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Strategies to improve the delivery of tobacco use treatment in primary care practice (Protocol)

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[Intervention Protocol]

Strategies to improve the delivery of tobacco use treatment in primary care practice

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effectiveness of strategies to increase the delivery of evidence-based tobacco treatment interventions in primary care settings on smoking cessation and provider behaviours.

BACKGROUND

Description of the condition

Tobacco use is the leading cause of premature morbidity and mortality worldwide (World Health Organization 2008). One hundred million tobacco-related deaths occurred in the 20th century, and this number is expected to increase to one billion people in the 21st century (Peto 2001). From a chronic illness perspective, tobacco users have a 50% to 70% greater chance of dying from stroke or coronary heart disease than non-smokers, and 85% of cancers of the trachea, bronchus, and lung are directly attributable to tobacco use (McGill 2000; USDHHS 2004). Tobacco use is also a significant risk factor for other major causes of death including cancer, chronic obstructive pulmonary disease, and lower respiratory tract infections (USDHHS 2004; World Health Organization 2008).

There is overwhelming evidence to support both the 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 2000). Smoking cessation is also considered to be among the most cost-effective preventive interventions available to clinicians (Tengs 1995; Cromwell 1997; Franco 2007; Eddy 2009).

Description of the intervention

Primary care practice, also known as family medicine or general practice, has been identified as an important setting for intervening with tobacco users. Internationally primary care practice can vary in its organization as well as structure. This can include differences in payment structures and staffing models, as well as in the emphasis placed on evidence-based practice and disease pre-

vention. In addition to intervention by physicians, there has been increasing involvement in many countries of allied health professionals (i.e. nurses, pharmacists, respiratory therapists) working in tobacco treatment delivery.

Evidence-based guidelines for the delivery of tobacco treatment exist in many countries which emphasize the important role of primary care clinicians in tobacco treatment delivery. The World Health Organization (WHO) has called for smoking cessation to be integrated into primary health care globally, as it is seen as the most suitable health system 'environment' for providing advice and support on smoking cessation (World Health Organization 2008; Vardavas 2013).

Five strategies (the 5As) underpin evidence-based smoking cessation treatment in clinical settings, as described in clinical practice guidelines: *Ask* (identify smoking status); *Advise* people who smoke to quit; *Assess* readiness to quit; *Assist* with making a quit attempt, including providing behavioural counselling and prescribing first-line smoking cessation medications; and *Arrange* follow-up (Fiore 2008).

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 (Young 2001; Hu 2003; CTUMS 2006; Longo 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. counselling, self-help materials, quit-smoking medications, or follow-up support) are below 20% (Curry 2000; Gottlieb 2001; Young 2001; De Pue 2002; Hu 2003; Piper 2003; Longo 2006).

How the intervention might work

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 2005). There is a lack of implementation knowledge and research to inform the design and delivery of tobacco treatment interventions into routine primary care practice internationally. These strategies include the provision of training, real-time counselling prompts, provider performance feedback, and adjunctive counselling for smokers by health professionals in the practice. Multi-component interventions that combine practice-, provider- and patient-level intervention strategies have been shown to be the most effective method for increasing provider performance in the delivery of smoking cessation treatment and improving cessation rates among patients (Grimshaw 2001; Anderson 2004; Fiore 2008; Papadakis 2010).

Why it is important to do this review

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 2008; Reda 2012; Carson 2012; Stead 2013; Boyle 2014). They have been focused on the effect of providing advice on abstinence, and have not examined the impact of interventions to improve provider performance in the delivery of advice and other evidence-based smoking cessation treatments. There have been two previous published meta-analyses of strategies to influence provider behaviour in the primary care setting. Anderson 2004 reviewed the literature published up to 2001 and Papadakis 2010 published an update which covered the literature prior to 2009 (Papadakis 2010). Our review will provide an update of those findings.

OBJECTIVES

To assess the effectiveness of strategies to increase the delivery of evidence-based tobacco treatment interventions in primary care settings on smoking cessation and provider behaviours.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled trials (RCTs), cluster-randomized controlled trials (cluster-RCTs) with at least four clusters, non-randomized controlled trials, and controlled before-after studies, as defined by the Cochrane Effective Practice and Orgnaization of Care Group (Cochrane EPOC group).

Types of participants

Providers of care in primary healthcare settings and their patients who smoke, or whose smoking behaviour is not documented. We will not cover studies that solely address the behaviour of pregnant women or adolescents in this review, as they are adressed by other Cochrane reviews (Coleman 2012; Chamberlain 2013; Stanton 2013). For the purposes of this review, we define primary care as family medicine or general medical practice. We will not include public health or community interventions in our definition of primary care, nor will we cover interventions delivered in dental offices or pharmacies. We will include trials which cover the whole practice population, as well as those which include specific subpopulations recruited from primary care settings (e.g. people with

chronic obstructive pulmonary disease (COPD), or people with diabetes).

Types of interventions

To be included in this review, the study must involve an intervention strategy designed to increase tobacco treatment delivery, and must be compared to a control group. If there are two or more active arms compared to the controls, we will include both arms. We will also include head-to-head comparisons of two or more active interventions.

Intervention components may be delivered by any health professional, including doctors, nurses, and adjunctive clinical staff from primary care practice settings.

Types of outcome measures

Primary outcomes

The primary outcome measure will be smoking abstinence. For smoking abstinence we will report in the 'Summary of findings' table the timeframe of follow-up assessment and methodology used for the assessment of smoking abstinence:

1. Point prevalence (defined as prevalence of abstinence during a time window immediately preceding the follow-up)
2. Continued or prolonged abstinence between the quit date and follow-up time

We will consider participants lost to follow-up to be still smoking. For the pooled analysis we will report on smoking abstinence for the following time-frames: less than six months, and six months or longer.

Secondary outcomes

i) Practitioner performance in 5As delivery (intermediate outcomes):

- Ask;
- Advise;
- Assess;
- Assist (which we will further divide into 'discuss medications', 'prescribe medications', 'set a quit date', 'provide counselling'); and
- Arrange

ii) Participant quit attempts, defined as abstinence from smoking for a period of 24 hours or more.

Search methods for identification of studies

Electronic searches

We will search the following databases:

- Cochrane Tobacco Addiction Group Specialized Register;
- Cochrane Central Register of Controlled Trials (CENTRAL);
- MEDLINE (via PubMed);
- EMBASE; and
- Trial registers: both www.clinicaltrials.gov and the International Clinical Trials Registration Platform (ICTRP) WHO ICTRP .

We will develop search strategies for the following keyword terms: ('smoking' or 'smoking cessation' or 'tobacco-use cessation', or 'tobacco-use-disorder) AND ('primary health care' or 'physicians' or 'family practice' or 'general practice' or 'general practitioners' or 'physicians, family'). We will set standard search strings using the Cochrane Highly Sensitive Search Strategy for identifying randomized controlled trials, as well as 'controlled trials' or 'evaluation studies'. We will apply no restrictions by language or by publication status. See Appendix 1 for the PubMed search strategy.

Searching other resources

We will search for additional studies by scanning the reference lists of included studies and previous relevant reviews.

Data collection and analysis

Selection of studies

SP and GP will independently review titles and abstracts of reports for possible inclusion, and will subject those selected to a full-text assessment. We will use data management software (DistillerSR) to support the screening process. We will link together multiple reports of the same study. We will review in full text any reports which we can not fully assess using the title and abstract. Two authors (from SP, GP and SK) will independently assess all the full-text articles retrieved, and will resolve any discrepancies by discussion with the third author, who will act as arbiter. A content expert (AP) will act as an arbiter for disagreements about the intervention or content of the study. We will discuss methodological discrepancies with another author (GW), who is expert in clinical trials and meta-analyses. We will include in the review those studies which meet the inclusion criteria. We will list and report the characteristics of the excluded studies, together with the reason for exclusion.

We will exclude trials if they:

- reported on medical residents rather than primary care practitioners;
- evaluated simple physician advice or counselling in the absence of any other intervention component to increase delivery of such advice or counselling;

- evaluated the efficacy of pharmacotherapy without evaluation of any other smoking cessation intervention;

- involved both primary care and specialist settings for which outcome data could not be extracted exclusively for primary care settings;

- measured the impact of the intervention at the level of the community rather than at the level of the practice, practitioner or patient.

Data extraction and management

Two authors (from SP, GP and SK) will extract data independently and categorize studies for subgroup analysis. We will employ a standardized electronic data collection form (DistillerSR). We will collect the following information from each of the selected studies:

- lead and corresponding authors' information;
- year of publication;
- year(s) intervention was delivered;
- country in which intervention was delivered;
- methods of recruitment of healthcare practices and patients within practices;
- inclusion criteria, including subpopulations;
- type of study design (RCT, cluster-RCT, non-RCT, controlled before-and-after study);
- methods of randomization, allocation, concealment and blinding;
- respondent (patient, provider, other: specify);
- data collection method (interview, telephone, mail survey);
- characteristics of study participants (age, sex, co-morbidities, readiness to quit);
- duration of intervention (in weeks); details of the intervention;
- description of the control group or comparator intervention arm;
- outcomes measures and definitions used and time point at which they were assessed (in weeks);
- use of biochemical validation and response rate;
- methods for managing missing data;
- for each outcome:
    - number of participants in each arm;
    - loss to follow-up rate;
    - number of events in each arm;
    - estimate effect with confidence interval;
    - intraclass correlation coefficient (ICC) (cluster-RCTs only);

- for cluster-RCT whether adjustment for clustered data was conducted in analysis;
- funding and declaration of interest for primary investigators; and
- conclusions of the trial authors.

Methods for categorizing details of intervention

We will categorize intervention strategies into four groups, based on the level at which they are designed to intervene (i.e. patient, provider, practice, system level). We will further categorize interventions as either a single or a multi-component intervention. For the purposes of this review, we define single-component interventions as those which include only one intervention strategy. We define multi-component interventions as interventions which include two or more intervention strategies, at any level. We have identified a preliminary list of intervention strategies based on previous systematic reviews (Anderson 2004; Fiore 2008; Papadakis 2010). We will create additional categories as appropriate to describe other intervention modalities identified in the literature.
Within each of these categories, we will classify the interventions by the type of strategy:

Patient-level:

- access to adjunctive counselling
- provision of tailored print materials ·
- demonstration of carbon monoxide levels
- spirometry
- internet- and text-based interventions
- access to cost-free medications

Provider-level:

- provider training
- provider performance feedback

Practice-level:

- automated screeners
- screeners
- checklists
- electronic medical record (EMR) and decision support
- academic detailing
- increased duration of visit

System-level:

- provider incentives

Assessment of risk of bias in included studies

Two authors will independently assess the risk of bias of the included studies, using Cochrane's 'risk of bias' tool (Higgins 2011). We will assess the following domains:

- sequence generation
- allocation concealment
- blinding of participants and personnel
- blinding of outcome assessors
- incomplete outcome data

We will categorize the risk of bias for each of these domains as low, unclear or high.
Additionally, we will assess the following other sources of bias specific to this review:

- selection bias due to recruitment of participants within clusters after allocation;
- balanced baseline characteristics for cluster-RCT design (yes/no);
- adjustment for cluster-randomized design (yes/no); and
- funding source.

For the reporting of provider tobacco treatment delivery, we will compare provider self-reported versus objective assessments.
For the reporting of smoking outcomes we will assess:

- biochemical validation (yes/no)

Measures of treatment effect

For each study we will calculate the risk ratio (RR) and 95% confidence interval (CI) for each intervention group versus control group for smoking abstinence and practitioner performance in 5As delivery.

Unit of analysis issues

We will include studies using cluster-randomisation in the meta-analysis using the patient-level data and adjusted using the ICC reported in the paper. See below (Sensitivity analysis) for the handling of cluster-RCTs that do not control for clustering.

Dealing with missing data

We will report the number of participants lost to follow-up for each outcome in each study. We will consider any participants with missing data as having returned to active smoking, and will include them in the denominator for calculating the risk ratio. We will not impute missing data for 5As interventions.

Assessment of heterogeneity

We will assess statistical heterogeneity amongst subgroups of clinically comparable studies using the I^2 statistic (Higgins 2003). We will consider an I^2 value greater than 50% to indicate substantial heterogeneity.

Assessment of reporting biases

We will not prepare funnel plots for this review, but will consider whether any trials which have been registered but have not published final results may be subject to publication bias.

Data synthesis

Where appropriate, we will perform meta-analysis using a Mantel-Haenszel fixed-effect model.

Subgroup analysis and investigation of heterogeneity

We will use subgroup analysis to investigate the effects of differences in:

- intervention level (patient, provider, practice, system, multi-component) as well as strategies within these levels
- multi-component interventions, categorized according to the levels at which they intervene, the number of intervention components, and the type of components, using the categories above. We will conduct comparisons based on the characteristics of multi-component interventions as appropriate
- country of intervention
- patient populations/co-morbidities, including diabetes, COPD (where available).

Sensitivity analysis

We will use sensitivity analyses to examine the effect on estimates of excluding studies with the following characteristics:

- non-randomized study design
- studies scoring high or unclear on 'risk of bias' assessments
- studies in which the respondent was the provider (i.e. self report)
- outlying studies
- trials which did not control for the clustered nature of the data. For cluster-randomized trials in which the ICC was not reported, we will use sensitivity analysis to test the impact of low and high ICC estimates on outcomes. Based on previously published data for primary care practices, we will assume for purposes of the sensitivity analysis that the minimum and maximum ICC values for smoking abstinence were 0.01 and 0.05 respectively, and 0.05 and 0.15 for the delivery of the 5As strategies (Baskerville 2001).

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Appendix: PubMed search strategy

Search	Query
#28	(#23 AND #24 AND #27) (smoking terms, primary care terms, study terms (no animals))
#27	(#26 NOT #20) (All study terms NOT animals)
#26	(#25 OR #21 OR #22) (Cochrane with eval and clinical)
#25	(#13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19) (Cochrane Search)
#24	(#8 OR #9 OR #10 OR #11 OR #12) (Primary Care Terms)
#23	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7) (Smoking Terms)
#22	clinical trial
#21	evaluation studies
#20	(animals [mh] NOT humans [mh])
#19	trial [ti]
#18	randomly [tiab]
#17	clinical trials as topic [mesh: noexp]
#16	placebo [tiab]
#15	randomized [tiab]
#14	controlled clinical trial [pt]
#13	randomized controlled trial [pt]
#12	general practitioner*
#11	general practice*
#10	family physician*
#9	primary care
#8	primary health care

(*Continued*)

#7	tobacco use disorder
#6	tobacco use cessation
#5	smoking/therapy
#4	smoking/prevention and control
#3	smoking cessation
#2	nicotine
#1	tobacco

CONTRIBUTIONS OF AUTHORS

Roles and responsibilities*	
Task	**Who has agreed to undertake the task?**
Draft the protocol	Sophia Papadakis, George Wells, Shannon Kelly
Develop a search strategy	Sophia Papadakis, Shannon Kelly
Search for trials (usually 2 people)	Sophia Papadakis, Shannon Kelly
Obtain copies of trials	Sophia Papadakis, Gillian Pritchard
Select which trials to include (2 + 1 arbiter)	Sophia Papadakis, Gillian Pritchard, Andrew Pipe
Extract data from trials (2 people)	Sophia Papadakis, Gillian Pritchard
Enter data into Review Manager 5	Gillian Pritchard
Carry out the analysis	Sophia Papadakis, George Wells, Shannon Kelly
Interpret the analysis	Sophia Papadakis, George Wells, Shannon Kelly
Draft the final review	Sophia Papadakis, George Wells, Andrew Pipe
Update the review	Sophia Papadakis, George Wells, Andrew Pipe

DECLARATIONS OF INTEREST

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Sophia Papadakis is employed by the University of Ottawa Heart Institute, which has received educational and research grants from Pfizer Canada, the Heart and Stroke Foundation of Ontario, Public Health Agency of Canada, Ontario Ministry of Health and Long Term Care. S. Papadakis is an inventor of the Ottawa Model for Smoking Cessation and has received royalties from a project funded by Pfizer Canada.

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Shannon Kelly: None known

Gillian Pritchard: None known

George Wells: None known