, 2.0]	1	2.01 [1.7, 2.3]	1	1.57 [0.88, 2.8]	–	–	2	6.27 [4.5,8.8]	–	–	–	–	3	13.75 [9.9, 19.1]
Tailored print	2	1.50 [1.1, 2.1]	–		–	–	–	–	–	–	–	–	–	–	–	–
Practitioner-level																
Training	2	0.89 [0.62,1.3]	1	1.29 [0.96, 1.7]	–	–	–	–	–	–	–	–	–	–	–	–
Performance feedback		–	2	2.91 [0.75, 11.2]	2	1.38 [0.84, 2.3]	1	2.86 [1.4, 5.9]	–	–	–	–	2	9.43 [5.2, 17.2]	1	47.4 [2.8, 795.7]
Practice-level																
Screeners/vital stamp	2	0.88 [0.78, 0.99]	3	1.44 [1.3, 1.6]	3	0.59 [0.5, 0.6]	–	–	1	0.60 [0.46, 0.79]	1	0.57 [0.44, 0.74]	–	–	1	0.25 [0.17, 0.37]
Checklist	–	–	–	–	–	–	–	–	–	–	–	–	1	6.94 [3.8, 12.6]	1	–
Electronic prompts	–	–	4	1.65 [1.4, 1.9]	1	1.40 [1.2, 1.6]	2	2.27 [2.0, 2.6]		–		–	2	1.18 [1.0, 1.3]	1	2.32 [1.9, 2.8]
Academic detailing	1	0.96 [0.63, 1.5]		–	1	1.26 [1.0, 1.6]		–		–		–		–		0.72 [0.56, 0.92]
Increase length of stay	–	–		–	1	1.78 [1.2, 2.6]		–		–		–		–		–
System-level																
Provider incentives	1	1.21 [0.98, 1.5]	1	1.38 [1.2, 1.6]	1	1.08 [0.80, 1.5]	–	–	–	–	–	–	–	–	1	2.93 [2.6, 3.3]
Multi-component	7	2.19 [1.7, 2.8]	6	1.79 [1.6, 2.1]	7	1.60 [1.4, 1.8]	3	1.92 [1.4, 2.7]	5	3.45 [2.8, 4.2]	4	9.29 [6.8, 12.8]	1	1.22 (0.8–1.9)	1	8.53 [5.1, 14.2]

k= number of studies. Odds ratios (OR) and 95% CI have been adjusted to reflect clustering for all trials who reported ICC values within the publication.

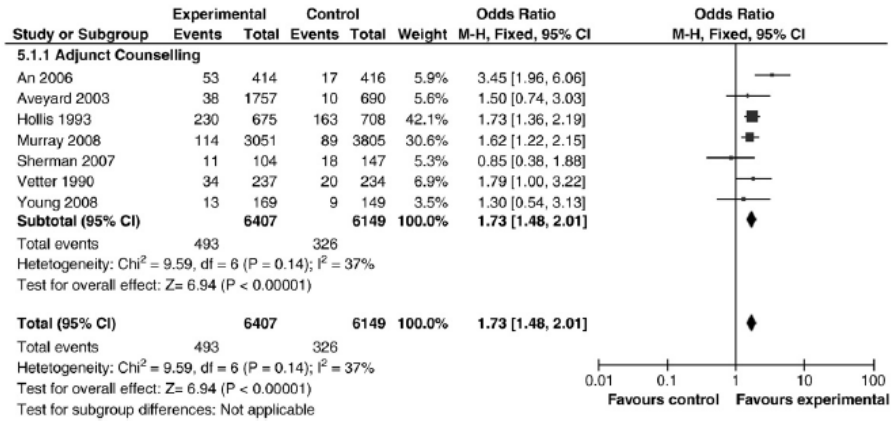


Fig. 2. Meta-analysis of smoking abstinence at 6 or 12 months for adjunct counselling in the primary care setting (includes studies published before January 1, 2009).

Provider 5As performance

Dubey et al. looked at the effect of a one-page checklist reminder which prompted practitioners to provide evidence-based recommendations for preventive interventions. The study found a significant increase in the rate of cessation assistance being documented in patient charts (Dubey et al., 2006).

Electronic prompts

Smoking abstinence

No trials were identified that assessed the impact of electronic prompts on smoking abstinence.

Provider 5As performance

Evidence from four trials found electronic medical-record (EMR) prompts increased the rates at which practitioners are "asking" about smoking status [OR 1.65; 95% CI 1.4, 1.9] (Szpunar et al., 2006; Bonevski et al., 1999; Weingarten et al., 1989; Frank et al., 2004). Evidence from a smaller pool of trials was also found to support the value of EMR prompts on the delivery of the other 5As in primary care settings.

Academic detailing

Academic detailing is a form of educational outreach in which intervention is provided to physicians in their office by a trained health care provider to support quality improvement in a particular area of practice (Goldstein et al., 2003). A single trial examined academic detailing which included support with developing a quality improvement plan, support facilitating changes to the practice, and feedback and monitoring during implementation of practice changes (Yano et al., 2008).

Smoking abstinence

No significant change on smoking abstinence was documented within the single academic detailing intervention identified.

Provider 5As performance

A modest but significant impact was identified on rates of "advising". These results remained significant in the sensitivity analysis.

Increasing length of physician consult

Smoking abstinence

No studies were identified which examined the effect of increased consult length on smoking abstinence.

Provider 5As performance

A modest but significant impact on the delivery of smoking cessation advice was observed in a single trial which examined the impact of increasing physician consult length (Wilson et al., 1992).

System-level interventions

System-level interventions were defined as changes to the environment external to the primary practice setting (e.g. financial incentives to physicians, the provision of cost-free pharmacotherapy for patients).

Provider incentives

Smoking abstinence

No significant effects were observed for provider incentives on smoking abstinence.

Provider 5As performance

Two controlled trial evaluations did not find a significant impact of a financial incentive to physicians on rates of provider "advice" (Roski et al., 2003; An et al., 2008). Provider incentives were found to have a small impact on rates of "asking" about smoking status (OR 1.38 [95% CI 1.20, 1.58]); however, this effect did not remain significant in the sensitivity analysis.

Cost-free cessation medications

No published studies have examined, in isolation, the provision of cost-free medication to patients in the primary care setting. Several multi-component interventions included cost-free NRT in addition to other interventions and are described below (Twardella and Brenner, 2007; Katz et al., 2002; Grandes et al., 2000; Young et al., 2002; Katz et al., 2004).

Multi-component interventions

Ten studies involving 13,831 patients were identified which evaluated multi-component interventions.

Smoking abstinence

Seven trials evaluated the efficacy of multi-component interventions on smoking abstinence (Twardella and Brenner, 2007; Katz et al., 2002; Grandes et al., 2000; Katz et al., 2004; Pieterse et al., 2001; Unrod et al., 2007; Joseph et al., 2004). The pooled OR of smoking cessation calculated for a multi-level intervention compared to control is 2.2 [95% CI 1.7, 2.8]. A Forest plot for smoking abstinence among identified multi-component trials is presented in Fig. 3. The observed effects for multi-component trials remained significant within the sensitivity analysis.

Provider 5As performance

The pooled OR calculated for multi-component interventions compared to control for provider performance showed significant increases in 5As delivery within intervention practices: "ask" [1.79, 95% CI 1.6, 2.1], "advise" [1.6, 95% CI 1.4, 1.8], "assess" [1.9, 95% CI 1.4, 2.7], "assist" with medications [3.45, 95% CI 2.8, 4.2], "assist" with setting a quit date [9.3, 95% CI 6.8, 12.8], and "arrange" [8.5, 95% CI 5.1, 14.2] (Katz et al., 2002; Young et al., 2002; Katz et al., 2004; Pieterse et al., 2001; Unrod et al., 2007; Joseph et al., 2004).

Sensitivity analysis

The impact of the scenarios tested in the sensitivity analysis on each of the effect estimates is presented in Table 4. The exclusion of non-randomized controlled trials had a minimal impact on the pooled ORs for all outcomes.

Quality assessment

The results of the quality assessment are summarized in Table 5. There was significant variability in the quality of the studies included in the present review. Our quality assessment found that only 33% of cluster randomized trials reported ICC values within the publication and few studies (5%) adjusted for practice-level clustering within the analysis. Less than half of trials which reported on smoking abstinence included biochemical validation and most studies reported a loss to follow-up of greater than 20%. Only a small proportion of trials used blinding — a reflection of the impracticality of blinding for the majority of intervention strategies being evaluated.

Discussion

Principal findings

Wide-spread, systematic dissemination of smoking cessation interventions has not occurred in clinical practice settings (Fiore et al., 2008; Ebbert and Hays, 2008).

Understanding which strategies hold the most promise for increasing the uptake of evidence-based smoking cessation interventions in primary-care practice will assist in guiding future research, policy, and most importantly practice.

Our review found evidence from multiple trials supporting the value of multi-component interventions in increasing the delivery of smoking cessation treatment, and ultimately, smoking abstinence. We also identified several single component interventions which appear to have an important role in supporting the integration of smoking cessation interventions within the primary-care practice setting. These strategies include the provision of adjunct counseling for smokers, real-time counseling prompts for practitioners, and practitioner-performance feedback.

Table 6 presents an overall summary of the evidence grades for each of the strategies for increasing provider delivery of 5As for smoking cessation and smoking abstinence in primary care settings.

One previous systematic review reported on nineteen educational and practice-based strategies for increasing smoking cessation treatments in primary care published before 2001 (Anderson and Jane-Llopis, 2004). The present review provides a contemporary summary of the state of knowledge in this important area of preventative practice and includes eighteen new trials which have been published since the last systematic review. This review also provides a previously unavailable summary of evidence for each of the available strategies in increasing the uptake of tobacco treatment in primary care and an evaluation of the quality of that evidence.

Multi-component strategies

Multi-component interventions appear to hold significant promise for influencing practitioners' behaviours. Multiple large-scale controlled trials have demonstrated an impact on physician behaviours and patient cessation rates (grade A). This finding is consistent with an earlier review which found that multi-component interventions, combining education and practice-based supports, to be more effective than single component programs involving either education or practice-based approaches alone (Anderson and Jane-Llopis, 2004). It is important to note that no trials have examined head-to-head comparisons of single- and multi-component interventions.

Multi-component interventions are based on an ecological model of behaviour change which suggests that behaviours are affected by multiple levels of influence, each of which can positively or negatively influence individuals (Sallis and Owen, 1999). The efficacy of multi-component interventions is likely the result of a synergistic effect produced when the practices, practitioners, and patients are all enabled to make the required behaviour changes. All of the multi-component interventions identified in the review were designed to intervene with at least two levels and in some trials up to four levels. Table 7 presents an overview of intervention components used within each of the multi-component trials identified within the review. Trials employed between two and six sub-component strategies within the active intervention group. The two trials which used only two intervention components produced ORs for smoking abstinence of less than 2.0; those which employed three or more components resulted in ORs for smoking abstinence between 2.8 and 6.4.

Despite strong evidence regarding the efficacy of multi-component interventions, it is unclear which intervention components are necessary to produce the desired outcomes. There was considerable variability in the components evaluated within the multi-component intervention models (see Table 7). Interventions included provider training (100%), screeners (40%), desktop resources (20%), performance feedback (40%), academic detailing (40%), adjunct counseling (50%), and cost-free NRT (50%). Many of the multi-component interventions combined low-cost strategies (i.e. screeners and quit kits) with more costly strategies, such as cost-free pharmacotherapy, audit and feedback, and intensive follow-up counseling. Understanding whether higher-cost intervention strategies are in fact necessary to produce increased rates of smoking cessation requires further investigation, as does the need for a better understanding of which combinations are most cost-effective. Specifically, the incremental impact of including adjunct counseling, cost-free medications and academic detailing when delivered as one component of a multi-level intervention would seem important given the significant cost involved with each of these strategies.

Single-component strategies

Good evidence (grade A) was found to support the importance of linking smokers identified in primary care settings to supplemental,

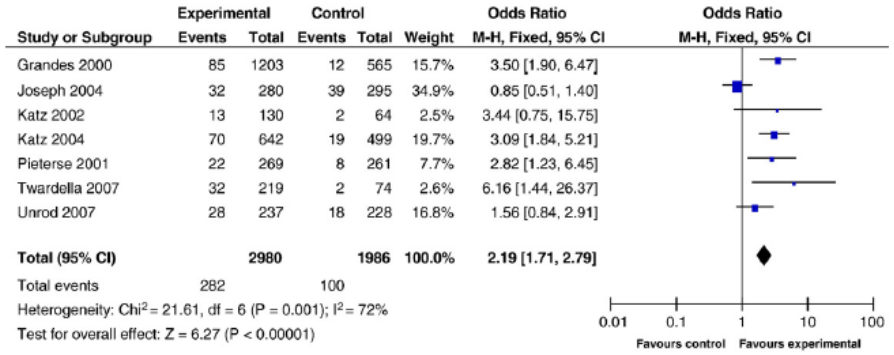


Fig. 3. Forrest plot for smoking abstinence at 6 or 12 months among multi-component interventions (includes studies published before January 1, 2009).

Table 4
Summary of odds ratios [95% CI] for sensitivity analysis of trials evaluating strategies to support the delivery of smoking cessation treatments in primary care settings (review includes studies published before January 1, 2009).

Intervention/outcome	RCT designs[a]		Minimal ICC estimate[b]		Maximum ICC estimate[c]	
	k	Effect estimate OR [95% CI]	*k*	Effect estimate OR [95% CI]	*k*	Effect estimate OR [95% CI]
Patient-level						
Adjunct counselling						
Abstinence	6	1.73 [1.48, 2.01]	7	1.77 [1.48, 2.12]	7	1.83 [1.51, 2.20]
Arrange	3	13.76 [9.90, 19.09]	3	35.28 [21.31, 58.4]	3	42.3 [24.45, 73.1]
Tailored print						
Abstinence	1	1.37 [0.78, 2.39]	2	1.50 [1.06, 2.11]	2	1.50 [1.06, 2.11]
Practitioner level						
Training						
Abstinence	2	0.89 [0.62, 1.28]	2	0.95 [0.61, 1.50]	2	0.94 [0.57, 1.55]
Ask	1	1.29 [0.96, 1.74]	1	1.27 [0.70, 2.31]	1	1.17 [0.45, 3.03]
Performance feedback						
Ask	1	2.91 [0.75, 11.2]	2	2.91 [0.75, 11.23]	2	2.91 [0.75, 11.23]
Advise	1	2.36 [1.12, 4.95]	2	1.38 [0.84, 2.27]	2	1.38 [0.84, 2.27]
Assess	1	2.86 [1.38, 5.90]	1	2.86 [1.38, 5.90]	1	2.86 [1.38, 5.90]
Practice level						
Screener/vital stamp						
Abstinence	–	–	2	0.88 [0.78, 0.99]	2	0.88 [0.78, 0.99]
Ask	1	5.41 [4.20, 6.97]	2	1.44 [1.33, 1.57]	2	1.44 [1.33, 1.57]
Advise	1	3.96 [3.05, 5.14]	3	0.59 [0.54, 0.64]	3	0.59 [0.54, 0.64]
Checklist						
Assist	1	6.94 [3.81,12.64]	1	8.36 [1.98, 35.35]	1	4.50 [0.58, 35.15]
Electronic prompts						
Ask	3	1.33 [1.12, 1.59]	4	1.65 [1.42, 1.91]	4	1.65 [1.42, 1.91]
Advise	–	–	1	1.40 [1.19, 1.64]	1	2.98 [2.52, 3.53]
Assist	1	2.00 [2.51, 2.64]	2	1.18 [1.03, 1.34]	2	1.18 [1.03, 1.34]
Academic detailing						
Abstinence	1	0.96 [0.63, 1.47]	1	0.96 [0.63, 1.47]	1	0.96 [0.63, 1.47]
Advise	2	1.26 [1.02, 1.56]	2	1.48 [1.09, 2.00]	2	1.63 [1.15, 2.31]
System level						
Incentives						
Abstinence	1	1.21 [0.98, 1.49]	1	1.21 [0.92, 1.60]	1	0.92 [0.58, 1.45]
Multi-component						
Abstinence	5	1.89 [1.44, 2.49]	7	2.12 [1.59, 2.82]	7	2.38 [1.73, 3.28]
Ask	4	1.70 [1.45, 1.99]	6	1.85 [1.53, 2.23]	6	1.97 [1.60, 2.42]
Advise	4	1.63 [1.37, 1.95]	7	1.57 [1.33, 1.85]	7	1.56 [1.31, 1.85]
Assess	2	6.03 [4.85, 7.49]	3	6.23 [4.45, 8.73]	3	6.57 [4.54, 9.52]
Assist-Quit Date	3	8.39 [6.09, 11.6]	4	6.12 [4.19, 8.95]	4	6.92 [4.44, 10.79]
Assist – Meds	4	3.58 [2.91, 4.40]	5	3.48 [2.63, 4.61]	5	3.63 [2.63, 5.00]
Assist – Self Help	1	6.38 [3.58, 11.35]	1	6.64 [3.43, 12.87]	1	6.24 [2.88, 13.51]
Arrange	1	8.53 [5.13, 14.18]	1	8.59 [4.82, 15.30]	1	8.50 [4.27, 16.92]

k = number of studies; *N* = number of patients.
[a] Analysis includes only those trials which employed randomized controlled trial designs.
[b] The minimum ICC value for outcomes was assumed to be 0.01 and 0.05 for 5As strategies.
[c] The maximum ICC value for outcomes was assumed to be 0.05 and 0.15 for 5As strategies.

Table 5
Quality assessment of trials evaluating strategies to support the delivery of smoking cessation treatments in primary care settings[a] (review includes studies published before January 1, 2009).

Assessment criteria	Overall	Patient-level	Provider-level	Practice-level	System-level	Multi-component
Randomized controlled trial design	28/37 (76)	9/10 (90)	3/4 (75)	8/11 (73)	2/2 (100)	6/10 (60)
Sample size calculation (including method of calculation, number of clusters, cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty)	17/37 (46)	5/10 (50)	3/4 (75)	6/11 (55)	0/2 (0)	3/10 (30)
Blinding of study participants was used to control for performance bias	6/37 (16)	2/10 (20)	1/4 (25)	2/11 (18)	0/2 (0)	1/10 (10)
Flow diagram of clusters and individual participants through each stage of the evaluation	20/37 (54)	5/10 (50)	1/4 (25)	7/11 (64)	1/2 (50)	6/10 (60)
Point estimates for each primary and secondary outcome and the estimated effect size and its precision along with the numbers in each group	24/37 (65)	9/10 (90)	3/4 (75)	5/11 (45)	1/2 (50)	6/10 (60)
A coefficient of intracluster correlation (ICC or *k*) for each primary outcome reported[b]	7/21 (33)	0/2 (0)	1/3 (33)	1/4 (25)	0/2 (0)	5/10 (50)
The use of biochemical validation of self-reported smoking abstinence[c]	11/24 (46)	5/9 (56)	2/2 (100)	0/2 (0)	1/1 (100)	3/10 (30)
A description of participant follow-up of 80% or greater to minimize attrition bias[d]	10/29 (35)	3/10 (30)	1/4 (25)	0/3 (0)	1/2 (50)	5/10 (50)

[a] Data presented as: number or trials who met criteria/total number of trials for which criteria was relevant (%).
[b] Assessed only for trials which used a cluster randomized design.
[c] Biochemical validation was assessed only for trials which reported on smoking abstinence.
[d] Assessed only for projects in which follow-up data was collected versus chart abstraction.

external smoking cessation counseling in order to increase smoking abstinence, as well as increasing the frequency at which providers are "arranging" follow-up counseling. Additional research is required to strengthen evidence to support the value of adjunct counseling in enhancing 5As delivery; at present, the main impact appears to be on the rates of long term patient smoking abstinence.

Our review found that the addition of smoking status to the clinic 'vital sign stamp' alone increases rates of "asking" (grade A) but does not appear to influence practitioner behaviours beyond the "ask" strategy. This suggests the 'vital sign stamp' must be coupled with other strategies as part of any systematic approach to addressing smoking.

Evidence from multiple trials was found to support the value of real-time reminders (e.g. checklists and EMR prompts) on rates of "asking" (grade A). Positive evidence was also identified regarding the impact of electronic prompts on other 5As strategies; however, this evidence is limited to a smaller pool of trials (grade B). Additional research is recommended to expand the evidence concerning the possible value of electronic medical record prompts in increasing other 5As strategies.

The evidence regarding the value of performance-feedback to practitioners in increasing 5As delivery was mixed. Other reviews of interventions in primary care settings have documented a small to moderate benefit of performance-feedback on provider behaviours (Jamtvedt et al., 2006a,b). Further research is required to better understand the possible impact of performance-feedback on 5As delivery and also on rates of smoking cessation.

We found insufficient evidence to support the value of training-based interventions in influencing physician behaviours or smoking abstinence when delivered in isolation. These findings are consistent with the results of previous reviews (Fiore et al., 2008; Lancaster et al., 2000). A review by the Cochrane collaboration found that practitioner

Table 6
Evidence grades for primary care smoking cessation strategies on smoking abstinence and provider performance in the delivery of the 5As (Ask, Advise, Assess, Assist, Arrange) for smoking cessation in clinical settings (review includes studies published before January 1, 2009).

Intervention	Smoking abstinence	Provider performance in of 5As						
		Ask	Advise	Assess	Assist	Assist	Assist	Arrange
						Discuss medications	*Set quit date*	
Patient level								
Adjunct counselling	A	B	D	–	–	B	–	A
Tailored print	B		–	–	–	–	–	–
Practitioner level								
Training	E	D	–	–	–	–	–	–
Performance Feedback	–	B	C	B	C	–	–	B
Practice level								
Screeners/vital stamp	D	B	C	–	–	D	D	D
Checklist	–	–	–	–	B	–	–	–
Electronic prompts	–	A	B	B	B	–	–	B
Academic detailing	D	–	B	–	–	–	–	C
Increase length of stay	–	–	C	–	–	–	–	–
System level								
Provider incentives	D	B	D	–	–	–	–	B
Multi-component	A	A	A	A	B	A	A	B

Strength of evidence classification	Criteria
Strength of evidence = A	Multiple well-designed randomized controlled trials, directly relevant to the recommendation, yielded a consistent pattern of findings.
Strength of evidence = B	Some evidence from randomized clinical trials supported the recommendation, but the scientific support was not optimal. For instance, only one randomized trial or multiple non randomized controlled trials.
Strength of evidence = C	Mixed evidence or evidence from single non-randomized trial.
Strength of evidence = D	No evidence from single RCT trial or multiple non randomized trials.
Strength of evidence = E	No evidence from multiple randomized controlled trials.

Table 7
Overview of the intervention components used within multi-component interventions (review includes studies published before January 1, 2009).

Author (publication year)	Patient level	Provider level		Practice level			System level		Number of intervention components	Number of levels targeted
	Counselling	Training	Feedback	Screener	Desktop resource/tools	Academic detailing	Incentive	Free NRT		
Puschel et al. (2008)		•				•			2	2
Unrod et al. (2007)		•			•				2	2
Twardella and Brenner (2007)		•					•	•	3	2
Joseph et al. (2004)		•				•			2	2
Katz et al. (2004)	•	•	•	•				•	5	4
Young et al. (2002)	•	•	•	•		•		•	6	4
Katz et al. (2002)	•	•	•	•				•	5	4
Pieterse et al. (2001)	•	•		•					3	3
Grandes et al. (2000)	•	•			•			•	4	4
Kottke et al. (1992)		•	•			•			3	2

training was associated with a positive effect on the rates of delivery of cessation interventions; however, only two of the eight trials were able to document an increase in smoking abstinence resulting from training-based interventions (Lancaster et al., 2000). A second review, found insufficient evidence to recommend provider education systems as stand-alone interventions, but did recommend provider education when delivered as part of other system changes such as system-prompts (Fiore et al., 2008).

Evidence from two RCTs indicates that financial incentives for practitioners are not effective in increasing either the rates of 5As delivery or smoking abstinence (grade D). This finding supports reports by previous authors that financial incentives alone do not address the barriers to delivering cessation intervention in primary care practice and as such, are insufficient to transform outcomes of interest (Coleman et al., 2001).

Quality assessment

The most significant weakness observed across the trials was the lack of adjustment for cluster-level effects. Our sensitivity analysis explored the impact of low and high estimated ICC values on effect estimates. While the lack of reporting and adjustment for clustering did not appear to impact on the findings of the present review, future trials should ensure that ICC values are reported and that the sample size calculation and analysis account for the cluster design. Greater consideration of the nested nature of patient, physician, and practice data would increase the quality of smoking cessation research in the primary care setting. Finally, despite the overall number of published studies examining the impact of provider, practice, and system-level supports on smoking outcomes, only a limited number have provided high-quality evidence. Additional high-quality trials are required to guide future practice.

Limitations

There are limitations in this review which should be noted. First, studies included in this review used non-homogenous definitions of smoking abstinence. While the most rigorous definition of smoking abstinence reported within each trial was used when calculating effect sizes, information on continuous abstinence was not always available. As such, the inclusion of less rigorous definitions of smoking abstinence (e.g. point prevalence abstinence in the last 7-days) may over-estimate long-term abstinence rates. This challenge is one that is typical of meta-analyses of smoking-cessation interventions. Second, meta-analysis data is presented using crude ORs. Several trials included in this review document differences between groups at baseline and have adjusted for these differences in their analysis. While it is not typical for an adjusted OR to be reported in meta-analyses, the baseline differences reported in several trials should be noted. Finally, the review was limited to English language publications. Previous research has not however found there to be a systematic bias in restricting reviews of medical practices to English language publications; the English language restriction is not expected to have an impact on the findings of the present meta-analysis (Morrison et al., 2009).

Conclusion

This review provides new information on the value of strategies for enhancing the integration of clinical smoking cessation interventions into primary-care practice. The review suggests that there is no single intervention strategy that can assist with improving the delivery of all 5As. Multi-component interventions appear to hold promise for improving outcomes. Future trials should attempt to isolate which components of multi-component interventions are required to optimize cost-effectiveness and to validate the value of specific single-component interventions, such as adjunct counseling, provider feedback, real-time provider prompts, and cost-free medications.

Conflict of interest statement
The authors declare there is no conflict of interest.

Acknowledgments

This work was supported by the Ontario Tobacco Research Unit and the Canadian Institute of Health Research Strategic Training Program in Tobacco Research and Population Intervention in Chronic Disease Prevention.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.ypmed.2010.06.007.

References

An, L.C., Zhu, S.H., Nelson, D.B., et al., 2006. Benefits of telephone care over primary care for smoking cessation: a randomized trial. Arch. Intern. Med. 166, 536–542.
An, L.C., Bluhm, J.H., Foldes, S.S., et al., 2008. A randomized trial of a pay-for-performance program targeting clinician referral to a state tobacco quitline. Arch. Intern. Med. 168, 1993–1999.
Anderson, P., Jane-Llopis, E., 2004. How can we increase the involvement of primary health care in the treatment of tobacco dependence? A meta-analysis. Addiction 99, 299–312.
Andrews, J.O., Tingen, M.S., Waller, J.L., Harper, R.J., 2001. Provider feedback improves adherence with AHCPR Smoking Cessation Guideline. Prev. Med. 33, 415–421.
Aveyard, P., Griffin, C., Lawrence, T., Cheng, K.K., 2003. A controlled trial of an expert system and self-help manual intervention based on the stages of change versus standard self-help materials in smoking cessation. Addiction 98, 345–354.
Baskerville, N.B., Hogg, W., Lemelin, J., 2001. The effect of cluster randomization on sample size in prevention research. J. Fam. Pract. 50, W241–W246.
Benowitz, N.L., 2003. Cigarette smoking and cardiovascular disease: pathophysiology and implications for treatment. Prog. Cardiovasc. Dis. 46, 91–111.

Bentz, C.J., Bayley, K.B., Bonin, K.E., et al., 2007. Provider feedback to improve 5A's tobacco cessation in primary care: a cluster randomized clinical trial. Nicotine Tob. Res. 9, 341–349.

Bonevski, B., Sanson-Fisher, R.W., Campbell, E., Carruthers, A., Reid, A.L., Ireland, M., 1999. Randomized controlled trial of a computer strategy to increase general practitioner preventive care. Prev. Med. 29, 478–486.

Campbell, M.K., Elbourne, D.R., Altman, D.G., CONSORT group, 2004. CONSORT statement: extension to cluster randomised trials. BMJ 328, 702–708.

Centers for Disease Control and Prevention, 1993. Smoking cessation during previous year among adults—United States, 1990 and 1991. MMWR Morb. Mortal Wkly. Rep. 42, 504.

Coleman, T., Wynn, A.T., Barrett, S., Wilson, A., Adams, S., 2001. Intervention study to evaluate pilot health promotion payment aimed at increasing general practitioners' antismoking advice to smokers. BMJ 323, 435–436.

CTUMS, 2006. Canadian Tobacco Use Monitoring Survey (CTUMS) 2006.

Curry, S.J., 2000. Organizational interventions to encourage guideline implementation. Chest 118, 40S–46S.

DePue, J.D., Goldstein, M.G., Schilling, A., et al., 2002. Dissemination of the AHCPR clinical practice guideline in community health centres. Tob. Control 11, 329–335.

Dubey, V., Mathew, R., Iglar, K., Moineddin, R., Glazier, R., 2006. Improving preventive service delivery at adult complete health check-ups: the Preventive health Evidence-based Recommendation Form (PERFORM) cluster randomized controlled trial. BMC Fam. Pract. 7, 44.

Ebbert, J.O., Hays, J.T., 2008. The missing link in tobacco control. CMAJ 179, 123–124.

Eckert, T., Junker, C., 2001. Motivation for smoking cessation: what role do doctors play? Swiss Med. Wkly. 131, 521–526.

Eddy, D.M., 1992. David Eddy ranks the tests. Harv. Health Lett. 17, 10–11.

Fiore MC, Jaén CR, Baker TB, et al., 2008. Treating tobacco use and dependence: 2008 update. Clinical Practice Guideline.

Frank, O., Litt, J., Beilby, J., 2004. Opportunistic electronic reminders. Improving performance of preventive care in general practice. Aust. Fam. Physician 33, 87–90.

Gaziano, T.A., Galea, G., Reddy, K.S., 2007. Scaling up interventions for chronic disease prevention: the evidence. Lancet 370, 1939–1946.

Goldstein, M.G., Niaura, R., Willey, C., et al., 2003. An academic detailing intervention to disseminate physician-delivered smoking cessation counseling: smoking cessation outcomes of the Physicians Counseling Smokers Project. Prev. Med. 36, 185–196.

Gottlieb, N.H., Guo, J.L., Blozis, S.A., Huang, P.P., 2001. Individual and contextual factors related to family practice residents' assessment and counseling for tobacco cessation. J. Am. Board Fam. Pract. 14, 343–351.

Grandes, G., Cortada, J.M., Arrazola, A., 2000. An evidence-based programme for smoking cessation: effectiveness in routine general practice. Br. J. Gen. Pract. 50, 803–807.

Health Canada, 1999. Statistical Report on the Health of Canadians.

Hollis, J.F., Lichtenstein, E., Vogt, T.M., Stevens, V.J., Biglan, A., 1993. Nurse-assisted counseling for smokers in primary care. Ann. Intern. Med. 118, 521–525.

Hu, S., McAlister, A.L., Meshack, A.F., Margois, J.A., 2003. Physician's views and practices of smoking cessation. Tex. Med. 99, 57–63.

Jaakkimainen, L., Schult, S., Klein-Geltink, J., Thiruchelvam, D., Kopp, A., 2006. Ambulatory physician care for adults. In: Jaakkimainen, L., Upshur, R., Klein-Geltink, J.E., Leong, A., Maaten, S., Schultz, S.E., Wang, L. (Eds.), Primary Care in Ontario: ICES Atlas. Institute for Clinical Evaluative Sciences, Toronto.

Jamtvedt, G., Young, J.M., Kristoffersen, D.T., O'Brien, M.A., Oxman, A.D., 2006a. Audit and feedback: effects on professional practice and health care outcomes. Cochrane Database Syst. Rev. 2 CD000259.

Jamtvedt, G., Young, J.M., Kristoffersen, D.T., O'Brien, M.A., Oxman, A.D., 2006b. Does telling people what they have been doing change what they do? A systematic review of the effects of audit and feedback. Qual. Saf. Health Care 15, 433–436.

Joseph, A.M., Arikian, N.J., An, L.C., et al., 2004. Results of a randomized controlled trial of intervention to implement smoking guidelines in Veterans Affairs medical centers: increased use of medications without cessation benefit. Med. Care 42, 1100–1110.

Kahn, R., Robertson, R.M., Smith, R., Eddy, D., 2008. The impact of prevention on reducing the burden of cardiovascular disease. Circulation.

Katz, D.A., Muehlenbruch, D.R., Brown, R.B., Fiore, M.C., Baker, T.B., Smoking Cessation Guideline Study Group, A.H.R.Q., 2002. Effectiveness of a clinic-based strategy for implementing the AHRQ Smoking Cessation Guideline in primary care. Prev. Med. 35, 293–301.

Katz, D.A., Muehlenbruch, D.R., Brown, R.L., Fiore, M.C., Baker, T.B., AHRQ Smoking Cessation Guideline Study Group, 2004. Effectiveness of implementing the agency for healthcare research and quality smoking cessation clinical practice guideline: a randomized, controlled trial. J. Natl. Cancer Inst. 96, 594–603.

Kottke, T.E., Brekke, M.L., Solberg, L.I., Hughes, J.R., 1989. A randomized trial to increase smoking intervention by physicians. Doctors Helping Smokers, Round I. JAMA 261, 2101–2106.

Kottke, T.E., Solberg, L.I., Brekke, M.L., Conn, S.A., Maxwell, P., Brekke, M.J., 1992. A controlled trial to integrate smoking cessation advice into primary care practice: Doctors Helping Smokers, Round III. J. Fam. Pract. 34, 701–708.

Kreuter, M.W., Chheda, S.G., Bull, F.C., 2000. How does physician advice influence patient behavior? Evidence for a priming effect. Arch. Fam. Med. 9, 426–433.

Lancaster, T., Silagy, C., Fowler, G., 2000. Training health professionals in smoking cessation. Cochrane Database Syst. Rev. 3 CD000214.

Lennox, A.S., Bain, N., Taylor, R.J., McKie, L., Donnan, P.T., Groves, J., 1998. Stages of change training for opportunistic smoking intervention by the primary health care team. Part 1: randomized controlled trial of the effect of training on patient smoking outcomes and health professional behaviour as recalled by patients. Health Educ. J. 57, 140.

Lennox, A.S., Osman, L.M., Reiter, E., et al., 2001. Cost effectiveness of computer tailored and non-tailored smoking cessation letters in general practice: randomised controlled trial. BMJ 322, 1396.

Longo, D.R., Stone, T.T., Phillips, R.L., et al., 2006. Characteristics of smoking cessation guideline use by primary care physicians. Mol. Med. 103, 180–184.

McPhee, S.J., Bird, J.A., Fordham, D., Rodnick, J.E., Osborn, E.H., 1991. Promoting cancer prevention activities by primary care physicians. Results of a randomized, controlled trial. JAMA 266, 538–544.

Meyer, C., Ulbricht, S., Baumeister, S.E., et al., 2008. Proactive interventions for smoking cessation in general medical practice: a quasi-randomized controlled trial to examine the efficacy of computer-tailored letters and physician-delivered brief advice. Addiction 103, 294–304.

Milch, C.E., Edmunson, J.M., Beshansky, J.R., Griffith, J.L., Selker, H.P., 2004. Smoking cessation in primary care: a clinical effectiveness trial of two simple interventions. Prev. Med. 38, 284–294.

Moher, D., Schulz, K.F., Altman, D.G., CONSORT Group (Consolidated Standards of Reporting Trials), 2001. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. J. Am. Pediatr. Med. Assoc. 91, 437–442.

Morrison A., Moulton K., Clark M., Polisena J., Fiander M., Mierzwinski-Urban M., et al., 2009. English-language restriction when conducting a systeamntic review-based meta-analyses: systematic review of published studies.

Murray, R.L., Coleman, T., Antoniak, M., et al., 2008. The effect of proactively identifying smokers and offering smoking cessation support in primary care populations: a cluster-randomized trial. Addiction 103, 998–1006 discussion 1007-8.

Ossip-Klein, D.J., McIntosh, S., Utman, C., Burton, K., Spada, J., Guido, J., 2000. Smokers ages 50+: who gets physician advice to quit? Prev. Med. 31, 364–369.

Pederson, L.L., 1982. Compliance with physician advice to quit smoking: a review of the literature. Prev. Med. 11, 71–84.

Pieterse, M.E., Seydel, E.R., DeVries, H., Mudde, A.N., Kok, G.J., 2001. Effectiveness of a minimal contact smoking cessation program for Dutch general practitioners: a randomized controlled trial. Prev. Med. 32, 182–190.

Piper, M.E., Fiore, M.C., Smith, S.S., et al., 2003. Use of the vital sign stamp as a systematic screening tool to promote smoking cessation. Mayo Clin. Proc. 78, 716–722.

Puschel, K., Thompson, B., Coronado, G., Huang, Y., Gonzalez, L., Rivera, S., 2008. Effectiveness of a brief intervention based on the '5A' model for smoking cessation at the primary care level in Santiago, Chile. Health Promot. Int. 23, 240–250.

Robson, J., Boomla, K., Fitzpatrick, S., et al., 1989. Using nurses for preventive activities with computer assisted follow up: a randomised controlled trial. BMJ 298, 433–436.

Roski, J., Jeddeloh, R., An, L., et al., 2003. The impact of financial incentives and a patient registry on preventive care quality: increasing provider adherence to evidence-based smoking cessation practice guidelines. Prev. Med. 36, 291–299.

Rothemich, S.F., Woolf, S.H., Johnson, R.E., et al., 2008. Effect on cessation counseling of documenting smoking status as a routine vital sign: an ACORN study. Ann. Fam. Med. 6, 60–68.

Sallis, J., Owen, N., 1999. Ecological models. In: Glanz, K., Lewis, F., Rimer, B. (Eds.), Health Behavior and Health Education: Theory, Research, and Practice. Jossey Bass, San Francisco, pp. 404–424.

Sherman, S.E., Estrada, M., Lanto, A.B., Farmer, M.M., Aldana, I., 2007. Effectiveness of an on-call counselor at increasing smoking treatment. J. Gen. Intern. Med. 22, 1125–1131.

Stead, L., Bergson, G., Lancaster, T., 2008. Physician advice for smoking cessation. Cochrane Database Syst. Rev. 2 CD000165.

Szpunar, S.M., Williams, P.D., Dagroso, D., Enberg, R.N., Chesney, J.D., 2006. Effects of the tobacco use cessation automated clinical practice guideline. Am. J. Manag. Care 12, 665–673.

Tengs, T.O., Adams, M.E., Pliskin, J.S., et al., 1995. Five-hundred life-saving interventions and their cost-effectiveness. Risk Anal. 15, 369–390.

Twardella, D., Brenner, H., 2007. Effects of practitioner education, practitioner payment and reimbursement of patients' drug costs on smoking cessation in primary care: a cluster randomised trial. Tob. Control 16, 15–21.

Unrod, M., Smith, M., Spring, B., DePue, J., Redd, W., Winkel, G., 2007. Randomized controlled trial of a computer-based, tailored intervention to increase smoking cessation counseling by primary care physicians. J. Gen. Intern. Med. 22, 478–484.

Vetter, N.J., Ford, D., 1990. Smoking prevention among people aged 60 and over: a randomized controlled trial. Age Ageing 19, 164–168.

Vogt, F., Hall, S., Marteau, T.M., 2005. General practitioners' and family physicians' negative beliefs and attitudes towards discussing smoking cessation with patients: a systematic review. Addiction 100, 1423–1431.

Weingarten, M.A., Bazel, D., Shannon, H.S., 1989. Computerized protocol for preventive medicine: a controlled self-audit in family practice. Fam. Pract. 6, 120–124.

Wilson, A., McDonald, P., Hayes, L., Cooney, J., 1992. Health promotion in the general practice consultation: a minute makes a difference. BMJ 304, 227–230.

World Health Organization, 2002. Smoking Statistics.

Yano, E.M., Rubenstein, L.V., Farmer, M.M., et al., 2008. Targeting primary care referrals to smoking cessation clinics does not improve quit rates: implementing evidence-based interventions into practice. Health Serv. Res. 43, 1637–1661.

Young, J.M., Ward, J.E., 2001. Implementing guidelines for smoking cessation advice in Australian general practice: opinions, current practices, readiness to change and perceived barriers. Fam. Pract. 18, 14–20.

Young, J.M., D'Este, C., Ward, J.E., 2002. Improving family physicians' use of evidence-based smoking cessation strategies: a cluster randomization trial. Prev. Med. 35, 572–583.

Young, J.M., Girgis, S., Bruce, T.A., Hobbs, M., Ward, J.E., 2008. Acceptability and effectiveness of opportunistic referral of smokers to telephone cessation advice from a nurse: a randomised trial in Australian general practice. BMC Fam. Pract. 9, 16.

Zwar, N.A., Richmond, R.L., 2006. Role of the general practitioner in smoking cessation. Drug Alcohol Rev. 25, 21–26.

Appendix B- Provider Recruitment Letter

DATE

INSERT NAME

INSERT ADDRESS

RE: ADDRESS SMOKING CESSATION WITH PATIENTS IN PRIMARY CARE

Dear Dr. (Insert Name),

Over the past three years we have been working on creating a network of hospitals in Eastern Ontario that are using a common approach to systematically identify and intervene with all smokers while they are in hospital. We have referred to this approach for intervening with smokers in clinical settings as the "Ottawa Model for Smoking Cessation". Seventeen of the hospitals in our region are implementing the "Ottawa Model for Smoking Cessation" and we have seen a significant increase (15% to 25%) in the number of smokers who quit smoking following visit to hospital as a result of the program.

We believe that the systematic approach for addressing tobacco use in hospital also has application in the primary care setting. We would like to conduct a study to evaluate a version of the Ottawa Model for Smoking Cessation that has been adapted for use in busy primary care practices. We are hoping to evaluate the program in a group of 6 to 8 primary care group practices in Ottawa and the surrounding area.

We would like to invite your practice to take part in the study. Participation in the study will offer your practice with specialized onsite training in smoking cessation and support with implementing simple tools within your practice for identifying smokers and providing brief assistance with quitting. Half of the practices involved in the study will also have access to a specialized follow-up telephone counselling program which will provide follow-up support to smokers from your practice who are ready to make a quit attempt for a period of two months.

This study is being conducted by the University of Ottawa Heart Institute in collaboration with an investigator from the University of Waterloo, Sophia Papadakis. We look forward to the involvement of local primary care clinicians in the evaluation of this new approach for addressing smoking in clinic settings. I would greatly appreciate hearing back from you on your interest in participating in the pilot study. Please contact Sophia Papadakis at SPapadakiS@ottawaheart.ca or at 613-761-5489 to discuss the involvement of your clinic in this pilot study further.

Sincerely,

Andrew Pipe
Medical Director
Prevention and Rehabilitation Centre
University of Ottawa Heart Institute

Sophia Papadakis
Ph.D. Candidate
Health Studies and Gerontology
University of Waterloo

Appendix C - Program Summary

:· Program Summary

UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

OTTAWA MODEL FOR SMOKING CESSATION IN PRIMARY CARE
MODÈLE D'OTTAWA POUR L'ABANDON DU TABAC EN SOINS DE PREMIÈRE LIGNE

" Initial, effective smoking cessation counselling can be delivered as part of routine clinical practice in as little as 2 minutes."

– Andrew Pipe, MD, CM Chief, Division of Prevention and Rehabilitation, University of Ottawa Heart Institute

WORKING TOGETHER TO HELP PATIENTS QUIT

CIGARETTE SMOKING IS THE LEADING PREVENTABLE CAUSE OF DEATH AND DISABILITY IN OUR REGION.
Tobacco use is a major risk factor for each of the leading chronic diseases including: cancer, heart disease, stroke and respiratory illness. Moreover, smoking exacts a high toll on the health of Canadians and places a heavy financial burden on the health care system.

SMOKING – THE GOLD STANDARD PREVENTATIVE INTERVENTION.
Many of the negative effects of smoking on health can be reversed if smokers are able to successfully quit, making it the single most powerful preventative intervention in clinical practice. If your patient smokes, helping them to quit is far more important to their health than many other common preventative treatments including hypertension treatment and the use of statins.

MOST SMOKERS WANT TO QUIT
Despite the declines in smoking, there are still an estimated 180,000 smokers in the Ottawa-Carleton region. More than 60% of smokers want to quit and 40% will make at least one attempt to quit each year but only 5% will be successful without assistance. Smokers who try to quit with the help of best practice counselling and cessation medications will experience double or triple the success with quitting compared to smokers who try to quit cold turkey.

PRIMARY CARE CLINICS ARE AN IMPORTANT SETTING FOR IDENTIFYING AND INTERVENING WITH SMOKERS.
Advice from a health professional about quitting smoking increases quit rates by up to 30%. As such clinicians in the primary care setting can play a crucial role in motivating their patients to make a quit attempt and ensuring they receive best practice interventions to support a quit attempt. Simple, systematic changes in the way we interact with smokers can help more patients quit smoking and improve the overall health of our community.

UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

OTTAWA MODEL FOR SMOKING CESSATION IN PRIMARY CARE
MODÈLE D'OTTAWA

THE OTTAWA MODEL FOR SMOKING CESSATION.... SIMPLE, SYSTEMATIC, SUSTAINABLE

Helping patients quit smoking is not new to clinicians. However, success with helping patients to quit smoking can be enhanced by ensuring your clinical setting has a system in place for intervening with smokers. The Ottawa Model for Smoking Cessation is a systematic approach for addressing smoking among patients.

The goal of the Ottawa Model for Smoking Cessation is to identify and offer support to all smokers using best practice guidelines. The model involves a common approach to identifying the smoking status of patients at each clinic visit, advising all smokers to quit, providing assistance in quitting while in the clinic and ensuring follow-up counselling once they leave the clinic to assist them in remaining smoke-free.

THE OTTAWA MODEL FOR SMOKING CESSATION

- Identify smoking status of all patients at each clinic visit
- Clear, strong, personalized advice to quit
- Support making a quit attempt (brief counselling, pharmacotherapy, quit date, self help)
- Follow-up support for 3 to 6 months

HOW SUCCESSFUL HAS THE MODEL BEEN?

The Ottawa Model for Smoking Cessation was developed based on the experience of the Ottawa Heart Institute. The approach has led to an absolute 15% increase in the long-term cessation rate (from 35% to 50% at 6-month follow-up) among cardiac patients.

The Ottawa Model is now in place in 18 hospitals in the region and more than 7,000 smokers have received intervention, resulting in over 1,200 smokers which have quit as a result of the program! In 2008 the Ottawa Model was identified as an Ontario Chronic Disease Prevention best practice by the Ministry of Health and Long-Term Care.

PILOT STUDY DESIGN

THE OTTAWA MODEL FOR SMOKING CESSATION IN PRIMARY CARE: PILOT STUDY EVALUATION

We believe the model has application in the primary care setting. We are presently conducting a pilot study to evaluate the feasibility and effectiveness of an adaptation of the Ottawa Model for Smoking Cessation in the Primary Care setting.

WHAT IS THE PURPOSE OF THE PILOT STUDY?

The purpose of this study is (1) to determine if the Ottawa Model for Smoking Cessation is feasible in the primary care setting (2) to determine if the Ottawa Model for Smoking Cessation increases the rates at which evidence-based smoking cessation treatments are delivered to patients and patient success with quitting; and (3) to determine if adjunct telephone-based smoking cessation counselling improves outcomes compared to clinic supports alone.

WHO WILL PARTICIPATE IN THE STUDY?

The study will involve six to eight primary care practices in the Ottawa and surrounding region (Champlain District).

HOW DOES THE PROGRAM WORK?

Our team will work with you to ensure you have a clinical protocol in place for smoking cessation which is based on the best available knowledge of smokers and treatments. This includes:

- Support conducting a baseline assessment of current tobacco control practice and survey of your patients
- Resources to assist with integrating best-practices into your clinic's routines
- Training for clinical staff in evidence-based smoking cessation interventions
- Evaluation of program effectiveness in your clinic
- Links to resources to support smokers ready to quit between clinic visits

HOW WILL WE EVALUATE THE PROGRAM?

The study uses a cluster randomized control trial design. All practice sites will participate in a baseline assessment and post-implementation survey to determine the impact of the program. All practices will also receive a 3-month practice level intervention designed to integrate evidence-based smoking cessation practices into your daily clinical routines including onsite training for your clinical staff, a waiting room screener, consult form and a quit plan for smokers ready to quit in the next 30 days. Half of the practices participating in the pilot study will be randomly assigned to a follow-up counselling (FC) group. This will allow us to compare the incremental impact of including telephone follow-up counseling as part of a program to assist smokers identified in primary care clinics quit smoking. If you are assigned to the FC group your patients will also have access to the smoker's follow-up program which will provide 3-months of telephone-based counseling to smokers making a quit attempt.

UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

OTTAWA MODEL FOR SMOKING CESSATION IN PRIMARY CARE
MODÈLE D'OTTAWA POUR L'ABANDON DU TABAC EN SOINS DE PREMIÈRE LIGNE

KEY PILOT STUDY ACTIVITIES:

As part of the pilot we will work in partnership with your clinic to better understand your current routines and how we can systematize the delivery of best practices for smoking cessation as part of your daily clinic routines.

Phase 1 Program Introduction: Task force is formed to assist with evaluation activities and development of a smoking cessation protocol within your practice.

Phase 2 Baseline Assessment: All practices will be asked to participate in a survey of 55 consecutive smokers from your clinic. Smokers will be asked to complete a survey 10-15 minutes in length at the end of their visit at the clinic and provide contact information so that we may follow-up with them by phone in 4 months time to assess their smoking status. Following the baseline assessment half of the clinics will be selected at random to participate in the basic program and the other half in the basic program plus telephone follow-up counselling.

Phase 3 Planning Your Tobacco Control Protocol: Members of our project team will work with your clinic over a 2 to 3-month period to integrate the Ottawa Model for Smoking Cessation into your clinical practice setting. Tools such as the checklist style smoking consult form as well as a patient waiting room screener and quit plan will be available to your clinic to assist with efficiently integrating best practices for smoking cessation into your busy clinic. Our team will work with you to adapt these tools for use in your clinical setting.

Phase 4 Train Clinical Staff: A training workshop for all physicians, nurses, and allied health professionals working in your clinic will be delivered by a team from the University of Ottawa Heart Institute (Dr. Andrew Pipe, Sophia Papadakis, Debbie Aiken, Dr. Bob Reid). All practices will be provided with feedback on the results of their baseline assessment at the workshop.

Phase 5 Implement Program ('Go Live'): Following the training session the clinic will begin implementing the Ottawa Model for Smoking Cessation in the clinic. Practices randomized to the Follow-up Counselling arm will also implement the smoker's follow-up system.

Phase 6 Follow-up Assessment (Measuring Results): At least 1-month following the 'go-live' date of the smoking cessation program, we will re-survey 55 smokers from your clinic to determine the impact of the program.

Phase 7 Sustaining the Program: We will work with your clinic to address any areas requiring improvement and to implement ongoing quality improvement plans for the smoking cessation model.

The pilot study is funded through a grant from the Canadian Tobacco Control Research Institute, the Ontario Tobacco Control Research Unit and the Ministry of Health and Long Term Care.

IMPLEMENTING THE OTTAWA MODEL IN YOUR CLINIC

PHASE 1
Program Introduction
:- Partnership
:- Needs Assessment
:- Task force formation

PHASE 2
Baseline Assessment
:- Baseline evaluation
:- Planning for action

PHASE 3
Planning Your Clinic Protocol
:- Training key contacts
:- Revising Policies
:- Preparing supports

PHASE 4
Train Clinical Staff
:- Training front line staff

PHASE 5
Implement Program
:- Providing the intervention

PHASE 6
Measuring Results
:- Post-implementation evaluation
:- Quality assurance assessment

PHASE 7
Sustaining the Program
:- Sharing results
:- Ongoing education
:- Feedback to staff

UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

OTTAWA MODEL FOR SMOKING CESSATION IN PRIMARY CARE
MODÈLE D'OTTAWA POUR L'ABANDON DU TABAC EN SOINS DE PREMIÈRE LIGNE

OTTAWA MODEL PRACTICE TOOLS FOR PRIMARY CARE

These tools have been developed to support the integration of best practices for smoking cessation into your busy clinic. As required we will work with you to customize the tools to meet the specific needs of your clinic.

Waiting Room Survey

Smoking Cessation Consult Form

Quit Plan for Smokers Ready to Quit

Booklet for Smokers not ready to quit.

FLOW DIAGRAM FOR THE OTTAWA MODEL FOR SMOKING CESSATION IN PRIMARY CARE

Waiting Room Survey completed by all patients

Designated staff person (nurse/clerk) reviews waiting room screener for smoking status

Has patient used any form of tobacco in past 7-days? OR past 6-months?

NO → END

YES → **Smoking Cessation Consult Form and Flag** added to patient chart.

MD ADVISE Strong, Personalized, Advice to Quit with Offer of Support

Is Patient ready to quit in next 30 days?

YES → Congratulate Patient and Reinforce Decision. Refer to Designated Nurse.

Nurse provides Quit Plan to Patient and Completes Smoking Consult Form

Step 1: Choose quit smoking medication
- Screen for contraindications to smoking aids
- Assess patient preference
- Nicotine addiction (time to first cig, # cigs)
- Cost factors
- Review dosing and instructions

Step 2: Set Quit Date

Step 3: Review Preparing for your Quit Date

Step 4: Review Smoker's Follow-up System

Document Plan on Consult Form.

Arrange Follow-up Appointment / Register in Smoker's Follow-up System. File consult form to chart/EMR.

NO → **Provide Self-Help Booklet** *"For smokers not ready to quit"*

Brief counselling. Inform patient of follow-up call in 1 month

IVR Group

Patient agrees to follow-up call in 1-month?

NO → END

YES → Register in IVR follow-up system File consult form to chart.

Appendix D - Provider Information Sheet and Consent Form

Patient Information Sheet & Consent Form

Comparative evaluation of two interventions for integrating smoking cessation into routine primary care practice: A cluster-randomized trial

Student Investigator: Sophia Papadakis, MHA, PhD candidate,
Health Studies and Gerontology, University of Waterloo
Faculty Supervisor: Paul McDonald, PhD, Associate Professor,
Health Studies and Gerontology, University of Waterloo
Co-Investigators: Roy Cameron, PhD, University of Waterloo
Robert Reid, PhD, MBA, University of Ottawa Heart Institute
Andrew Pipe, MD, University of Ottawa Heart Institute
Stephen Brown, University of Waterloo

Please read this Information Sheet and Consent Form carefully and ask as many questions as you like before deciding whether to participate.

Introduction:

You have been asked to participate in a research project entitled: **"***Comparative evaluation of two interventions for integrating smoking cessation into routine primary care practice: A cluster-randomized trial."*

The purpose of this study is to determine if adjunct telephone-based smoking cessation counselling increases the rate at which evidence-based smoking cessation treatments are delivered to patients and smoking abstinence among smokers identified in family doctors offices. We hope this study will inform the design and delivery of smoking cessation interventions within primary care practice settings.

What is involved in this study?

All providers (physicians and nurses) in the practices will be asked to complete a provider survey at baseline and 4-months later. The survey will take approximately 10 minutes of your time to complete. The survey will ask about your attitudes, knowledge and confidence with delivering smoking cessation interventions.

Your practice will be randomly assigned to either the practice supports (PS) intervention group or the follow-up counseling (FC) group. If you are assigned to the PS group you will receive a 3-month practice level intervention designed to integrate evidence-based smoking cessation practices into your daily clinic routines including training, a waiting room screener, consult form and a quit plan for smokers ready to quit in the next 30 days. If you are assigned to the CF group you will receive the same intervention as the PS group plus your patients will have access to a quit smoking follow-up counseling program.

The researchers also wish to approach a cross sectional sample of 55 consecutive eligible patients attending your clinic for a non urgent medical appointment to participate in this study pre and post implementation of the intervention. The purpose of the assessment is to determine if the intervention assisted with the delivery of evidence-based smoking cessation strategies and helped more patients quit smoking.

Procedure:

A total of six to eight practices will be involved in this research study. We request that all practices identify a contact person who can work with study staff in implementing the study protocol. All clinics who agree to take part in this study are expected to provide reasonable assistance in the implementation of the study protocol. The study has been designed to provide minimal disruption to your clinic.

Baseline Exit Survey and Telephone Follow-up

We will survey a sample of 55 eligible smokers from your practice prior to the delivery of the study intervention to establish a pre-intervention rate of evidence-based smoking cessation treatment delivery for your clinic as well as smoking abstinence. The baseline assessment will begin on a mutually agreed upon start date. Upon check to the clinic patients will be asked to review an Information Sheet and Consent Form about their participation in the study. Consenting patients will be asked to complete a patient exit survey. The exit survey will take 5-10 minutes for patients to complete and will ask about smoking habits and their encounter with clinic staff. Your clinic will be provided with a research assistant on site to assist with data collection activities pre and post intervention.

Patients will also be asked to complete a follow-up telephone interview 4-months following their clinic visit. During the interview patients will be asked about their smoking status and experience with smoking over the past 4-months. Because this is a research study we may ask patients who have been able to quit smoking to provide a saliva sample to prove they have been able to successfully quit. Patients will be selected at random to provide a cotinine sample. If they are selected we will mail a home cotinine saliva test to the participant's home at the time of the 4-month follow-up telephone call. Patients will be asked to return the kit in a pre-paid return envelope within 48 hours. Patient participation is completely voluntary and patients may choose to skip questions on the survey or telephone interview if they do not wish to answer them.

Randomization

Your practice will be paired with another practice in the Eastern Ontario region who performed similarly on baseline rates of screening for smoking and rates of advising smokers to quit. One practice from each of the pairs will be randomly assigned to the PS group of CF group. Your practice will have a 50/50 chance of being assigned to either intervention group.

Practice Support (PS) Group

If your practice is assigned to the PS Group, your practice will receive feedback on the results of the baseline practice audit, a 1-hour training workshop will be provided to all professional and administrative staff working in intervention clinics. Your practice will be supported with implementing: (a) a waiting room screener, (b) smoking cessation consult form, and (c) patient quit smoking plan to assist with the integrating evidence-based cessation strategies into your practice routine.

Follow-up Counselling (FC) Group

If your practice is assigned to the CF Group your practice will receive the same smoking cessation training and practice support tools delivered to the PS group (as described above). In addition, patients in

the FC group who are smokers and are willing to set a quit date within the next 30 days will be enrolled in an interactive voice response (IVR)-mediated telephone follow-up and counselling system. The IVR system will automatically contact patients via telephone 7 days before their TQD, and 5, 14, 30, and 60 days after their TQD to check the patients' smoking status, potential concerns, and their risk of relapse. During the calls, the IVR system will pose a series of questions concerning current smoking status, confidence in staying smoke-free over the time period until the next planned call, and the use of pharmacotherapy, self-help materials and other forms of cessation support. If patients identify that they have resumed smoking but want to make another quit attempt soon or indicate that their confidence in remaining smoke-free is low (less than 7 on a 10-point scale), the IVR system will flag the patient in a software interface in order to ensure that they are contacted by a smoking cessation specialist. The smoking cessation specialist will provide additional assistance, consisting of up to three 20-minute telephone counselling sessions over an 8-week period. For participants who were not smoking but whose confidence in remaining smoke-free was low, the nurse-specialist will assist them to identify tempting situations that were undermining confidence. The smoking cessation specialist and the participant will then work to develop strategies to deal with these situations using cue control, healthful alternatives, pharmacotherapy, and/or social support. Patients who are not ready to quit in the next 30 days but report a willingness to quit smoking in the next 6-months will receive two IVR follow-up telephone calls 30 and 60 days following their clinic visit to reassess readiness to quit. If patients report at the 30 or 60 day call a readiness to quit smoking in the next 30 days, they will receive a 10-20 min counselling session with the smoking cessation specialist to set a quit date and develop a quit plan. The participant will then be enrolled in the 60-day IVR mediated telephone follow-up and counselling program as described above.

Post-Implementation Follow-up Assessment

Following a three month implementation phase a follow-up assessment will be conducted. The methods described in the baseline survey will be repeated in a second sample of 55 patients from your practice in order to establish the interventions effectiveness.

Benefits of Participation:

All practices participating in this study will receive specialized training in smoking cessation, practice based support tool and patient self-help materials. If your practice is randomized to the CF group your patients will also have access to follow-up smoking cessation counselling program. You may not receive any additional direct benefit from your participation in this research. Your participation in this research may allow the researchers to evaluate and refine an approach to integrating smoking cessation assistance into routine primary care practice among practices in our region.

Risks and Discomforts of Participation:

The risks and discomforts of participation are minimal. Your clinic will be asked to identify the smoking status of all persons scheduled for a non urgent follow-up appointment at your clinic. There is a time commitment involved for members of the clinic staff to complete the smoking cessation training and integrate the practice support tools into your practice routines. There may be some minimal disruption to your clinic during the collection of pre and post intervention data. To minimize this burden your practice will be provided with the support of a research assistant during the data collection period.

Compensation /Remuneration:

There will be no financial remuneration for participation in this study. By participating in the study and signing this Consent, you are not waiving your legal rights that may be available to you.

Confidentiality:

All data gathered, including responses to questionnaires and interviews will remain confidential. Only the Principal Investigator and research staff will review survey and interview responses provided by consenting provider and patients. All personal information will be coded, then it will be stripped of identifiers, and will be assigned a research ID number. Paper copies of surveys and interviews will be kept in a locked filing cabinet. We will also use a secure electronic database that is password protected and only accessible by the Investigators and our research staff to store electronic copies of data. The data will be destroyed fifteen years following their publication. Your practice and patients will remain anonymous in any publications or reports on the results of this study.

Ethics:

This project has been reviewed and received ethics clearance through the Office of Research Ethics (ORE) at the University of Waterloo. If you have any comments or concerns resulting from your involvement in this study you may contact the Director of the ORE at 519-888-4567 Ext. 6005.

Participation:

Participation in research is completely voluntary. You are free to choose to participate or not to participate in this research study. If you agree to participate in this study, you may choose to withdraw your participation at any time by providing written letter to the Principal Investigator. You may also choose not to answer any specific questions.

Should you require any additional information about the study, you may contact Sophia Papadakis, Student Investigator at 613-761-5489 or by mail at H-2300, Ottawa Heart Institute, 40 Ruskin Street, Ottawa, ON, K1Y 4W7.

CONSENT FORM

I agree to participate in a study being conducted by the Department of Health Studies and Gerontology at the University of Waterloo and the University of Ottawa Heart Institute titled "*Comparative evaluation of two interventions for integrating smoking cessation into routine primary care practice: A cluster-randomized trial"*. I have made this decision based on the information I have read in the information letter.

As a participant in this study, I realize that I am being asked to complete a brief questionnaire prior to and following the implementation of the intervention in my clinic, that my practice will be randomized to one of the two intervention groups, and that a sample of my consenting patients will be surveyed by research staff upon exit from their clinic appointment and by telephone 4-months following their visit to clinic. I may decline answering any of the questionnaire items, if I so choose. All information which I provide will be held in confidence and neither I nor my patients will not be identified in any way in the final report. I understand that I may withdraw this consent at any time.

I also understand that this project has been reviewed by and has received ethics clearance through the office of Research Ethics at the University of Waterloo and that I may contact this office if I have any concerns or comments resulting from my involvement in this study.

_____

Provider's Name (Please Print)

_____ _____

Provider's Signature Date

_____

Name of Investigator/Delegate (Please Print)

_____ _____

Signature of Investigator/Delegate Date

Appendix E - Provider Survey

CLINIC NAME: _____	
NAME: _____ **AGE:** _____	**GENDER:** ☐ Male ☐ Female
Have you previously completed smoking cessation training? ☐ Yes ☐ No	
How would you describe the importance placed on smoking cessation within your clinic setting? ☐ Extremely important ☐ Very important ☐ Important ☐ Somewhat important ☐ Not important	**As a practitioner, how would you describe the importance you place personally on helping your patients quit smoking?** ☐ Extremely important ☐ Very important ☐ Important ☐ Somewhat important ☐ Not important
Are the following practice supports in place in your clinic? (check those which are in place) ☐ Formalized process to screen for smoking status ☐ Consult forms to guide you through quit smoking counselling ☐ Self-help materials for smokers	

On a scale of 1 to 10, how would you describe your confidence in the following areas:
(1 being not very confident and 10 being extremely confident)

QUESTION	RESPONSE
Advising patients to quit smoking	1 2 3 4 5 6 7 8 9 10
Providing brief smoking cessation counselling (<3 minutes)	1 2 3 4 5 6 7 8 9 10
Prescribing quit smoking medications	1 2 3 4 5 6 7 8 9 10
Setting a quit date with patients	1 2 3 4 5 6 7 8 9 10
Providing smoking cessation counselling	1 2 3 4 5 6 7 8 9 10
Arranging timely follow up for patients planning to quit	1 2 3 4 5 6 7 8 9 10

Appendix F - Sample Tobacco Use Survey

WEST CARLETON
family health centre
keeping our community healthy

Tobacco Use Survey

Last Name:

First Name:

Address:

Tel: Date of Birth: dd /mm / yy

PLEASE COMPLETE THE FOLLOWING QUESTIONS:	ANSWER HERE
1. Have you used any form of tobacco in the past 6 months?	☐ Yes ☐ No – Please return this survey to your family doctor or nurse practitioner.
2. Have you used any form of tobacco in the past 7 days?	☐ Yes – Please continue to question 3. ☐ No – Please skip to questions 18 – 27 (flip side).
3. What form of tobacco do you currently use?	☐ Cigarettes ☐ Pipe ☐ Cigar ☐ Smokeless tobacco
4. How many years in total have you been smoking?	_____years
5. How many cigarettes do you usually smoke per day?	_____cigarettes / day or _____cigarettes / month
6. How soon after you wake up do you smoke your first cigarette?	☐ Within 5 minutes ☐ 6-30 minutes ☐ 31-60 minutes ☐ >60 minutes
7. How many quit attempts (lasting >24 hours) have you made in the past year?	☐ No attempts ☐ 1-2 attempts ☐ 3 or more attempts
8. Do others smoke in your home?	☐ Yes ☐ No
9. Which of the following best describes your feelings about smoking right now?	☐ I would like to quit in the next 30 days. ☐ I would like to quit in the next 6 months. ☐ I am not planning on quitting in the next 6 months.
10. On a scale from 1-5, how important is it to you to quit smoking?	1 2 3 4 5 (1=not important at all, 5=extremely important)
11. On a scale from 1-5, how confident are you that you can quit smoking?	1 2 3 4 5 (1=not at all confident, 5=extremely confident)
12. What are your reasons for wanting to quit smoking?	☐ Health reasons ☐ Children/Spouse ☐ Financial (save money) ☐ Social ☐ Other: _____
13. What concerns, if any, do you have about quitting smoking?	☐ Weight gain ☐ Withdrawal symptoms ☐ I won't be successful ☐ Stress ☐ Depression ☐ Boredom ☐ Social ☐ Other: _____
14. Have you previously used quit smoking medications?	Nicotine Replacement Therapy: ☐ Gum ☐ Patch ☐ Inhaler ☐ Bupropion (Zyban) ☐ Varenicline (Champix)
15. Does your drug benefit plan cover quit smoking medications?	☐ Yes ☐ No ☐ Don't know ☐ No benefit plan
16. Are you presently receiving follow-up telephone calls from the Quit Smoking Program?	☐ Yes ☐ No
17. How many caffeinated drinks (eg. coffee, tea, pop) do you consume per day?	_____drinks

THANK YOU. Please return this survey to your family doctor or nurse practitioner.

WEST CARLETON
family health centre
keeping our community healthy

Tobacco Use Survey

Last Name:

First Name:

Address:

Tel: Date of Birth: dd /mm / yy

We understand that you have recently quit smoking. Congratulations!

PLEASE COMPLETE THE FOLLOWING QUESTIONS:

18. When did you quit?

_____
Quit Date (dd/mm/yy):

19. What form of tobacco were you smoking?

☐ Cigarettes ☐ Pipe ☐ Cigar
☐ Smokeless tobacco

20. How many years in total had you smoked before quitting?

_____ years

21. How many cigarettes were you smoking per day before you quit?

_____ cigarettes

22. Do others smoke in your home?

☐ Yes ☐ No

23. Did you use any smoking cessation medications to help you quit? If yes, please specify.

☐ No ☐ Yes - Please specify:
☐ Nicotine gum ☐ Nicotine patch
☐ Nicotine inhaler ☐ Champix
☐ Bupropion ☐ Other : _____

24. Are you still using these medications?

☐ Yes ☐ No

25. On a scale of 1 to 5, how important is it to you to stay smoke free?

1 2 3 4 5

(1=not important at all, 5=extremely important)

26. On a scale of 1 to 5, how confident are you that you will not return to smoking?

1 2 3 4 5

(1=not at all confident, 5=extremely confident)

27. What concerns, if any, do you have about staying smoke free?

☐ Weight gain ☐ Withdrawal symptoms
☐ Social ☐ Stress
☐ Depression ☐ Boredom
☐ I won't be successful ☐ Other: _____

THANK YOU. Please return this survey to your family doctor or nurse practitioner.

Appendix G – PS Group Sample Provider Consult Form

UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

OTTAWA MODEL FOR SMOKING CESSATION IN PRIMARY CARE
MODÈLE D'OTTAWA POUR L'ABANDON DU TABAC EN SOINS DE PREMIÈRE LIGNE

Smoking Cessation Consult Form

Preferred language: ☐ English ☐ French ☐ Other (specify):_____

☐ First Visit ☐ Annual Exam ☐ Other Visit

PHYSICIAN CONSULT

ADVISE

Strong, Personalized, Unambiguous Advice to Quit and Offer of Assistance with Quitting

"You probably already know many of the risks involved with smoking, but I cannot stress enough how important it is to stop. Your _____ (e.g. family history, high cholesterol) makes it even more important for you to quit now. ***I would advise you to stop as soon as possible.***

"Quitting smoking is not always easy but we can help you with quitting and there are medications available to make quitting easier."

..... initial

ASSESS

"Would you be willing to make an attempt to quit smoking in the next month?"

☐ Yes ☐ No

FOR SMOKERS NOT READY TO QUIT IN THE NEXT 30 DAYS

ASSIST
Brief Counseling + self-help materials

"Quitting smoking takes a lot of determination and works best when you are ready to make the commitment to quit."

"If you do not feel you are ready to quit smoking then you should wait. On the other hand there is never really a good time to stop smoking and you should not postpone quitting by waiting for the right time."

"I'd like you to take these materials about getting ready to quit smoking home with you. Please look them over and think seriously about quitting soon. We have new ways to help you quit and when you're ready I can work with you to ensure you have a plan in place to help you deal with withdrawl, and _____."

☐ Provide Patient with copy of Information Sheet for Smokers not Ready to Quit

..... initial

QUIT PLAN FOR SMOKERS READY TO QUIT IN NEXT 30 DAYS

ASSIST
Patient Preference

"It's great to hear that you are ready to make a commitment to stop smoking. It's important that you have a plan for quitting smoking." (Provide patient with Quit Smoking Plan)

"Quit smoking medications are available and have been shown to double or triple the chances of being successful with quitting and staying quit. There are three types of quit smoking medications that are recommended: Nicotine replacement therapy, and two pill formats; Zyban and a newer product called Champix."

"Do you have a preference?" ☐ Yes ☐ No

ASSIST
Identify Contraindications

☐ Pregnant, breast feeding or planning pregnancy

Bupropion / Zyban
- ☐ History of seizure disorder or head trauma
- ☐ Presently taking Bupropion/ Zyban/ Wellbutrin
- ☐ Previous reaction to Bupropion/ Zyban/ Wellbutrin
- ☐ Pre-existing or current eating disorder
- ☐ Excessive use of alcohol/sedatives present or past
- ☐ Taking anti-depressants, antipsychotics, corticosteroids, MAO inhibitors, theophyline, cocaine or diet pills
- ☐ Taking a quinolone antibiotic (eg. ciprofloxacin,levoflozacin)
- ☐ Use of oral hypoglycemic products or insulin
- ☐ Severe hepatic impairment
- ☐ Central nervous system tumour

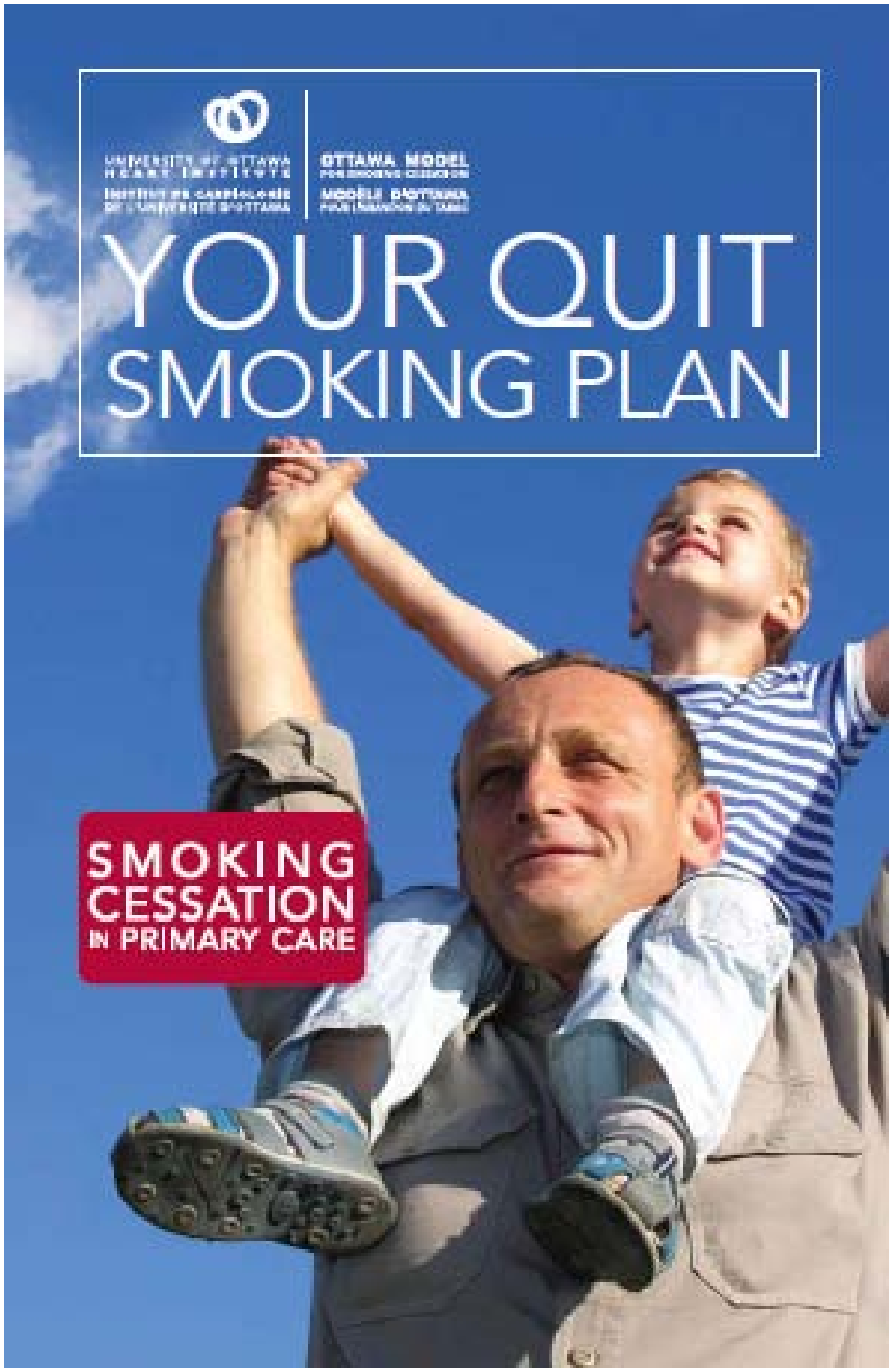
Varenicline / Champix
- ☐ Under the age of 18 years
- ☐ History of renal failure and is taking Cimetidine
- ☐ Using NRT in addition to Varenicline
- ☐ Previous drug reaction to Varenicline
- ☐ Has history of renal failure (check with physician)
- ☐ History of nausea and vomiting in past two months (check with physician)
- ☐ operates heavy machinery (avoid until reaction to medication is known)

NRT
- ☐ Dentures (avoid NRT gum)
- ☐ Allergy to adhesive (consider clear patch)

QUIT PLAN FOR SMOKERS READY TO QUIT IN NEXT 30 DAYS

ASSIST Select Pharmaco-therapy	☐ NRT	<10 cigs/cigs	10-20 cigs/day	20+ cigs/day
		☐ 7mg patch ☐ Inhaler ☐ 2mg gum/lozenge	☐ 14 mg patch ☐ Inhaler ☐ 2mg gum/lozenge	☐ 21 mg patch ☐ Inhaler ☐ 4mg gum/lozenge
	If time to first cig is <30 mins of waking consider higher dose NRT	14mg	21mg	28mg
	☐ **Varenicline** Days 1-3: 0.5mg once/day; Days 4-7: 0.5 mg BID; Days 8-12 weeks 1.0 mg twice daily. *Start 8 days before the quit date.			
	☐ **Bupropion** - Days 1-3: 150 mg daily (in the morning); Days 4-12 weeks 150 mg BID. *Start 8 days before the quit date.			
	☐ **No medication prescribed**			
ASSIST Set Quit Date	*"Here is a calendar of the next month. I'd like you to pick your quit date."* QUIT DATE: _____ (dd/mm/yy)			
ASSIST Provide Quit Plan	☐ Reviewed medications instruction sheet with patient (Step 1) ☐ Reviewed "Preparing for quit date" sheet with patient (Step 3) ☐ Remind patient that he/she will need to cut back on caffeine by half after quit date.			..... initial
ARRANGE FOLLOW-UP	☐ Refer patient to community-based smoking cessation program for supplemental support (See list on back of quit plan) OR ☐ Arrange for follow-up in clinic in next 4-8 weeks			
Review	Signature: _____			

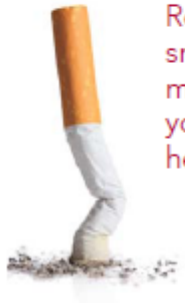
Appendix H – PS Group Quit Plan



We recommend that anyone getting ready to stop smoking have a personalized plan for quitting.

YOUR QUIT PLAN INCLUDES SIX STEPS:

By completing each of these steps you will very significantly increase your chances of quitting successfully.



Remember, quitting smoking is the single most important thing you can do for your health!

STEP 1

CHOOSING A QUIT SMOKING MEDICATION - PATCH OR PILL?

We recommend that all smokers take advantage of available quit smoking medications. These medications have been shown to **double or triple** the chance of being successful with quitting. We will work with you to choose the right quit smoking medication for you. There are three types of medications for you to choose from:

1. Nicotine Replacement Therapy (NRT) – Patch, Inhaler, Gum or Lozenge
2. Varenicline (Champix®) – Pill
3. Bupropion (Zyban®) – Pill

Option 1:

☐ Nicotine Replacement Therapy (NRT)

NRT works by reducing withdrawal symptoms (anxiety, irritability, headaches, and difficulty concentrating...) that typically occur when people quit smoking as well as reduce your urge to smoke. The idea is that you will use the NRT to deal with cravings and withdrawal symptoms – and week by week, you will reduce the amount of NRT while adapting to life as a non-smoker.

NRT comes in the form of a patch, gum, inhaler or lozenge. Each form can be used alone or **often two forms of NRT are used together**. The type, amount and length of NRT treatment can be tailored to meet your needs.

The advantages of using NRT instead of smoking:

- You will receive much less nicotine than if you were to continue smoking.
- Your body is not exposed to the 4,000+ chemicals in cigarette smoke.

You will be more successful in quitting if you are using an amount of NRT that is sufficient to make you feel completely comfortable and using the NRT for as long as it takes! We can help ensure your plan includes the appropriate levels of NRT!

TREATMENT PLAN

NRT	20+ cigarettes/day	10-20 cigarettes/day	less than 10 cigarettes/day	Instructions	Possible Side Effects
Patch ☐ 	Step 1 21 mg One patch daily Weeks 1 through 6 Step 2 14 mg One patch daily Weeks 7 & 8 Step 3 7 mg One patch daily Weeks 9 & 10	Step 2 14 mg One patch daily Weeks 1 through 6 Step 3 7 mg One patch daily Weeks 7 & 8	Step 3 7 mg One patch daily Weeks 1 through 6 $25-30/week	▷ Apply the patch to a clean, dry, non hairy area on the upper part of your body (arms, chest, back). ▷ Replace the patch with a new one every 24 hours. ▷ Be sure to remove the old patch before putting on a new one. ▷ If you have difficulty sleeping remove your nicotine patch at bedtime.	▷ headache ▷ dizziness ▷ nausea ▷ flushing ▷ stomach upset ▷ skin irritation ▷ trouble sleeping
Inhaler ☐ 	▷ Provides hand to mouth motion of smoking ▷ Puff continuously for 20 mins (1 cartridge) or as needed to manage cravings. ▷ Use 6-12 cartridges per day for first 6 weeks. ▷ Reduce the amount of cartridges used per day in weeks 6-12. ▷ Some smokers require 1-2 cartridges per day beyond 12 weeks to manage cravings. $40/week			▷ You puff as needed to manage cravings ▷ Inhale 80 puffs over 20 minutes or until cravings are gone. Often, using the inhaler for 5 minutes is enough. ▷ Take slow puffs to avoid throat burn. ▷ Avoid eating or drinking 15 minutes before or during use.	▷ headache ▷ nausea ▷ mouth/throat irritation
Gum ☐ 	☐ 2mg (if you smoke your first cigarette 30 mins after you wake up) ☐ 4 mg (if you smoke your first cigarette within 30 mins of waking up) ▷ One piece every 1-2 hours for weeks 1 through 6 ▷ One piece every 2-4 hours for weeks 7 through 9 ▷ One piece every 4-8 hours for weeks 10 through 12 $40-55/week			▷ Nicotine gum should be chewed slowly until you can taste the nicotine or feel a slight tingling in your mouth, then stop chewing. ▷ Place the gum between your cheek and gum. After one minute, repeat the process until cravings are resolved. ▷ Chew each piece for about 30 minutes. ▷ Avoid eating or drinking 15 minutes before or during use.	▷ clings to dental work ▷ nausea, hiccups ▷ jaw pain ▷ mouth soreness
Lozenge ☐				▷ Place the lozenge in your mouth and let it dissolve, moving it back and forth from time to time. ▷ Each lozenge will last about 20-30 minutes. ▷ Avoid eating or drinking 15 minutes before or during using lozenge.	▷ nausea ▷ headache ▷ heartburn ▷ coughing ▷ hiccups

Option 2:
☐ Varenicline (Champix®)

Varenicline is the newest of the quit smoking medications and comes in pill form. Varenicline works in two ways. First it stimulates nicotine receptors in your brain so that your cravings for nicotine are dramatically reduced or even eliminated. Second, it reduces the satisfaction you get from smoking. Since smoking is less pleasurable you will be less likely to feel like smoking. Varenicline should be started 8 days **before** your quit date.

Treatment Plan	Instructions	Possible Side Effects
Day 1-3: 0.5 mg daily Day 4-7: 0.5 mg at breakfast and dinner Weeks 2-12: 1 mg at breakfast and dinner The usual duration of Varenicline is 12 weeks, however, some people may continue to take it for up to 24 weeks.	▷ Begin taking Varenicline 8 days **before** your quit date. ▷ Take the pill after a meal with a full glass of water. ▷ Do not engage in potentially hazardous tasks, such as operating machinery until you are sure this medication does not affect your mental alertness.	▷ nausea ▷ vomiting ▷ trouble sleeping ▷ headache ▷ abnormal dreams ▷ constipation ▷ gas ▷ allergic reaction (rare) ▷ altered/depressed mood The dosage can be adjusted to lessen the side effects. $36/week

If either you or your family notice agitation, depressed mood, or changes in behaviour that are not typical for you, or an allergic reaction stop taking the medication and contact your doctor and the quit smoking program immediately.

If you forget to take your medication, take it as soon as you remember as long as it's within a few hours. If more than a few hours have passed, do not take a double dose to make up for the missed pill, skip the dose and wait to take the next dose at the correct time.

Option 3:
☐ Bupropion (Zyban®)

Bupropion is another effective quit smoking medication. Bupropion is a pill you take to reduce your craving for tobacco. Bupropion affects regions of your brain responsible for producing cravings for tobacco and the symptoms of withdrawal. Bupropion should be started 8 days **before** your quit date.

Treatment Plan	Instructions	Possible Side Effects
Day 1-3: Take 150 mg or 1 tablet EVERY morning Day 4-Week 12: 150 mg TWICE DAILY (8 hours apart) The usual duration of Bupropion is 12 weeks, however, some people may continue to take it for up to 24 weeks.	▷ Begin taking Bupropion 8 days before your quit date ▷ Ensure at least 8 hours between doses ▷ Do not use alcohol while taking Bupropion	▷ Dry mouth ▷ Difficulty sleeping ▷ Nausea ▷ Constipation ▷ Shakiness ▷ Altered taste ▷ Anxiety ▷ Palpitations ▷ Seizures (rare) The dosage can be reduced to help lessen side effects. $15-21/week

STEP 2
SET YOUR QUIT DATE

We would like you to pick a quit date in the next 30 days.

Although there is **no perfect day to quit**, consider these suggestions before picking your date:

- Choose a date when your days will be relatively routine
- Consider choosing a Monday or a weekend
- Avoid selecting a day near a major deadline or when you are ill
- Avoid selecting a day near your birthday or another special event
- If you are a woman, avoid picking a date immediately before your menstrual cycle

MY QUIT DATE:

Day Month Year

May 2009

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

June 2009

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

July 2009

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

August 2009

S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

September 2009

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

October 2009

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

November 2009

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

December 2009

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

January 2010

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

STEP 3

PREPARING FOR YOUR QUIT DATE

Your will power is the most important tool for quitting. Spend some time thinking about the reasons you want to quit, the benefits to your health, and how your quitting will positively affect the people around you. Do some math and calculate all the money you'll be saving by quitting. Remind yourself why it's important for you to quit.

TWO TO THREE WEEKS BEFORE:

- Practice being smoke-free. Make your house and car smoke-free zones.
- Identify routines you may have which trigger you to smoke (e.g. morning coffee, breaks) and make an effort to change your routines.
- Identify situations in which you may be tempted to smoke, come up with a plan for how you will deal with these situations (e.g. stress, social events) once you've quit.

ONE WEEK BEFORE:

- Cut back the amount you smoke.
- Tell your friends, family and co-workers about your quit plan. Enlist their support.
- Avoid situations where you would be tempted to smoke.
- Make a list of all the reasons why you want to quit smoking.
- Plan different rewards for yourself for staying "smoke-free."
- If you are going to use **Varenicline** or **Bupropion**, begin taking your medication **8 days before your quit date.**

THE DAY BEFORE:

- If you are using NRT make sure you have the NRT ready for the morning.
- THROW OUT ALL YOUR CIGARETTES.
- Throw away your ashtrays and lighters.
- Think positively about the change you are about to make.
- Remind your friends, family and co-workers that tomorrow is your quit date and that you appreciate their support. If your family or friends smoke, ask them not to: smoke around you; offer you cigarettes; leave cigarettes around; or tease you about not smoking.

ON YOUR QUIT DAY:

- If you are using NRT apply the patch first thing in the morning.
- Make a conscious effort not to be around people who smoke until you feel ready.
- Keep yourself busy at times when you might normally smoke.
- You may feel the urge to smoke, but it usually passes in 3-5 minutes. When you feel the urge, do something else. Take deep breaths and let them out slowly. Drink a glass of water.
- Carry things to put in your mouth, like gum, the inhaler, hard candy or toothpicks.
- Use the nicotine inhaler or gum to help you through cravings.
- Cut back on the caffeine (eg coffee, tea, soft drinks) you drink by half.

STEP 4

MAKE THE COMMITMENT TO QUIT

Now is the time to make the commitment to quit

This quit smoking plan is a contract between myself and my doctor/nurse. I am committing to upholding my responsibilities as outlined in this plan and letting my smoking cessation counsellor know if I am having difficulty with quitting smoking.

Signature _____

(Sign your name here)

Date _____

Doctor/Nurse Signature _____

Date _____

STEP 5
YOUR FIRST FEW WEEKS AS A NON-SMOKER

What to expect in the first few days after quitting...

Withdrawal Symptoms:
It is normal to experience withdrawal symptoms when quitting smoking. Withdrawal symptoms usually **last 3-5 days but then decrease**. Symptoms may include: headache, dizziness, slight confusion, feeling anxious or fidgety, difficulty concentrating, or in rare cases, significant mood changes. The smoking cessation medications will help reduce, or eliminate, the withdrawal symptoms you experience while quitting. As part of the follow-up program, we will work with you to ensure your withdrawal symptoms are minimized.

Cut back on caffeine:
After quitting smoking we recommend that you cut back your intake of caffeine (i.e. coffee, tea, soft drinks) by at least half. This is because non-smokers are more affected by caffeine. To avoid the unpleasant effects associated with having too much caffeine such as 'caffeine jitters', nervousness, irritability, headaches, sleeplessness, heart palpitations it's important to reduce your caffeine intake. You can do so by cutting back on the cups you drink per day or switching to decaffeinated beverages.

Coughing:
Many smokers find that they cough more in the first few weeks after quitting. This is your lungs clearing themselves. Consider it a sign that you're getting healthier!

Increase in Appetite:
Experiencing an increase in appetite is normal while quitting smoking. Nicotine is an appetite suppressant – so when you smoke your body's hunger signs are suppressed. As your taste buds return to normal, food will begin to taste better too! If you do feel hungrier than normal, choose healthy snacks or drink water. See page 12 for more weight management tips.

Changes to your Mood:
People who quit smoking often experience changes to their mood including feeling depressed, short-tempered, irritable, frustrated or angry. Like other withdrawal symptoms, these changes to your mood are often most pronounced in the first few weeks after quitting and should pass. If you find you are experiencing extreme mood changes that are not normal for you please contact your doctor.

Cravings:
Cravings to smoke are also normal. These usually decrease over a 2-3 week period. It is important to remember that cravings normally **last only 3 to 5 minutes**. Try to keep yourself occupied for 3 -5 minutes, and the craving should pass. Resist cravings by:

- avoiding places and activities that give you the urge to smoke
- changing your routine so smoking doesn't fit in anymore
- reminding yourself of all the reasons for quitting
- noticing how much better you feel since you've quit
- asking a friend to help you resist the urge to smoke

When you feel the urge to smoke, think of the 4 Ds.

Delay - cravings will usually pass within 3-5 minutes, so try to delay smoking

Drink Water – drinking water helps to flush out the chemicals and toxins from your system

Distract – occupy yourself with a task to keep your mind off smoking

Deep Breaths – Deep breathing will help you relax and make the cravings go away. Inhale deeply, hold it for a couple of seconds and then release it slowly.

THE BENEFITS OF QUITTING ARE IMMEDIATE

- **Within 8 hours of quitting:** Carbon monoxide levels drop, oxygen levels go back to normal.
- **Within 48 hours of quitting:** The chances of having a heart attack start decreasing, and the senses of taste and smell start improving.
- **Within 72 hours of quitting:** Bronchial tubes relax, which makes breathing easier and lung capacity increases.
- **Within 2 weeks to 3 months of quitting:** Blood circulation gets better, and lung function improves by as much as 30%.
- **Within 6 months of quitting:** Coughing, tiredness, sinus congestion and shortness of breath all improve.
- **Within 1 year of quitting:** The risk of heart attack due to smoking falls to half that of someone who still smokes.
- **Within 10 years of quitting:** The risk of dying from lung cancer falls to half that of someone who still smokes.
- **Within 15 years of quitting:** The risk of dying from a heart attack becomes the same as for someone who has never smoked.

STEP 6
STAYING QUIT

Dealing with stress...
Stress is a normal part of everyday life. Many people smoke because they believe it helps them cope with stress. The truth is smoking can actually increase stress because nicotine causes your heart rate and blood pressure to rise. It is important to break the cycle of using cigarettes to cope with stress and anxiety. Think about (other than smoking) what's been helpful to you in the past to deal with stress. Choose different coping strategies or look at situations from a different point of view. You may find it helpful to join a support group or find a friend to quit with or talk to. Learn to relax and when you feel stress coming on take deep breaths through your nose.

Managing your Weight while Quitting
Most people who quit smoking worry about gaining weight. For some people, a gain of between 5 and 7 pounds during the first few months of quitting is normal. You'll be less likely to gain weight if you don't change your diet, stick to low-calorie snacks and increase your physical activity. Using nicotine replacement therapy, Varenicline or Bupropion as part of your quit attempt may also reduce any weight gain. If your eating habits have remained the same as they were when you smoked, you can easily shed this small gain with a brisk, 30 minute walk daily. We have also found that making a small change to your diet (e.g. dropping a snack) can reduce any weight gain.

Enjoying life without smoking
When a craving hits or your stress rises, think to yourself, 'what would a non-smoker do?'
Here is a list of activities that you can do instead of smoking!

- Go for a walk or take part in another form of exercise
- Take up a new hobby that involves your hands like painting or knitting or gardening
- Listen to music
- Find alternative pleasures – music, tea, conversation, walking, playing with your kids
- Practice relaxation
- Phone a friend
- Catch up on all those household projects you've been putting off

Avoid the temptation
You've worked too hard to go back to smoking; so be wise about it. There will be situations where you will be tempted to smoke. Most 'slips' occur in social or stressful situations, especially if alcohol is being consumed. You may want to try to avoid these settings in the first few weeks after quitting. Have a plan if you will be around smokers or in a stressful situation to ensure you stay on track with your new life as a non-smoker. If you are in a situation that you feel tempted to smoke remember the 4D's – Delay, Drink water, Distract, Deep breaths.

If you have a slip...
You may feel frustrated, angry or discouraged. Don't worry, that's normal! Should you have a slip, have a plan to get back on track and start stopping all over again! If you find yourself smoking:

Change the situation – stop smoking immediately, leave the room, throw out your cigarettes... and carry on with your quit attempt.

Talk positively to yourself – remind yourself of how far you have come, encourage yourself to keep at it.

Take action – find something else to do that makes it difficult to smoke (eg. shower), do physical activity, chew mint flavoured gum, find a bigger focus than your craving (eg. the news).

Ask for help – talk to someone to distract or encourage you.

Don't let a slip throw you off your quit smoking plan.

LOOKING FOR MORE SUPPORT?

There are several quit smoking programs in our region which offer telephone, group, or individual support with quitting smoking.

Smokers' Helpline Canadian Cancer Society
Tel: 1-877-513-5333
Appropriate for:
- Smokers who want to quit, may be thinking about quitting, or need support to remain smoke-free
- Family members

Hours: Mon to Thurs: 8:00 a.m. – 9:00 p.m.
Fri: 8:00 a.m. – 6:00 p.m.
Sat & Sun: 9:00 a.m. – 5:00 p.m.
www.smokershelpline.ca

Quit Smoking Program Heart Health Education Centre
University of Ottawa Heart Institute (UOHI)
Room H-2342 40 Ruskin Street, Ottawa, ON
Tel: 613-761-5464 Toll Free: 1-866-399-4432
Fax: 613-761-5309
Appropriate for: All adult smokers requiring assistance with making a cessation attempt
Hours: Clinic hours weekdays

A.C.E.S.S. Smoking Cessation Program
Ottawa Public Health (OPH)100 Constellation Crescent, Ottawa, ON Tel: 613-580-6744 or Toll Free: 1-866-426-8885
Description: This program is a partnership between Ottawa Public Health and Community Health Centres. 8-week group program offered fall, spring, and winter. The program offers subsidized NRT. Schedule and location of quit smoking programs posted 3 times per year.

UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

OTTAWA MODEL FOR SMOKING CESSATION
MODÈLE D'OTTAWA POUR L'ABANDON DU TABAC

Quit Smoking Program
Eastern Ontario Health Unit
Head Office: 1000 Pitt Street, Cornwall, ON
Tel: 613-933-1375 or Toll Free: 1-800-267-7120 (Ask for Health Line)
Appropriate for: All smokers
Various locations across five counties based on demand.
Hours: Offered in fall and winter

Out-Patient Smoking Cessation Program
Hawkesbury & District General Hospital
Contact: Diandre Gilbert
Tel: 613-632-1111 Ext. 168
Appropriate for: Residents of Ontario who are 18 and over and want to quit smoking using NRT.
Hours: Clinic hours weekdays and evenings

Renfrew County and District Health Unit
7 International Drive, Pembroke, ON
Tel: 613-732-3629 or Toll Free: 1-800-267-1097
Appropriate for: All smokers
Hours: Vary

Leeds, Grenville & Lanark District Health Unit
458 Laurier Boulevard, Brockville, ON
Tel: 613-345-5685 or Toll Free: 1-800-660-5853
Appropriate for: All smokers
Hours: Vary

ACKNOWLEDGEMENTS
Information in this quit plan has been adapted from the following sources:

One step at a time: For Smokers who don't want to quit. Canadian Cancer Society.

On the Road to Quitting: Guide to becoming a non-smoker. Health Canada.

Quit: You have it in you. Smoke Free Ontario. Ontario Ministry of Health Promotion.

U.S. Department of Health and Human Services. Treating Tobacco use and dependence: Clinical practice guideline 2008 update.

Appendix I- Sample Clinic Poster

IT'S YOUR TIME TO QUIT.
WE CAN HELP.

ASK US ABOUT OUR
QUIT SMOKING PROGRAM

Appendix J - Sample Feedback Report Baseline

SMOKING CESSATION IN PRIMARY CARE

Smoking Prevalence

Patients Screener	885
Smokers	115 (13%)
Completed Surveys	N=70
Daily Smokers	68 (97.1%)
Non Daily	2 (2.9%)
Type of Patient	
Annual Exam	14 (20.9)
Follow-up Visit	17 (25.4)
Other	36 (53.7)

SMOKING CESSATION IN PRIMARY CARE

Profile of Daily Smokers

Variable	N (%)
% Male	**29 (43.3%)**
Mean Age (SD); Range	**46.5 (13.5)**; 19-72
Mean Years Education (SD)	**14.2 (2.6)**
Mean Cigarettes per Day (SD); Range	**14.9 (9.0)**; 1-42
Mean Years Smoked (SD)	**27.6 (13.7)** 3-60
Quit Attempts (%) No attempts 1-2 attempts 3 or more attempts	 **26 (38.8)** **28 (41.8)** **13 (19.4)**
Time to First Cigarette Smoke ≤30 mins of waking (%) Smoke >30 mins (%)	 **37 (55.2%)** **30 (44.8%)**
Readiness to Quit Next 30 Days Next 6-months Not Ready	 **22 (33.3%)** **30 (45.5%)** **14 (21.2%)**

SMOKING CESSATION IN PRIMARY CARE

5A's Delivery

5As	Doctor	Other Staff
Ask	38 (61.3%)	6 (23.8%)
Advise today **Advise last 12-months**	28 (45.2%) 51 (78.5%)	7 (17.1%) 13 (37.1%)
Assess	26 (38.8%)	4 (6.3%)
Assist	28 (43.8%)	4 (6.7%)
Assist **Discussed Medication** **Prescribed Medication** **Self-Help** **Quit Date**	18 (30.0%) 12 (20.0%) 4 (6.7%) 6 (10.0%)	2 (8.1%) 1 (1.7%) 1 (1.7%) -
Arrange – follow-up	13 (19.4%)	
How long did he/she speak to you about smoking Not at all Less than 2 minutes 2-5 minutes 5-10 minutes more than 10 minutes	 26 (43.3) 17 (28.3) 9 (15.0) 6 (10.0) 2 (3.3)	

SMOKING CESSATION IN PRIMARY CARE

Confidence, Importance, Motivation

Question	
On a scale from 1 to 10 how confident are you that you will be able to quit? (10 being very confident)	4.9 (2.8)
On a scale from 1 to 10 how Important is it to you to quit? (10 being very important)	6.8 (3.2)
What role does your doctor's advice play in motivating you to quit? Very important Important Somewhat important Not at all important	 19 (28.4%) 13 (19.4%) 27 (40.3%) 8 (11.9%)
What role does the advice of other staff members play in motivating you to quit? Very important Important Somewhat important Not at all important	 13 (20.3%) 12 (18.8%) 26 (40.6%) 13 (20.3%)

Appendix K - Sample Feedback Report Follow-up

UNIVERSITY OF OTTAWA
HEART INSTITUTE
INSTITUT DE CARDIOLOGIE
DE L'UNIVERSITÉ D'OTTAWA

OTTAWA MODEL
FOR SMOKING CESSATION
IN PRIMARY CARE

MODÈLE D'OTTAWA
POUR L'ABANDON DU TABAC
EN SOINS DE PREMIÈRE LIGNE

EVALUATION REPORT

Insert Clinic Name

SUMMARY

Smoking is the most preventable cause of death and disability in our region. Helping a patient who smokes quit is perhaps the most important preventative intervention clinicians can offer to patients.

Most patients who smoke want to quit. A health professional's advice to quit can play a powerful role in motivating a patient to make a quit attempt.

Quitting isn't easy. However, providing patients with strategic guidance and support will increase the odds a patient will be successful with quitting.

As part of the Ottawa Model for Smoking Cessation a partnership was established with the <Insert Clinic Name>. The program involved ensuring the clinic processes and health professionals were using state of the art approaches to addressing smoking with patients.

The program involved:

- An assessment of current processes
- Support implementing best practices for smoking cessation
- Practice tools to systematize the delivery of smoking cessation treatments
- Training for all providers in smoking cessation
- Specialized training for dedicated counselors at the clinic
- Access to the smoker's follow-up system
- Collection of baseline and follow-up evaluation data

We are pleased to be collaborating with <Insert Clinic Name> in improving the delivery of smoking cessation in our region and are committed to continuing to work together to ensure there are systems and supports in your setting to help your patients and the residents in this region – QUIT.

IN THIS REPORT

In this report we present the results of the evaluation completed at the <Insert Clinic Name> as part of the implementation of the Ottawa Model for Smoking Cessation in Primary Care Pilot Program.

DATA COLLECTION METHODS

Data presented in this report is based on the collection of data from two samples of daily smokers screened before and after the implementation of the Ottawa Model for Smoking Cessation at the clinic.

Baseline data collection occurred from XX to XX and included a sample of XX patients who smoked.

Follow-up data collection occurred from XX to XX and included a sample of XX patients who smoked.

RESULTS

- Two and a half times more patients had their smoking status assessed and were advised to quit at the follow-up compared to baseline.

- There was a threefold increase in the number of patients who report they received assistance with quitting as well as a prescription for a quit smoking medication.

- 16% of smokers reported that they had a follow-up appointment to discuss smoking arranged compared to 0% at baseline.

- Among smokers who reported they were ready to quit in the next 30 days, a 37% increase in the rate advise to quit was provided was documented and a 31% increase in the number of patients who received assistance with quitting.

SMOKING PREVALENCE AT CLINIC

PARAMETER	BASELINE Jan 26 – Feb 28 2009	FOLLOW-UP July 20 – Sept 15 2009
Patients Screened	1824	1238
Smoking Prevalence	15.3%	13.5%

PROFILE OF SMOKERS

PARAMETER	BASELINE	FOLLOW-UP	Δ
Mean Age (SD)	**36 (12.5)**	**40.8 (13.5)**	+3.2
% Male	**24 (42.9%)**	**23 (51.9%)**	-1
Mean Years Education (SD)	**16.1 (3.9)**	**15.6 (3.99)**	-0.5
Mean Cigarettes/Day (SD); Range	**13.1 (9.2);** 1-40	**14.2 (9.6);** 1-45	+1.1
Mean Years smoking (SD); Range	**16.4 (14.0);** 0.4-57	**23.2 (14.6);** 1-60	+6.8
Time to First Cigarette Smoke ≤30 mins of waking (%) Smoke >30 mins (%)	 **30 (53.6%)** **26 (46.4%)**	 **29 (56.9)** **22 (43.1)**	 -1 -4
Readiness to Quit Next 30 Days Next 6-months Not Ready	 **21 (38.2%)** **17 (30.9%)** **17 (30.9%)**	 **17 (34.7)** **20 (40.8)** **12 (24.5)**	 -4 -3 -5

PROVIDER PERFORMANCE OF TOBACCO TREATMENT STRATEGIES ("5A'S")

Best Practice Area	BASELINE % *Jan-Feb 2009*	FOLLOW-UP % *July-Sept 2009*	% Δ	P=
Ask *Today's Visit (Doctor)* *Today (Other Staff)*	35.7 9.3	73.1 67.9	+ 37.4 + 58.6	.001 .000
Advise Today's visit *Last 12-months*	23.2 57.1	57.7 61.8	+ 34.5 + 4.7	.002 ns
Assess *Today's visit* *Last 12-months*	23.2	60.0 69.1	+36.8	.000
Assist *Today's visit* *Last 12-months*	17.0	51.0 46.4	+34.0 -	.000
Medications *Today's visit* *Last 12-months*	14.5	32.7 35.7	+18.2	.045
Prescription	5.5	15.1	+ 9.6	ns
Quit Date	16.1	7.5	- 8.6	ns
Self-Help Material	9.1	20.8	+11.7	ns
Arrange Follow-up visit to address smoking	0	16.1	+16.1	.019

NOTES:

REDUCTIONS IN QUIT DATES BEING SCHEDULED ARE EXPECTED GIVEN THIS ACTIVITY HAS NOW BEEN DESIGNATED TO SMOKING CESSATION COUSELLORS AT THE CLINIC

HOW WE DID WITH SMOKERS READY TO QUIT

Best Practice Area	BASELINE % *Jan-Feb 2009*	FOLLOW-UP % *July-Sept 2009*	% Δ
Ask *Today's Visit (Doctor)* *Today (Other Staff)*	 33.3 10.5	 76.9 68.8	 + 41.7 + 58.3
Advise Today's visit *Last 12-months*	 19.0 52.4	 56.3 52.9	 + 37.3 +0.5
Assess *Today's visit* *Last 12-months*	 27.8	 73.3 76.5	 +45.5
Assist *Today's visit* *Last 12-months*	 22.2	 53.3 52.9	 +31.1 -
Medications *Today's visit* *Last 12-months*	 30.0	 37.5 41.2	 +7.5
Prescription *Physician today* *Staff today*	 15.0 5.6	 12.5	 - 2.5
Quit Date	42.9	12.5	- 30.4
Self-Help Material	10.0	18.8	+8.8
Arrange Follow-up visit to address smoking	0	29.4	+29.4

RECOMMENDATIONS

The smoking cessation pilot program evaluation has documented some important increases in rates at which patients are advised and assisted with quitting. Congratulations on the improvements made!

We would like to recommend a couple of activities moving forward:

- **Communicate Results:** Communicate results to all members of the clinical team.

- **Commit to continuing with the protocol as a new standard of care at the clinic:** Ensure clinic staff remain committed to addressing smoking as a priority issue with patients.

- **Set Annual Targets:** Determine what targets the clinic would like to achieve and if success should be measured on an annual basis or at each visit. We would recommend a target of 85% of smokers be advised about quitting at each clinic encounter and 85% of smokers receiving assisting ready smokers with quitting.

- **Quality Improvement Plan for Screening, Advising and Referring:** Work collaboratively with the UOHI to identify challenges in systematizing the screening, advising and referring patients into clinic routines. Develop action plan for addressing these quality improvement areas. Careful monitoring of these changes.

- **Institute monthly quality audits** to ensure the processes and systems developed are maintained over the next year. I am attaching a template we would suggest using for conducting these quality audits. It will be important to identify a staff member responsible for this activity.

- **Consider Introducing New Program Components in the New Year:** Discuss with the UOHI the clinics interest in introducing new supports for patients interested in quitting. This includes introducing the smoker's telephone follow-up system which was tested as part of the pilot program in half of the pilot sites. The UOHI will also have $100.00 vouchers for smoking cessation medications available to distribute to patients as part of a new program through Health Canada over the next year.

Appendix L - Sample Clinic Implementation Workplan

INSERT CLINIC NAME

WORKPLAN FOR OTTAWA MODEL FOR SMOKING CESSATION PILOT STUDY

Activity	Most Responsible	Start Date	End Date
PHASE 1: PROGRAM INTRODUCTION AND SIGN-ON			
1.1 Introductory meeting with management team			
1.2 Provider consent forms signed			
1.3 Assign primary contact for implementation activities (time limited role)			
1.4 Form smoking cessation task force to support program implementation			
1.5 Review work plan and implementation steps and identify timelines with task force			
1.6 Complete practice needs assessment (template provided)			
1.7 General information session with clinical team meeting AND/OR introductory information distributed to team members			
1.8 Designate clinic smoking cessation coordinator (ongoing role)			
PHASE 2: BASELINE ASSESSMENT			
2.1 Identify Preferred Start Date for Data Collection			
2.2 Identify process for distribution of baseline assessment			
2.3 Site Visit (Protocol, Logistics, Staff Roles)			
2.4 Assign contact for RAs (if different from lead)			
2.5 Identify designated location (locked cabinet) to store			
2.6 Collect data			
2.7 Complete telephone follow-up contacts			
PHASE 3A: PLANNING YOUR CLINIC TOBACCO CONTROL PROTOCOL			
3.1 Review OMSC standard processes	Task Force		
3.2 Review of current clinic smoking cessation practices and patient flow	Task Force		
3.3 Determine and document required revisions to OMSC processes - Tobacco question - Collection of Smoking Profile - Consult Form - Electronic versus paper-based documentation - Registration of Patient (if required)	Task Force		
3.4 Determine roles and responsibilities in program delivery - Clerks - Nursing staff - Smoking cessation resource person - Physicians	Task Force		
3.5 Select date for training workshop (see Phase 4)	Task Force		
3.6 Determine smoking cessation assistance for clinic staff	Task Force		
3.7 Complete tool and processes modifications (as required)			
3.8 Identify 'Go Live' date for program	Task Force		
3.9 Prepare and print program materials			
3.10 Order supplemental materials (posters, samples, CCS Smoking Brochures)			
3.11 Designate staff person for reordering materials	Task Force		
PHASE 3B: RANDOMIZATION TO INTERVENTION GROUP			
3.12 Obtain group assignment from Methods Centre			
PHASE 3C: IMPLEMENT IVR SYSTEM (FOR PRACTICES ASSIGNED TO FOLLOW-UP COUNSELLING ONLY)			
3.13 Designate staff person for data entry			
3.14 Train designated staff person on data entry and report generation			

3.15 Run quality assurance check			
PHASE 4: TRAINING CLINIC STAFF			
4.1 Schedule Training workshop			
4.2 Determine if MANPRO credits are of interest			
4.3 Submit relevant information to College of Physicians			
4.4 Arrange Logistics (location, catering, equipment)			
4.5 Send communication to clinic staff with RSVP			
4.6 Prepare summary of data collected during baseline assessment			
4.7 Clinicians completes provider survey (1-page) at training session			
4.8 Conduct Training workshop			
4.9 Schedule Intensive training for smoking cessation coordinator(s)			
4.10 Incorporate training into employee orientation program			
PHASE 5: PROGRAM IMPLEMENATION			
5.1 Access to IVR system is activated			
5.2 Designate person for data entry of the Consult Form into web-based system			
5.3 Train designated person on accessing and using IVR system			
5.4 Begin screening patients with waiting room screener			
5.5. Implement new smoking cessation forms and protocols			
5.6 Place other materials in designated areas (posters, self help materials)			
5.7 Internal audit system established			
5.8 Quality assurance checks conducted bi-monthly			
5.9 Conduct follow-up clinic needs assessment			
5.10 Identify issues processes			
5.11 Resolve issues as required			
PHASE 6A: POST-ASSESSMENT			
6.1 Schedule date for post-assessment			
6.2 Identify staff contact for RAs			
6.3 Review baseline process and revise as required			
PHASE 7: PROGRM SUSTAINABILITY			
7.1 Conduct quarterly quality assurance checks			
7.2 Quarterly review of performance date by senior management/task force			
7.3 Problem solve as required to improve quality of implementation activities			
7.4 Annual quality improvement and training plan created for clinic based on need			

Appendix M - Needs Assessment

The Needs Assessment Tool provides us with necessary demographic information regarding your clinic, such as the number of patients, staff… The Clinic Practices for Treating Tobacco Use and Dependence reflects your clinic practice for tobacco treatment ***before*** implementation of the "Ottawa Model." It is not uncommon for most clinics to have few if any of these practices in place.

Date of Completion:
Name of Clinic:
Key Contact Person:
Tel#:
E-Mail:

DEMOGRAPHIC DATA

Type of Clinic (e.g FHT, FHN, FHG, FHO, other)	
Single Site or Multiple Sites (please identify all sites)	
Does Clinic Use EMR, Paper Charts, Both (Name of EMR System)	
Number of clinic visits annually	
Number of unique clinic patients seen annually	
Number of unique clinic patients (total)	
Proportion of patients who are smokers (if known)	
Teaching/Non-Teaching	
Chief Physician	
Director	
# Nurse Managers	
# Nurse Educators	
# Advanced Practice Nurses/Clinical Nurse Specialists	
# RN's	
# RNA's/RPN's	
# Other Health Care Professionals (e.g., social workers, dieticians, occupational therapists)	
# Support staff (IT, administrative)	
# Physician Housestaff	
# Medical Residents	
# Medical Consultants	
Clinic hours:	

Best Practices for Treating Tobacco Use and Dependence ("The Ottawa Model"): Pre-Post Assessment

Practice	Yes	No	Comments
1. Clinic task force formed			
2. Clinic tobacco control protocol developed			
3. Tobacco use queried and documented for all clinic patients			
4. Training tobacco dependence treatment offered to health care providers in last year			
5. Dedicated staff to provide tobacco dependence treatment			
6. Documentation in place to gather information of smoking history from patients			
7. Consult form or other documentation in place to assess 5As delivery			
8. Processes to follow-up tobacco users for at least one month after clinic visit in place.			
9. Process to evaluate quality or program implementation in place			
10. Processes to provide feedback to clinicians about performance in place.			

Include Samples of the Following if applicable:

- Current Questions for assessing smoking status of patients and other characteristics of smokers
- Current Waiting Room Screeners/Questionnaires
- Current Smoking Consult Forms
- Current practices for addressing smoking with patients

Appendix N - FC Group Provider Consult Form

uOttawa
Service de santé
Health Services

Smoking Cessation Consult Form

Last Name:
First Name:
Address:
City: Postal Code:
Tel: Date of Birth: dd /mm / yy

Preferred language: ☐ English ☐ French ☐ Other (specify):_____

☐ First Visit ☐ Annual Exam ☐ Other Visit

PHYSICIAN CONSULT

ADVISE

Strong, Personalized, Unambiguous Advice to Quit and Offer of Assistance with Quitting

"You probably already know many of the risks involved with smoking, but I cannot stress enough how important it is to stop. Your _____ (e.g. family history, high cholesterol) makes it even more important for you to quit now. ***I would advise you to stop as soon as possible.***

"Quitting smoking is not always easy but we can help you with quitting and there are medications available to make quitting easier." ☐

ASSESS

"Would you be willing to make an attempt to quit smoking in the next month?" ☐ Yes ☐ No

SMOKER NOT READY TO QUIT

ASSIST
Brief Counseling + self-help materials

"Quitting smoking takes a lot of determination and works best when you are ready to make the commitment to quit."

"If you do not feel you are ready to quit smoking then you should wait. On the other hand there is never really a good time to stop smoking and you should not postpone quitting by waiting for the right time."

"I'd like you to take these materials about getting ready to quit smoking home with you. Please look them over and think seriously about quitting soon. We have new ways to help you with quitting and when you're ready I can work with you to ensure you have a plan in place to deal with withdrawl, and _____."

☐ Provide Patient with copy of Information Sheet for Smokers not Ready to Quit

"We'd like to check in with you in a few weeks time to see if you are interested in quitting smoking. Would you be okay with us arranging to follow-up with you in 30 and 60 days time to see if you are ready to quit? The call will be placed by our automated smoker's follow-up system. This is a great way to check in with you. If you are interested in quitting at that time we will arrange to connect you to our smoking cessation counsellor."

☐ Yes ☐ No

Is the number we have on file the best one to reach you at during the day?

☐ Yes ☐ No Alternate: ( )_____ ☐

SMOKERS READY TO QUIT IN NEXT 30 DAYS

ASSIST
Patient Preference

"It's great to hear that you are ready to make a commitment to stop smoking. It's important that you have a plan for quitting smoking. I would like to arrange for you to meet with a quit smoking counselor. She/he will work with you to develop your personalized quit plan."

"Quit smoking medications are available and have been shown to double or triple the chance of being successful with quitting and staying quit. There are three types of quit smoking medications that are recommended: Nicotine replacement therapy, and two pill formats; Zyban and a newer product called Champix. The counselor will determine with you which option is best for you."

MD/AHP to submit referral to "FHT Smoking Cessation"

Name:_____

TO BE COMPLETED BY SMOKING CESSATION COUNSELOR

☐ Provide Patient with Copy of Quit Plan

"Quit smoking medications are available and have been shown to double of triple the chance of being successful with quitting. There are three types of quit smoking medications that are recommended: Nicotine replacement therapy, and two pill formats; Bupropion/Zyban and a newer product called Varenicline/Champix."

"Do you have a preference?" ☐ Yes ☐ No

SMOKERS READY TO QUIT IN NEXT 30 DAYS

ASSIST
Identify Contraindications

☐ Pregnant, breast feeding or planning pregnancy

Bupropion (Zyban)
- ☐ History of seizure disorder or head trauma
- ☐ Presently taking Bupropion/ Zyban/ Wellbutrin
- ☐ Previous reaction to Bupropion/ Zyban/ Wellbutrin
- ☐ Pre-existing or current eating disorder
- ☐ Excessive use of alcohol/sedatives present or past
- ☐ Taking anti-depressants, antipsychotics, corticosteroids, MAO inhibitors, theophyline, cocaine or diet pills
- ☐ Taking a quinolone antibiotic (eg. ciprofloxacin,levoflozacin)
- ☐ Use of oral hypoglycemic products or insulin
- ☐ Severe hepatic impairment
- ☐ Central nervous system tumour

Varenicline (Champix)
- ☐ Under the age of 18 years
- ☐ History of renal failure and is taking Cimetidine
- ☐ Using NRT in addition to Varenicline
- ☐ Previous drug reaction to Varenicline
- ☐ Has history of renal failure (check with physician)
- ☐ History of nausea and vomiting in past two months (check with physician)
- ☐ operates heavy machinery (avoid until reaction to medication is known)

NRT
- ☐ Dentures/TMJ/Partial/Crown (avoid NRT gum)
- ☐ Allergy to adhesive (consider clear patch)

ASSIST
Select Pharmaco-therapy

☐ NRT	<10 cigs/day	10-20 cigs/day	20+ cigs/day
	☐ 7mg patch ☐ Inhaler ☐ 2mg gum/lozenge	☐ 14 mg patch ☐ Inhaler ☐ 2mg gum/lozenge	☐ 21 mg patch ☐ Inhaler ☐ 4mg gum/lozenge
If time to first cig is <30 mins of waking consider higher dose NRT	14mg	21mg	28mg

☐ **Varenicline** Days 1-3: 0.5mg once/day; Days 4-7: 0.5 mg BID; Days 8-12 weeks 1.0 mg twice daily.
*Start 8 days before the quit date.

☐ **Bupropion** - Days 1-3: 150 mg daily (in the morning); Days 4-12 weeks 150 mg BID.
*Start 8 days before the quit date.

☐ **No medication prescribed**

ASSIST
Set Quit Date

"Here is a calendar of the next month. I'd like you to pick your quit date." QUIT DATE: _____ (dd/mm/yy)

ASSIST
Provide Quit Plan

- ☐ Reviewed medications instruction sheet with patient (Step 1)
- ☐ Reviewed "Preparing for quit date" sheet with patient (Step 3)
- ☐ Remind patient that he/she will need to cut back on caffeine by half after quit date.

ARRANGE
IVR Follow-up

"As part of our quit smoking program we will be getting in touch with you by phone to follow-up on your progress over the next 2 months. The calls will be placed at a time that is convenient for you using our automated telephone follow-up system. The automated calls are a great way for us to learn about how you are doing. If, for any reason, you are struggling with your quit attempt you will be able to connect to our smoking cessation counsellors who will work with you to address any difficulties you may be having. We greatly appreciate if you can answer the phone for these calls and let us know how you are doing. You should expect to receive your first call 7 days before your quit date."

☐ Reviewed Telephone Follow-up Program Instructions (Step 4 in Quit Plan)

What is the best time of the day to call you?
☐ 7AM-9AM ☐ 9AM-1PM ☐ 1PM-5PM ☐ 5PM-9PM ☐ Anytime

What is the best number to reach you at this time? ( )_____
☐ Same as above Alternate Phone Number: ( )_____

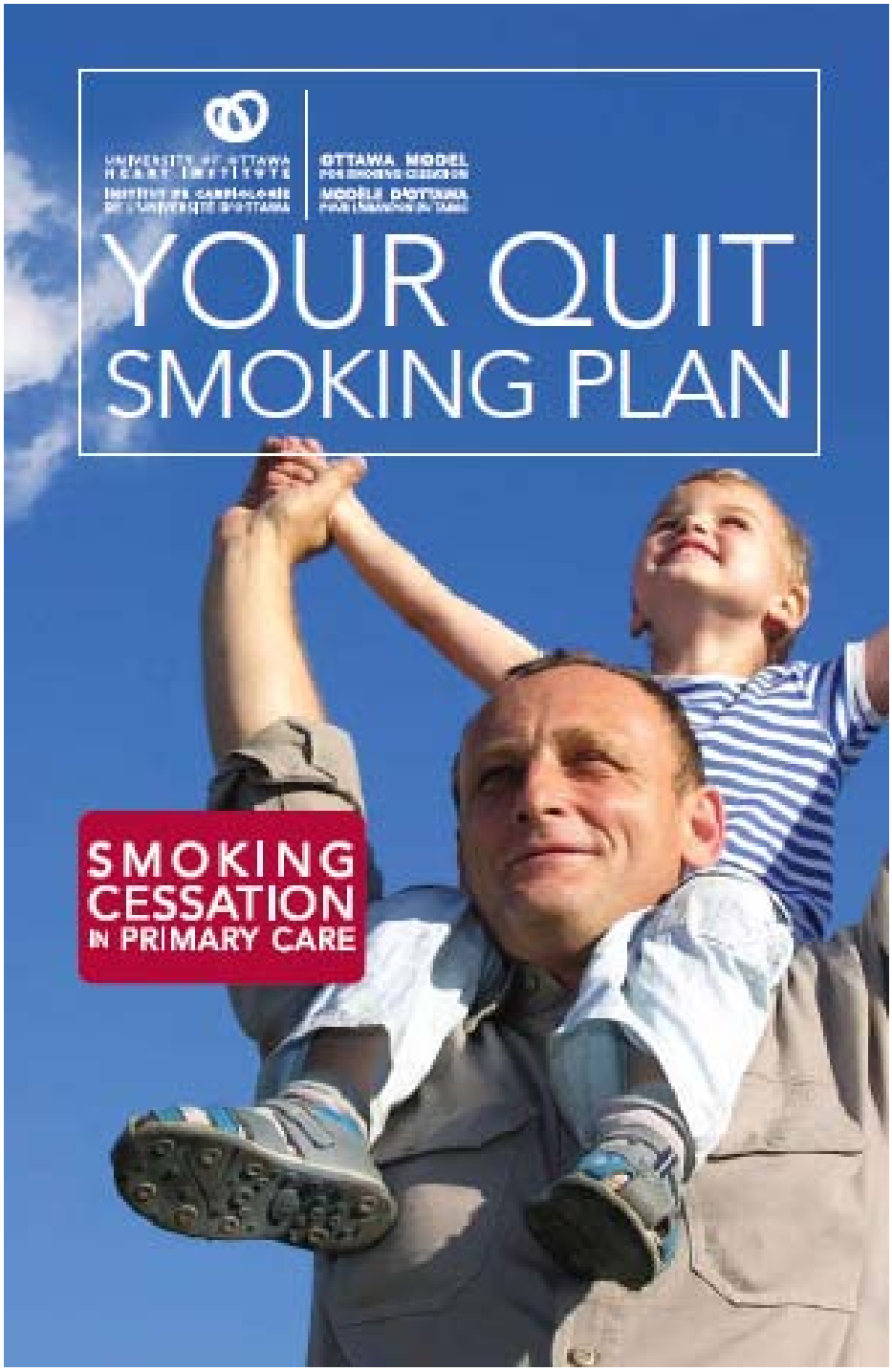
If patient is unable to receive calls, why?
☐ No telephone ☐ Unable to speak English or French
☐ Already receiving calls through hospital-based smoking cessation program
☐ Refused ☐ Other: _____

Review

Name of MD/AHP:_____

Signature: _____ Date _____

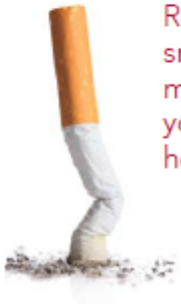
Appendix O – FC Group Quit Plan



We recommend that anyone getting ready to stop smoking have a personalized plan for quitting.

YOUR QUIT PLAN INCLUDES SIX STEPS:

By completing each of these steps you will very significantly increase your chances of quitting successfully.



Remember, quitting smoking is the single most important thing you can do for your health!

STEP 1
CHOOSING A QUIT SMOKING MEDICATION - PATCH OR PILL?

We recommend that all smokers take advantage of available quit smoking medications. These medications have been shown to **double or triple** the chance of being successful with quitting. We will work with you to choose the right quit smoking medication for you. There are three types of medications for you to choose from:

1. Nicotine Replacement Therapy (NRT) – Patch, Inhaler, Gum or Lozenge
2. Varenicline (Champix®) – Pill
3. Bupropion (Zyban®) – Pill

Option 1:
☐ Nicotine Replacement Therapy (NRT)

NRT works by reducing withdrawal symptoms (anxiety, irritability, headaches, and difficulty concentrating...) that typically occur when people quit smoking as well as reduce your urge to smoke. The idea is that you will use the NRT to deal with cravings and withdrawal symptoms – and week by week, you will reduce the amount of NRT while adapting to life as a non-smoker.

NRT comes in the form of a patch, gum, inhaler or lozenge. Each form can be used alone or **often two forms of NRT are used together**. The type, amount and length of NRT treatment can be tailored to meet your needs.

The advantages of using NRT instead of smoking:

:- You will receive much less nicotine than if you were to continue smoking.
:- Your body is not exposed to the 4,000+ chemicals in cigarette smoke.

You will be more successful in quitting if you are using an amount of NRT that is sufficient to make you feel completely comfortable and using the NRT for as long as it takes! We can help ensure your plan includes the appropriate levels of NRT!

TREATMENT PLAN

NRT	20+ cigarettes/day	10-20 cigarettes/day	less than 10 cigarettes/day	Instructions	Possible Side Effects
Patch ☐ 	Step 1 21 mg One patch daily Weeks 1 through 6 Step 2 14 mg One patch daily Weeks 7 & 8 Step 3 7 mg One patch daily Weeks 9 & 10	Step 2 14 mg One patch daily Weeks 1 through 6 Step 3 7 mg One patch daily Weeks 7 & 8	Step 3 7 mg One patch daily Weeks 1 through 6 $25-30/week	∴ Apply the patch to a clean, dry, non hairy area on the upper part of your body (arms, chest, back). ∴ Replace the patch with a new one every 24 hours. ∴ Be sure to remove the old patch before putting on a new one. ∴ If you have difficulty sleeping remove your nicotine patch at bedtime.	∴ headache ∴ dizziness ∴ nausea ∴ flushing ∴ stomach upset ∴ skin irritation ∴ trouble sleeping
Inhaler ☐ 	∴ Provides hand to mouth motion of smoking ∴ Puff continuously for 20 mins (1 cartridge) or as needed to manage cravings. ∴ Use 6-12 cartridges per day for first 6 weeks. ∴ Reduce the amount of cartridges used per day in weeks 6-12. ∴ Some smokers require 1-2 cartridges per day beyond 12 weeks to manage cravings. $40/week			∴ You puff as needed to manage cravings ∴ Inhale 80 puffs over 20 minutes or until cravings are gone. Often, using the inhaler for 5 minutes is enough. ∴ Take slow puffs to avoid throat burn. ∴ Avoid eating or drinking 15 minutes before or during use.	∴ headache ∴ nausea ∴ mouth/throat irritation
Gum ☐ 	☐ 2mg (if you smoke your first cigarette 30 mins after you wake up) ☐ 4 mg (if you smoke your first cigarette within 30 mins of waking up)			∴ Nicotine gum should be chewed slowly until you can taste the nicotine or feel a slight tingling in your mouth, then stop chewing. ∴ Place the gum between your cheek and gum. After one minute, repeat the process until cravings are resolved. ∴ Chew each piece for about 30 minutes. ∴ Avoid eating or drinking 15 minutes before or during use.	∴ clings to dental work ∴ nausea, hiccups ∴ jaw pain ∴ mouth soreness
Lozenge ☐	∴ One piece every 1-2 hours for weeks 1 through 6 ∴ One piece every 2-4 hours for weeks 7 through 9 ∴ One piece every 4-8 hours for weeks 10 through 12 $40-55/week			∴ Place the lozenge in your mouth and let it dissolve, moving it back and forth from time to time. ∴ Each lozenge will last about 20-30 minutes. ∴ Avoid eating or drinking 15 minutes before or during using lozenge.	∴ nausea ∴ headache ∴ heartburn ∴ coughing ∴ hiccups

Option 2:
☐ Varenicline (Champix®)

Varenicline is the newest of the quit smoking medications and comes in pill form. Varenicline works in two ways. First it stimulates nicotine receptors in your brain so that your cravings for nicotine are dramatically reduced or even eliminated. Second, it reduces the satisfaction you get from smoking. Since smoking is less pleasurable you will be less likely to feel like smoking. Varenicline should be started 8 days **before** your quit date.

Treatment Plan	Instructions	Possible Side Effects
Day 1-3: 0.5 mg daily Day 4-7: 0.5 mg at breakfast and dinner Weeks 2-12: 1 mg at breakfast and dinner The usual duration of Varenicline is 12 weeks, however, some people may continue to take it for up to 24 weeks.	∴ Begin taking Varenicline 8 days **before** your quit date. ∴ Take the pill after a meal with a full glass of water. ∴ Do not engage in potentially hazardous tasks, such as operating machinery until you are sure this medication does not affect your mental alertness.	∴ nausea ∴ vomiting ∴ trouble sleeping ∴ headache ∴ abnormal dreams ∴ constipation ∴ gas ∴ allergic reaction (rare) ∴ altered/depressed mood The dosage can be adjusted to lessen the side effects. $36/week

If either you or your family notice agitation, depressed mood, or changes in behaviour that are not typical for you, or an allergic reaction stop taking the medication and contact your doctor and the quit smoking program immediately.

If you forget to take your medication, take it as soon as you remember as long as it's within a few hours. If more than a few hours have passed, do not take a double dose to make up for the missed pill, skip the dose and wait to take the next dose at the correct time.

Option 3:
☐ Bupropion (Zyban®)

Bupropion is another effective quit smoking medication. Bupropion is a pill you take to reduce your craving for tobacco. Bupropion affects regions of your brain responsible for producing cravings for tobacco and the symptoms of withdrawal. Bupropion should be started 8 days **before** your quit date.

Treatment Plan	Instructions	Possible Side Effects
Day 1-3: Take 150 mg or 1 tablet EVERY morning Day 4-Week 12: 150 mg TWICE DAILY (8 hours apart) The usual duration of Bupropion is 12 weeks, however, some people may continue to take it for up to 24 weeks.	∴ Begin taking Bupropion 8 days before your quit date ∴ Ensure at least 8 hours between doses ∴ Do not use alcohol while taking Bupropion	∴ Dry mouth ∴ Difficulty sleeping ∴ Nausea ∴ Constipation ∴ Shakiness ∴ Altered taste ∴ Anxiety ∴ Palpitations ∴ Seizures (rare) The dosage can be reduced to help lessen side effects. $15-21/week

STEP 2
SET YOUR QUIT DATE

We would like you to pick a quit date in the next 30 days.

Although there is **no perfect day to quit**, consider these suggestions before picking your date:

- Choose a date when your days will be relatively routine
- Consider choosing a Monday or a weekend
- Avoid selecting a day near a major deadline or when you are ill
- Avoid selecting a day near your birthday or another special event
- If you are a woman, avoid picking a date immediately before your menstrual cycle

MY QUIT DATE:

Day Month Year

May 2009

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

June 2009

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

July 2009

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

August 2009

S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

September 2009

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

October 2009

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

November 2009

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

December 2009

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

January 2010

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

STEP 3
PREPARING FOR YOUR QUIT DATE

Your will power is the most important tool for quitting. Spend some time thinking about the reasons you want to quit, the benefits to your health, and how your quitting will positively affect the people around you. Do some math and calculate all the money you'll be saving by quitting. Remind yourself why it's important for you to quit.

TWO TO THREE WEEKS BEFORE:

- Practice being smoke-free. Make your house and car smoke-free zones.
- Identify routines you may have which trigger you to smoke (e.g. morning coffee, breaks) and make an effort to change your routines.
- Identify situations in which you may be tempted to smoke, come up with a plan for how you will deal with these situations (e.g. stress, social events) once you've quit.

ONE WEEK BEFORE:

- Cut back the amount you smoke.
- Tell your friends, family and co-workers about your quit plan. Enlist their support.
- Avoid situations where you would be tempted to smoke.
- Make a list of all the reasons why you want to quit smoking.
- Plan different rewards for yourself for staying 'smoke-free.'
- If you are going to use **Varenicline** or **Bupropion**, begin taking your medication **8 days before your quit date.**

THE DAY BEFORE:

- If you are using NRT make sure you have the NRT ready for the morning.
- THROW OUT ALL YOUR CIGARETTES.
- Throw away your ashtrays and lighters.
- Think positively about the change you are about to make.
- Remind your friends, family and co-workers that tomorrow is your quit date and that you appreciate their support. If your family or friends smoke, ask them not to: smoke around you; offer you cigarettes; leave cigarettes around; or tease you about not smoking.

ON YOUR QUIT DAY:

- If you are using NRT apply the patch first thing in the morning.
- Make a conscious effort not to be around people who smoke until you feel ready.
- Keep yourself busy at times when you might normally smoke.
- You may feel the urge to smoke, but it usually passes in 3-5 minutes. When you feel the urge, do something else. Take deep breaths and let them out slowly. Drink a glass of water.
- Carry things to put in your mouth, like gum, the inhaler, hard candy or toothpicks.
- Use the nicotine inhaler or gum to help you through cravings.
- Cut back on the caffeine (eg. coffee, tea, soft drinks) you drink by half.

STEP 4
THE QUIT SMOKING FOLLOW-UP PROGRAM

We would like to follow your progress during your upcoming quit attempt. To do so, we will be enrolling you in our quit smoking follow-up program which will provide you with 5 follow up phone calls over the next two months. The quit smoking follow-up program is delivered by an automated telephone system which will call you on your chosen dates and times.

Each call will take less than five minutes!

- The system will call you 7 days before your quit date and then 3, 14, 30, and 60 days after your quit date.
- During the phone call, you will be asked a series of 'yes' or 'no' questions.
- If you have call display the follow-up system will appear on your call display as the "Help 2 Quit".

The automated calls are a great way for us to learn about how you are doing. If, for any reason, you are struggling with your quit attempt, you will be able to connect to our smoking cessation counsellor who will work with you to address any difficulties you may be having. We will work with you to adjust your plan to help you deal with cravings or temptations.

Even if you are doing fine, it's important to us to hear about how you are doing. **We greatly appreciate if you could ensure that you answer the calls and respond to the questions.**

Keeping in mind that your first phone call will be seven days before your quit date, please write down the date and time of your first phone call. You may find it helpful to write on your calendar the date and time of your phone calls.

First phone call: _____ _____
(DD/MM/YY) (Time)

Now is the time to make the commitment to quit

This quit smoking plan is a contract between myself and my doctor/nurse. I am committing to upholding my responsibilities as outlined in this plan and letting my smoking cessation counsellor know if I am having difficulty with quitting smoking.

Signature _____ Date _____
(Sign your name here)

Doctor/Nurse Signature _____ Date _____

STEP 5
YOUR FIRST FEW WEEKS AS A NON-SMOKER

What to expect in the first few days after quitting...

Withdrawal Symptoms:
It is normal to experience withdrawal symptoms when quitting smoking. Withdrawal symptoms usually **last 3-5 days but then decrease**. Symptoms may include: headache, dizziness, slight confusion, feeling anxious or fidgety, difficulty concentrating, or in rare cases, significant mood changes. The smoking cessation medications will help reduce, or eliminate, the withdrawal symptoms you experience while quitting. As part of the follow-up program, we will work with you to ensure your withdrawal symptoms are minimized.

Cut back on caffeine:
After quitting smoking we recommend that you cut back your intake of caffeine (i.e. coffee, tea, soft drinks) by at least half. This is because non-smokers are more affected by caffeine. To avoid the unpleasant effects associated with having too much caffeine such as 'caffeine jitters', nervousness, irritability, headaches, sleeplessness, heart palpitations it's important to reduce your caffeine intake. You can do so by cutting back on the cups you drink per day or switching to decaffeinated beverages.

Coughing:
Many smokers find that they cough more in the first few weeks after quitting. This is your lungs clearing themselves. Consider it a sign that you're getting healthier!

Increase in Appetite:
Experiencing an increase in appetite is normal while quitting smoking. Nicotine is an appetite suppressant – so when you smoke your body's hunger signs are suppressed. As your taste buds return to normal, food will begin to taste better too! If you do feel hungrier than normal, choose healthy snacks or drink water. See page 12 for more weight management tips.

Changes to your Mood:
People who quit smoking often experience changes to their mood including feeling depressed, short-tempered, irritable, frustrated or angry. Like other withdrawal symptoms, these changes to your mood are often most pronounced in the first few weeks after quitting and should pass. If you find you are experiencing extreme mood changes that are not normal for you please contact your doctor.

Cravings:
Cravings to smoke are also normal. These usually decrease over a 2-3 week period. It is important to remember that cravings normally **last only 3 to 5 minutes**. Try to keep yourself occupied for 3 to 5 minutes, and the craving should pass. Resist cravings by:

- avoiding places and activities that give you the urge to smoke
- changing your routine so smoking doesn't fit in anymore
- reminding yourself of all the reasons for quitting
- noticing how much better you feel since you've quit
- asking a friend to help you resist the urge to smoke

When you feel the urge to smoke, think of the 4 Ds.

Delay - cravings will usually pass within 3-5 minutes, so try to delay smoking

Drink Water – drinking water helps to flush out the chemicals and toxins from your system

Distract – occupy yourself with a task to keep your mind off smoking

Deep Breaths – Deep breathing will help you relax and make the cravings go away. Inhale deeply, hold it for a couple of seconds and then release it slowly.

THE BENEFITS OF QUITTING ARE IMMEDIATE

- **Within 8 hours of quitting:** Carbon monoxide levels drop, oxygen levels go back to normal.
- **Within 48 hours of quitting:** The chances of having a heart attack start decreasing, and the senses of taste and smell start improving.
- **Within 72 hours of quitting:** Bronchial tubes relax, which makes breathing easier and lung capacity increases.
- **Within 2 weeks to 3 months of quitting:** Blood circulation gets better, and lung function improves by as much as 30%.
- **Within 6 months of quitting:** Coughing, tiredness, sinus congestion and shortness of breath all improve.
- **Within 1 year of quitting:** The risk of heart attack due to smoking falls to half that of someone who still smokes.
- **Within 10 years of quitting:** The risk of dying from lung cancer falls to half that of someone who still smokes.
- **Within 15 years of quitting:** The risk of dying from a heart attack becomes the same as for someone who has never smoked.

STEP 6
STAYING QUIT

Dealing with stress…
Stress is a normal part of everyday life. Many people smoke because they believe it helps them cope with stress. The truth is smoking can actually increase stress because nicotine causes your heart rate and blood pressure to rise. It is important to break the cycle of using cigarettes to cope with stress and anxiety. Think about (other than smoking) what's been helpful to you in the past to deal with stress. Choose different coping strategies or look at situations from a different point of view. You may find it helpful to join a support group or find a friend to quit with or talk to. Learn to relax and when you feel stress coming on take deep breaths through your nose.

Managing your Weight while Quitting
Most people who quit smoking worry about gaining weight. For some people, a gain of between 5 and 7 pounds during the first few months of quitting is normal. You'll be less likely to gain weight if you don't change your diet, stick to low-calorie snacks and increase your physical activity. Using nicotine replacement therapy, Varenicline or Bupropion as part of your quit attempt may also reduce any weight gain. If your eating habits have remained the same as they were when you smoked, you can easily shed this small gain with a brisk, 30 minute walk daily. We have also found that making a small change to your diet (e.g. dropping a snack) can reduce any weight gain.

Enjoying life without smoking
When a craving hits or your stress rises, think to yourself, 'what would a non-smoker do?'
Here is a list of activities that you can do instead of smoking!

- Go for a walk or take part in another form of exercise
- Take up a new hobby that involves your hands like painting or knitting or gardening
- Listen to music
- Find alternative pleasures – music, tea, conversation, walking, playing with your kids
- Practice relaxation
- Phone a friend
- Catch up on all those household projects you've been putting off

Avoid the temptation
You've worked too hard to go back to smoking; so be wise about it. There will be situations where you will be tempted to smoke. Most 'slips' occur in social or stressful situations, especially if alcohol is being consumed. You may want to try to avoid these settings in the first few weeks after quitting. Have a plan if you will be around smokers or in a stressful situation to ensure you stay on track with your new life as a non-smoker. If you are in a situation that you feel tempted to smoke remember the 4D's – Delay, Drink water, Distract, Deep breaths.

If you have a slip…
You may feel frustrated, angry or discouraged. Don't worry, that's normal! Should you have a slip, have a plan to get back on track and start stopping all over again! If you find yourself smoking:

Change the situation – stop smoking immediately, leave the room, throw out your cigarettes… and carry on with your quit attempt.

Talk positively to yourself – remind yourself of how far you have come, encourage yourself to keep at it.

Take action – find something else to do that makes it difficult to smoke (eg. shower), do physical activity, chew mint flavoured gum, find a bigger focus than your craving (eg. the news).

Ask for help – talk to someone to distract or encourage you.

Don't let a slip throw you off your quit smoking plan. Don't hesitate to give us a call if you are having any trouble – we are here to help.

If you are having trouble staying quit, please call us at 613-761-4866

LOOKING FOR MORE SUPPORT?

There are several quit smoking programs in our region which offer telephone, group, or individual support with quitting smoking.

Smokers' Helpline Canadian Cancer Society
Tel: 1-877-513-5333
Appropriate for:
- Smokers who want to quit, may be thinking about quitting, or need support to remain smoke-free
- Family members

Hours: Mon to Thurs: 8:00 a.m. – 9:00 p.m.
Fri: 8:00 a.m. – 6:00 p.m.
Sat & Sun: 9:00 a.m. – 5:00 p.m.
www.smokershelpline.ca

Quit Smoking Program Heart Health Education Centre
University of Ottawa Heart Institute (UOHI)
Room H-2342 40 Ruskin Street, Ottawa, ON
Tel: 613-761-5464 Toll Free: 1-866-399-4432
Fax: 613-761-5309
Appropriate for: All adult smokers requiring assistance with making a cessation attempt
Hours: Clinic hours: weekdays

A.C.E.S.S. Smoking Cessation Program
Ottawa Public Health (OPH)100 Constellation Crescent, Ottawa, ON Tel: 613-580-6744 or Toll Free: 1-866-426-8885
Description: This program is a partnership between Ottawa Public Health and Community Health Centres. 8-week group program offered fall, spring, and winter. The program offers subsidized NRT. Schedule and location of quit smoking programs posted 3 times per year.

UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

OTTAWA MODEL FOR SMOKING CESSATION
MODÈLE D'OTTAWA POUR L'ABANDON DU TABAC

Quit Smoking Program
Eastern Ontario Health Unit
Head Office: 1000 Pitt Street, Cornwall, ON
Tel: 613-933-1375 or Toll Free: 1-800-267-7120 (Ask for Health Line)
Appropriate for: All smokers
Various locations across five counties based on demand.
Hours: Offered in fall and winter

Out-Patient Smoking Cessation Program
Hawkesbury & District General Hospital
Contact: Diandre Gilbert
Tel: 613-632-1111 Ext. 168
Appropriate for: Residents of Ontario who are 18 and over and want to quit smoking using NRT.
Hours: Clinic hours: weekdays and evenings

Renfrew County and District Health Unit
7 International Drive, Pembroke, ON
Tel: 613-732-3629 or Toll Free: 1-800-267-1097
Appropriate for: All smokers
Hours: Vary

Leeds, Grenville & Lanark District Health Unit
458 Laurier Boulevard, Brockville, ON
Tel: 613-345-5685 or Toll Free: 1-800-660-5853
Appropriate for: All smokers
Hours: Vary

ACKNOWLEDGEMENTS
Information in this quit plan has been adapted from the following sources:

One step at a time: For Smokers who don't want to quit. Canadian Cancer Society.

On the Road to Quitting: Guide to becoming a non-smoker. Health Canada.

Quit: You have it in you. Smoke Free Ontario. Ontario Ministry of Health Promotion.

U.S. Department of Health and Human Services. Treating Tobacco use and dependence: Clinical practice guideline 2008 update.

Appendix P - Booklet for Smokers Not Ready to Quit (FC Group Only)

LOOKING FOR MORE SUPPORT?

There are several quit smoking programs in our region which offer telephone, group, or individual support with quitting smoking.

Smokers' Helpline Canadian Cancer Society
Tel: 1-877-513-5333
Appropriate for:
- Smokers who want to quit, may be thinking about quitting, or need support to remain smoke-free
- Family members

Hours: Mon to Thurs: 8:00 a.m. – 9:00 p.m.
Fri: 8:00 a.m. – 6:00 p.m.
Sat & Sun: 9:00 a.m. – 5:00 p.m.
www.smokershelpline.ca

Quit Smoking Program Heart Health Education Centre
University of Ottawa Heart Institute (UOHI)
Room H-2342 40 Ruskin Street, Ottawa, ON
Tel: 613-761-5464 Toll Free: 1-866-399-4432
Fax: 613-761-5309
Appropriate for: All adult smokers requiring assistance with making a cessation attempt
Hours: Clinic hours weekdays and evenings

A.C.E.S.S. Smoking Cessation Program
Ottawa Public Health (OPH)100 Constellation Crescent, Ottawa, ON Tel: 613-580-6744 or Toll Free: 1-866-426-8885
Description: This program is a partnership between Ottawa Public Health and Community Health Centres. 8-week group program offered fall, spring, and winter. The program offers subsidized NRT. Schedule and location of quit smoking programs posted 3 times per year.

UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA
OTTAWA MODEL FOR SMOKING CESSATION
MODÈLE D'OTTAWA POUR L'ABANDON DU TABAC

Quit Smoking Program
Eastern Ontario Health Unit
Head Office: 1000 Pitt Street, Cornwall, ON
Tel: 613-933-1375 or Toll Free:
1-800-267-7120 (Ask for Health Line)
Appropriate for: All smokers
Various locations across five counties based on demand.
Hours: Offered in fall and winter

Out-Patient Smoking Cessation Program
Hawkesbury & District General Hospital
Contact: Dierdre Gilbert
Tel: 613-632-1111 Ext. 168
Appropriate for: Residents of Ontario who are 18 and over and want to quit smoking using NRT.
Hours: Clinic hours weekdays and evenings

Renfrew County and District Health Unit
7 International Drive, Pembroke, ON
Tel: 613-732-3629 or Toll Free: 1-800-267-1097
Appropriate for: All smokers
Hours: Vary

Leeds, Grenville & Lanark District Health Unit
458 Laurier Boulevard, Brockville, ON
Tel: 613-345-5685 or Toll Free: 1-800-660-5853
Appropriate for: All smokers
Hours: Vary

ACKNOWLEDGEMENTS
Information in this quit plan has been adapted from the following sources:

One step at a time: For Smokers who don't want to quit. Canadian Cancer Society.

On the Road to Quitting: Guide to becoming a non-smoker. Health Canada.

Quit: You have it in you. Smoke Free Ontario. Ontario Ministry of Health Promotion.

U.S. Department of Health and Human Services. Treating Tobacco use and dependence: Clinical practice guideline 2008 update.

SMOKING CESSATION IN PRIMARY CARE

FOR SMOKERS NOT READY TO QUIT

Quitting Smoking is not easy and you may not be ready to quit today. On the other hand there is never really a good time to stop smoking and you should not postpone stopping smoking by waiting for the right time.

Please take these materials about getting ready to quit smoking home with you and look them over and think seriously about quitting soon. We have new ways to help you quit and when you're ready to quit we can work with you to ensure you have a plan in place to help you deal with withdrawl, stress and weight gain.

Your doctor would like to follow-up with you in one month

Your doctor would like to check in with you in a few weeks time to see if you are interested in quitting smoking. To do so, we will be enrolling you in our automated follow-up program. The quit smoking follow-up program is delivered by an automated telephone system which will call you on your chosen dates and times. The automated calls are a great way for us to learn about how you are doing.

Each call will take less than five minutes!

- During the phone call, you will be asked a series of 'yes' or 'no' questions.
- If you have call display the follow-up system will appear on your call display as the "Help 2 Quit".
- The system will call you in 30 and 60 days time at the time you have chosen.
- If you are ready to quit smoking at that time we will connect you to our trained smoking cessation counsellor who will work with you to ensure you are well equipped to quit.

You can expect a call the week of: _____

Even if you're not interested in quitting smoking, it's important to us to follow-up with you. We greatly appreciate if you could ensure you answer the calls and respond to the questions.

If you have any questions or are interested in quitting before we call you in a months time, feel free to get in contact with our quit smoking counsellor at 613-761-4866.

Remember, quitting smoking is the single most important thing you can do for your health!

THE BENEFITS OF QUITTING ARE IMMEDIATE

- **Within 8 hours of quitting:** Carbon monoxide levels drop, oxygen levels go back to normal.
- **Within 48 hours of quitting:** The chances of having a heart attack start decreasing, and the senses of taste and smell start improving.
- **Within 72 hours of quitting:** Bronchial tubes relax, which makes breathing easier and lung capacity increases.
- **Within 2 weeks to 3 months of quitting:** Blood circulation gets better, and lung function improves by as much as 30%.
- **Within 6 months of quitting:** Coughing, tiredness, sinus congestion and shortness of breath all improve.
- **Within 1 year of quitting:** The risk of heart attack due to smoking falls to half that of someone who still smokes.
- **Within 10 years of quitting:** The risk of dying from lung cancer falls to half that of someone who still smokes.
- **Within 15 years of quitting:** The risk of dying from a heart attack becomes the same as for someone who has never smoked.

Appendix Q - Patient Exit Survey

SMOKING AND YOUR FAMILY DOCTOR STUDY PATIENT SURVEY

Thank you for taking part in this survey. Please read and respond to the questions below which relate to your smoking history and visit to the clinic today. By responding to this survey you are in no way obligated to make any changes to your smoking habits. We are simply conducting an assessment of how clinic staff address smoking with their patient's before and after they receive training and implement new processes in the clinic. Please be honest when answering the questions, it is the best way for us to evaluate the success of the program.

The survey should take about 10-15 minutes to complete. Please speak to the research assistant if you have any questions or concerns about any of the survey questions.

Thank you for your assistance.

ABOUT YOUR VISIT TO THE CLINIC TODAY

1. Have you completed this survey before?

- ☐ Yes
- ☐ No
- ☐ Don't know

2. a) Did your doctor ask you about your smoking status? (This includes any surveys you may have filled out)

Today:
- ☐ Yes
- ☐ No
- ☐ Don't Know

In the Last Year:
- ☐ Yes
- ☐ No
- ☐ Don't know

b) Did another member of the clinic staff ask you about your smoking status? (This includes any surveys you may have filled out)

Today:
- ☐ Yes
- ☐ No

In the Last Year:
- ☐ Yes
- ☐ No
- ☐ Don't Know
- ☐ Don't know

3. a) Did your doctor advise you to quit smoking?

Today:
- ☐ Yes
- ☐ No
- ☐ Don't Know

In the last year:
- ☐ Yes
- ☐ No
- ☐ Don't Know

b) Did another clinic staff member advise you to quit smoking?

Today:

- ☐ Yes
- ☐ No
- ☐ Don't Know

In the last year:

- ☐ Yes
- ☐ No
- ☐ Don't Know

4. a) Did your doctor ask if you were interested in quitting smoking?

Today:

- ☐ Yes
- ☐ No
- ☐ Don't Know

In the last year:

- ☐ Yes
- ☐ No
- ☐ Don't Know

b) Did another clinic staff member ask if you were interested in quitting smoking?

Today:

- ☐ Yes
- ☐ No
- ☐ Don't Know

In the last year:

- ☐ Yes
- ☐ No
- ☐ Don't Know

5. a) Did your doctor offer you assistance in quitting smoking?

Today:

- ☐ Yes
- ☐ No
- ☐ Don't Know

In the last year:

- ☐ Yes
- ☐ No
- ☐ Don't Know

b) Did another clinic staff member offer you assistance in quitting smoking?

Today:

- ☐ Yes
- ☐ No
- ☐ Don't Know

In the last year:

- ☐ Yes
- ☐ No
- ☐ Don't Know

6. How long did the doctor or nurse speak to you specifically about quitting smoking today?

- ☐ Not at all
- ☐ Less then 2 minutes
- ☐ 2-5 minutes
- ☐ 5-10 minutes
- ☐ More than 10 minute

7. Did your doctor or other staff provide you with *written materials* about quitting smoking?

Today:

- ☐ Yes
- ☐ No
- ☐ Don't Know

In the last year:

- ☐ Yes
- ☐ No
- ☐ Don't Know

8. Did you set a date to quit smoking <u>today</u>?

- ☐ Yes
- ☐ No

9. a) Did your doctor discuss with you available smoking cessation medications (like the nicotine patch or Varenicline/Champix or Bupropion)?

Today:

- ☐ Yes
- ☐ No
- ☐ Don't Know

In the last year:

- ☐ Yes
- ☐ No
- ☐ Don't Know

b) Did another member of the clinic staff discuss with you available quit smoking medications?

Today:

- ☐ Yes
- ☐ No
- ☐ Don't Know

In the last year:

- ☐ Yes
- ☐ No
- ☐ Don't Know

10. Did your doctor or another member of the staff provide you with a prescription or recommendation to use one of the smoking cessation medications listed above?

Today:

- ☐ Yes
- ☐ No
- ☐ Don't Know

In the last year:

- ☐ Yes
- ☐ No
- ☐ Don't Know

11. Did you schedule a follow-up appointment to discuss your smoking?

- ☐ Yes, please indicate date:_____
- ☐ No
- ☐ Unsure

12. How important is your doctor's advice to quit smoking in motivating you to want to quit?

- ☐ Very important
- ☐ Important
- ☐ Somewhat important
- ☐ Not at all important

13. How important is the advice of other clinic staff (e.g. nurse) in motivating you to want to quit smoking?

- ☐ Very important
- ☐ Important
- ☐ Somewhat important
- ☐ Not at all important

14. How satisfied were you with the support provided to you on smoking cessation while in clinic today?

- ☐ Extremely satisfied
- ☐ Very satisfied
- ☐ Satisfied
- ☐ Somewhat satisfied
- ☐ Not at all satisfied

15. How helpful were the clinic staff to you today as it relates to addressing smoking?

- ☐ Extremely helpful
- ☐ Very Helpful
- ☐ Helpful
- ☐ Somewhat helpful
- ☐ Not at all helpful

SOME INFORMATION ABOUT YOU

16. How many years of formal schooling have you completed? (please circle the appropriate number)

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23

grade school ***high school*** ***college/university***

17. Do you have any of the following conditions?:

Heart Disease	☐ Yes	☐ No	☐ Don't Know	
Heart Attack	☐ Yes	☐ No	☐ Don't Know	
Heart Failure	☐ Yes	☐ No	☐ Don't Know	
Stroke or Transient Ischemic Attack	☐ Yes	☐ No	☐ Don't Know	
Diabetes	☐ Yes	☐ No	☐ Don't Know	
Cancer	☐ Yes	☐ No	☐ Don't Know	
Chronic Bronchitis	☐ Yes	☐ No	☐ Don't Know	
Chronic Obstructive Pulmonary Disorder	☐ Yes	☐ No	☐ Don't Know	
High Blood Pressure	☐ Yes	☐ No	☐ Don't Know	
High Blood Cholesterol	☐ Yes	☐ No	☐ Don't Know	
Depression	☐ Yes	☐ No	☐ Don't Know	
Anxiety	☐ Yes	☐ No	☐ Don't Know	
Mental Illness	☐ Yes	☐ No	☐ Don't Know	☐ prefer not to answer
HIV/AIDS	☐ Yes	☐ No	☐ Don't Know	☐ prefer not to answer

18. What was the purpose of your visit today?

☐ Annual visit
☐ Follow-up
☐ Other: _____

YOUR SMOKING HISTORY

Age: _____**years**

Your Sex: ☐ Male ☐ Female

On average how many cigarettes do you smoke per day? _____cigs/day
If you do not smoke daily provide cigarettes you smoke per month _____cigs/month

How many years have you been smoking? _____years

How soon after you wake up do you smoke your first cigarette?
- ☐ After 60 minutes
- ☐ 31-60 minutes
- ☐ 6-30 minutes
- ☐ Within 5 minutes

How many quit attempts (lasting >24 hours) have you made in the past year?
- ☐ No attempts
- ☐ 1-2 attempts
- ☐ 3 or more attempts

Do others smoke in your home?
- ☐ Yes
- ☐ No

Are you exposed to second-hand smoke in your home or another place where you spend a lot of time?
- ☐ Yes
- ☐ No

Which of the following best describes your feelings about smoking right now?

- ☐ I would like to quit in the next 30 days
- ☐ I would like to quit in the next 6 months
- ☐ I am not planning on quitting in the next 6 months

On a scale of 1 to 10 how confident are you that you would be able to quit smoking at this time? (1=not at all confident, 10=extremely confident) **circle your response**

1	2	3	4	5	6	7	8	9	10

On a scale of 1 to 10 how important is it to you to quit smoking at this time?
(1=not important at all, 10=extremely important) **circle your response**

1	2	3	4	5	6	7	8	9	10

Thank you very much for taking the time to complete this survey. Please return the survey to the research assistant. Have a good day!

CONTACT INFORMATION SHEET

In order for us to contact you in four months time for the brief telephone interview, please provide us with the following information.

The best number to contact you is: ( ) _____

This is your number at: ⎥home □ work ⎥cellular

An alternate telephone contact is: ( )_____

This is your number at: ⎥home □ work ⎥cellular

Please indicate the best time to contact you:

____AM _____PM ____EVENING OTHER: _____

Please indicate the best day of the week to contact you:

___MON ___TUES ___WED ___THURS ___FRI ___SAT ___SUN

Your Mailing Address:

Street:_____ Apt:_____

City:_____ Province: _____

Postal Code: _____

Appendix R - 16-week Telephone Interview Script and Log Form

PRACTICE ID NUMBER: _____

STUDY ID NUMBER: _____

DATE: _____

INTERVIEWER: _____

INTERVIEW:

- ☐ **Not Completed**
- ☐ **Partially Completed**
- ☐ **Completed**

TELEPHONE SCRIPT AND RESPONSE LOG

"Good Morning/Afternoon/or Evening. My name is _____ and I am calling from the University of Ottawa Heart Institute. **May I please speak with Mr/Mrs/Ms X?"**

<u>If patient not at home</u>:
"Thank you. We would like to reach Mr/Mrs/Ms X. We will try again later. If Mr/Mrs/Ms X should like to contact us, we can be reached at 613-798-5555 ext: 17178.

<u>Once patient is on the phone</u>:
"Good Morning/Afternoon/or Evening Mr/Mrs/Ms X. This is _____ calling from the University of Ottawa Heart Institute in follow-up to the survey you completed in Dr. <insert doctors name> _____ office OR/ at the <insert clinic name>_____back in _____(state month). Thank you again for participating in our study which will help us evaluate a new program being implemented at your family doctors office / <insert clinic name>. It has been 16 weeks since you helped us with completing the written survey in the waiting room of your family doctors office and we are calling to complete the follow-up survey. This will take about 5-10 minutes of your time to complete.

Is this a good time for you to complete the survey?

- ☐ Yes - **If Yes**: Complete remainder of survey
- ☐ No - **If No:** No problem. Perhaps you could let me know what would be the best time to call you back. Note time on call log.

SECTION 1: SMOKING STATUS

"I have a series of questions for you related to your smoking habits. There are no right or wrong answers. In order to properly evaluate the program it is most helpful if you can be honest with your answers. All the responses you provide to us will be kept confidential."

1. "Have you smoked any form of tobacco in the last 12 weeks?" The response options are:

- A) No not a puff
- B) 1 to 5 cigarettes
- C) More than 5 cigarettes

2. "Have you smoked any form of tobacco (even a puff) in the last 7 days?"

- Yes – SKIP TO SECTION 3
- No

SECTION 2 – NOT SMOKING

That's great to hear you have been able to quit.

3. "Do you recall the approximate date that you quit smoking?"

Day _____ Month _____

4. "Did you use a quit smoking medication like the nicotine patch or varenicline or bupropion to help you quit smoking?"

- Yes
- No – Skip to question 6

5. "Which medication did you use?"

- patch
- gum
- inhaler
- varenicline/champix
- bupropion/zyban

6. "Have you sought/received counselling for smoking cessation from your primary care physician office?"

- Yes
- No

7. "Have you attended any other smoking cessation program?"

- Yes - Specify: _____
- No

"Because this is a research study, it would be very much appreciated if you could provide us with a saliva sample to document that you are not currently smoking. We would mail you a test kit to your home. Which only requires a few minutes to complete and we will provide you with a package to return the test to us at no cost to you."

8. Are you okay with us mailing you the test kit and have you return it to us by mail?"

- Yes
- No – "Okay we understand". Skip to question 20

If YES: Provide instructions about mail-out of NicAlert test to participant's home. Confirm mailing address and prepare kit to be mailed.

Great. I will be sending you the Saliva Sample Kit by mail. Instructions will be included – the test will take only a few minutes of your time to complete.

9. Can you confirm that you are not presently using a nicotine patch, gum or inhaler.

- Yes
- No

If yes, I see, because the saliva test will pick up on the nicotine in the product we would prefer to collect a breath sample from you. . To take the breath sample we have you blow into a carbon monoxide machine and the machine gives us a reading. The test takes less than a minute to complete. To obtain the breath sample we could have you come into the Heart Institute at the time of your choosing or we could arrange to have a staff member come to a public place in your community if that is easier for you.

10. Are you okay with us arranging to take a breath sample?

- Yes
- No - Skip to Question 20.

11. Can I also confirm that we have the correct mailing address – repeat address from contact sheet. Is this correct:

- Yes
- No

If NO: "May I have the correct address".

Mailing Address: _____

_____

_____

SECTION 3: FOR CURRENT SMOKERS (RESPONDED YES TO QUESTION 2)

"We know quitting smoking can be difficult. I have a couple of questions for you about what's happened since we last saw you at the clinic."

12. Have you attempted to quit smoking since your clinic appointment on (indicate date of appointment)?

- Yes
- No **– SKIP TO QUESTION 17**

13. "How soon after your quit date did you resume smoking?"

Date:_____ Month: _____

14. "What would you say was the primary reason you went back to smoking?"

Answer: _____

15. "Did you use a quit smoking medication like the nicotine patch or varenicline or bupropion when attempting to quit?"

- Yes
- No **– SKIP TO QUESTION 17**

16. "Which medication did you use?"

- Nicotine patch
- Nicotine gum
- Nicotine inhaler
- varenicline/champix
- bupropion/zyban

17. "How many cigarettes per day are you currently smoking?" #:_____

18. "How would you describe your feeling about quitting smoking right now. Do you want to quit smoking in the next?"

- 7 days
- 30 days
- 6 months or
- would you say you don't want to quit smoking

If patient enquires about support with quitting:

If you are interested in assistance with quitting there several programs available to help you. Please don't hesitate to call the Smoking Cessation Counsellor at any time should you feel you need support or information at 613 761-4866.

19. "Have you sought/received counselling for smoking cessation from your primary care physician office?"

- Yes
- No

CLOSING REMARKS:

My final questions for you relate to your primary care doctor.

20. Have you had an appointment with your doctor in the last 12-months?

- Yes
- No – SKIP TO QUESTION 24

21. Has your family doctor or another member of the clinic staff advised you to quit smoking in the last 12-months?

- Yes – IF YES (doctor, nurse, counsellor, pharmacist, other _____)
- No
- Unsure

22. In the last 12-months has your doctor or another member of the clinic staff recommended to you about available quit smoking medications?

- Yes – IF YES (doctor, nurse, counsellor, pharmacist, other _____)
- No
- Unsure

23. In the last 12-months, has your doctor or another member of the clinic staff written you a prescription for a quit smoking medication?

- Yes – IF YES (doctor, nurse, counsellor, pharmacist, other _____)
- No
- Unsure

24. On a scale from 1 to 10 (where 1 is not at all important and 10 is very important) how important is your doctor's advise and support in motivating you to want to quit smoking?
ANSWER: _____

25. Are you satisfied with the support you receive from your doctor as it relates to smoking?

- Yes
- No
- Unsure

"That concludes the interview. On behalf of the Heart Institute and Dr. <family doctor's name> thank you again Mr/Mrs/Ms (last name) for participating in our smoking cessation program.

IF WE ARE COLLECTING A CO TESTING: We appreciate your assistance with collecting the breath sample. A reminder that we will <review details agreed to for sample collection including location, date, time.>"

"Thank you again for taking the time to complete the survey. It is very much appreciated."

Appendix S - Power Calculations

Power	*ICC*	*Alpha*	*Group 1 Clusters/Patients*	*Group 2 Clusters/Patients*	*Prop Group 1*	*Prop Group 2*	*Differ*
0.3643	*0.01*	*0.05*	*4/55*	*4/55*	*0.05*	*0.10*	*0.05*
0.8156	*0.01*	*0.05*	*4/55*	*4/55*	*0.05*	*0.15*	*0.10*
0.9760	*0.01*	*0.05*	*4/55*	*4/55*	*0.05*	*0.20*	*0.15*
0.9985	*0.01*	*0.05*	*4/55*	*4/55*	*0.05*	*0.25*	*0.20*
1.00	*0.01*	*0.05*	*4/55*	*4/55*	*0.05*	*0.30*	*0.25*
0.2495	*0.01*	*0.05*	*4/55*	*4/55*	*0.10*	*0.15*	*0.05*
0.6670	*0.01*	*0.05*	*4/55*	*4/55*	*0.10*	*0.20*	*0.10*
0.9258	*0.01*	*0.05*	*4/55*	*4/55*	*0.10*	*0.25*	*0.15*
0.9919	*0.01*	*0.05*	*4/55*	*4/55*	*0.10*	*0.30*	*0.20*

Grey highlight = power > 80%

Appendix T - Effect estimates of published multi-component intervention studies

Author	Population	Measure[a]	FU [b]	Intervention	Ask	Advice	Assess	Quit Date	Medi-cations	Quit Rate
Katz (2004) Control Intervention Difference	>18 years >1 cig/d irrespective of intentions to quit	7-day ppa	6	- Counselling - Training - Screener - Feedback - Cost-Free NRT	67 87 20	38 47 9	30 73 43	1 27 26	14	9.8 15.4 5.6
Katz (2002) Control Intervention Difference	>1 cig >18 years irrespective of intentions to quit	7-day ppa	6	-Counselling - Training - Screener - Feedback	3	11	52	36	29	11.3 21.2 9.8
Grandes (2000) Control Intervention Difference	15-70 years >1 cig/d willing to stop smoking	co 6-months	12	- Counselling - Training - Desktop - Cost-Free NRT						2.1 7.07 4.97
Pieterse (2001) Control Intervention Difference	18-70 years >1 cig/d	ppa	12	- Counselling - Training - Screener						3.06 8.1 5.04
Twardella (2007) Control Intervention Difference	>10 cig/d 36-75 years irrespective of intentions to quit	ppa	12	- Training - Incentive - Cost-Free NRT						2.7 14.6 11.9
Unrod (2007) Control Intervention Difference	>18 years >100 cigs in lifetimes irrespective of intentions to quit	Not reported	6	- Training - Desktop	13.8	39.2	23.8	35.9	25.4	7.9 11.8 3.9

[a] *ppa = point prevalence abstinence; co = continuous abstinence*
[b] Follow-up reported in months

Appendix U - Patient Invite Letter and Eligibility Screener

UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

OUR CLINIC IS PARTICIPATING IN A STUDY: YOUR PARTICIPATION IS APPRECIATED

Dear Patient,

Our clinic is participating in a study being conducted by the University of Ottawa Heart Institute in collaboration with the University of Waterloo. The study is evaluating how well our clinic staff are doing with addressing health promotion with patients. Participation in the study is voluntary and all your answers will be kept confidential.

In order to determine if you are eligible to take part in the study please check YES or NO for each of the following questions:

Are you 18 years of age or older?	☐ Yes ☐ No
Have you smoked any form of tobacco (eg. cigarettes) in the past 7 days?	☐ Yes ☐ No
Do you have access to a telephone where we can reach you?	☐ Yes ☐ No
Are you able to complete a survey in either English or French?	☐ Yes ☐ No

IF YOU ANSWERED YES TO ALL THE QUESTIONS ABOVE, YOU ARE ELIGIBLE TO PARTICIPATE IN THE STUDY.

The survey will take 10 minutes to complete at the end of your visit today. If you do not have time to stay you can take a copy of the survey home with you and mail it back at your convenience. Our research assistant will provide you with a copy of the study materials and will answer any questions you may have.

Would you be willing to take part in our study? ☐ Yes ☐ No

Please drop this form off to our research assistant located in the clinic waiting room before heading into your clinic appointment today. **THANK YOU**

This project was reviewed and received research ethics approval through the Office of Research Ethics at the University of Waterloo and the University of Ottawa Heart Institute Human Research Ethics Board. Upon request a private area will be made available to respond to any questions you may have about the study.

Appendix V - Patient Information Sheet and Consent Form

Patient Information Sheet & Consent Form

Comparative evaluation of two interventions for integrating smoking cessation into routine primary care practice: A cluster-randomized trial

Student Investigator: Sophia Papadakis, MHA, PhD candidate Tel. 613-761-5489
University of Waterloo Health Studies and Gerontology:

Paul McDonald, PhD	Tel. 519-888-4567 ext. 35839
Roy Cameron, PhD.	Tel. 519-888-4567 ext. 84503
Stephen Brown, PhD	Tel. 519-888-4567 ext. 35500

University of Ottawa Heart Institute Minto Prevention and Rehabilitation Centre:

Andrew Pipe, MD	Tel. 613-761-4756
Robert Reid, PhD, MBA	Tel. 613-761-5058

Please read this Information Sheet and Consent Form carefully and ask as many questions as you like before deciding whether to participate.

Introduction:
You have been asked to participate in a research study being conducted by the University of Waterloo and the University of Ottawa Heart Institute with the support of your family doctor's office. The purpose of this study is to document how often your family doctor addresses smoking with his/her patients and the smoking status of patients in the 4-month period following their visit to the clinic. We are surveying smokers who attend this clinic before and after implementing an intervention program. The intervention program is designed to help clinic staff with assisting patients who smoke with quitting. We hope this study will provide valuable information about how best family doctors can help their patient's with quitting smoking.

Procedure:
If you agree to participate in the study you will be asked to complete the two phases of the study. **Phase One** involves the completion of a brief survey following your visit with your family doctor. The survey will take approximately 5-10 minutes to complete. The survey will collect information on whether or not your family doctor or another member of the staff provided information to you about smoking and if they offered you assistance with quitting. **Phase Two** of the research involves a telephone interview in 4-months time. The interview will take 5 to 10 minutes to complete and will be scheduled on a date and time that is convenient for you. You will be asked about your smoking status

and experiences with smoking over the past 3-months. Because this is a research study we may ask patients who have been able to quit smoking to provide a saliva sample to confirm they have been able to successfully quit smoking. To do so we would mail home saliva test kit to you along with return packaging at no cost to you. The kit simply requires you to spit into a container and mail it back to us. You are under no obligation to quit smoking as part of this study.

Risks and Discomforts of Participation:

There are no risks associated with your participation in this study. The time required to complete the 10 minute survey and complete the 10 minute telephone follow-up interview may be an inconvenience to you.

Benefits of Participation:

You may not receive any direct benefit from your participation in this research. Your participation in this research will allow the researchers to evaluate and refine a program for assisting family doctors in our region help their patients to quit smoking which may be of benefit for future patients.

Compensation /Remuneration:

There will be no financial remuneration for participation in this study. By participating in the study and signing this Consent, you are not waiving your legal rights that may be available to you.

Confidentiality:

As part of this research protocol, the Investigators and their clinical research staff will have access to your survey and telephone interview responses. Your responses may also be reviewed by representatives of the Heart Institute Human Research Ethics Board under the supervision of the Investigator. You will not be identifiable in publications or presentations.

All information you provide will be considered confidential unless release is required by law. Your survey and interview responses will be identified only by the study code you have been assigned. The data collected will be kept in a secure location and confidentially disposed of in fifteen years time. Your individual responses will not be shared with your family physician or the clinic staff, so please feel free to be honest with your responses.

Ethics:

This study has been reviewed and received ethics approval through the Office of Research Ethics (ORE) at the University of Waterloo and the Human Research Ethics Board (HREB) of the University of Ottawa Heart Institute. These bodies consider the ethical aspects of research projects involving human subjects. If you have any questions about your right as a research subject you may contact Dr. Susan Sykes, Director of the ORE at 519-888-4567, Ext. 36005 or the Chair of the Human Research Ethics Board at the University of Ottawa Heart Institute at 613-798-5555, extension 19865.

Participation:

Participation in research is completely voluntary. You are free to choose to participate or not to participate in this research study. If you agree to participate in this study, you may choose to withdraw your participation at any time by contacting the investigator at the telephone number provided. This will not affect your present or future care. You may also choose not to answer any specific questions.

Consent Form

Comparative evaluation of two interventions for integrating smoking cessation into routine primary care practice: A cluster-randomized trial

Consent to Participate in Research

I understand that I am being asked to participate in a research study about the delivery of smoking treatments by staff working in my family doctors office. This study has been explained to me by _____.

I have read and understood this two page Patient Information Sheet and Consent Form. All my questions at this time have been answered to my satisfaction. If I or any of my family members have any further questions about this study, we may contact Sophia Papadakis at 613-761-5489.

I also understand that this project has been reviewed and received ethics clearance through the Office of Research Ethics (ORE) at the University of Waterloo and the University of Ottawa Heart Institute Research Ethics Board. I may contact these office/boards with any questions or concerns.

I will receive a signed copy of this Patient Information Sheet and Consent Form.

I voluntarily agree to participate in this study.

_____
Patient's Name (Please Print)

_____ _____
Patient's Signature Date

_____
Name of Investigator/Delegate (Please Print)

_____ _____
Signature of Investigator/Delegate Date