MARGARET YOKLAAN JIN

### A STUDY ABOUT

### PERSONALIZED ACADEMIC DETAILING -

#### PILOT PROJECT

ON

### SMOKING CESSATION

By

### MARGARET JIN, BSC PHM, PHARMD.

A Thesis

Submitted to the School of Graduate Studies

in Health Research Methodology

for the Degree

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### University of Toronto BACHELOR OF SCIENCE PHARMACY (1998) Toronto, Ontario University of Toronto DOCTOR OF PHARMACY (2007) Toronto, Ontario

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AUTHOR: Margaret Jin, BSc PHM, PharmD (University of Toronto)

SUPERVISOR: Dr. Lisa Dolovich

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# Abstract

### A Study About Personalized Academic Detailing - Pilot Project on Smoking Cessation

### **Background:**

Academic detailing (AD) provides evidence-based education to healthcare professionals in their practice setting and has been found to improve knowledge and prescribing in many situations. Personalized academic detailing (PAD) is a new initiative by the Hamilton Family Health Team (FHT) in which pharmacists integrated within the FHT provide an AD service to prescribers in their office. **Objective:** 

To describe and determine the feasibility of a smoking cessation (SC) PAD program.

### Methods:

<u>Design</u>: Descriptive retrospective cohort pilot project

Setting: Primary Care Setting

<u>Participants:</u> FHT pharmacists, physicians, nurse practitioners (NPs) and their patients

### Intervention:

Pharmacists receive basic AD training and education (upskilling) on SC; and provide education to clinicians

### Feasibility Criteria for success:

- 1. PAD coordinator time to train pharmacists <40 hours
- 2. Average time for upskilling <20 hours
- 3. Average time for PAD session are <60 minutes and <30 minutes for initial and follow-up visits, respectively
- 4. Percentage of clinicians detailed within 3 and 6 months are >50% and >70%, respectively
- 5. Number of new SC referrals to the pharmacist at 3 and 6 months are >5 patients/1.0 full-time equivalent (FTE) pharmacist and >10 patients/1.0 FTE pharmacist, respectively.

### **Results:**

Eight pharmacists (5.8 FTE) received basic AD training and upskilling on SC PAD. Consent was obtained from 48/54 (88.9%) physicians and 9/10 (90.0%) NPs.

The PAD coordinator training time was 29.1 hours. The median time for upskilling was 3.1 hours. The median time for PAD session was 15 and 5 minutes for an initial visit and follow-up visit, respectively. The number of clinicians detailed within 3 and 6 months were 50/64 (78.1%) and 57/64 (89.1%), respectively. The number of new SC referrals at 3 and 6 months was 66 and 200 patients, respectively. **Conclusion:** 

This pilot study showed that the main study is feasible with respect to the management, resources, process and scientific components.

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## List of Abbreviations

AD = Academic Detailing AIDS = Acquired Immune Deficiency Syndrome ASPN = Ambulatory Sentinel Practice Network BC = British Columbia CADC = Canadian Academic Detailing Collaboration CADTH = Canadian Agency for Drugs and Technologies CE = Continuing Education CEP = Centre for Effective Practice CFP = Canadian Family Physician CI = Confidence Interval CME = Continuing Medical Education CNCP = Chronic Non-Cancer Pain COPD = Chronic Obstructive Pulmonary Disease CPG(s) = Clinical Practice GuidelinesDIRC = Drug Information Resource Centre DM = Diabetes Mellitus EMR = Electronic Medical Record F/U = Follow UpFHT(s) = Family Health Team(s) FP = Family Practice FTE = Full Time Equivalent GVT = Government HCP(s) = Health Care Professional(s) HFHT = Hamilton Family Health Team HOC = Health Quality Council ICC(s) = Intracluster correlation(s)LHIN(s) = Local Health Integration Network(s) Max = MaximumMD(s)= Medical Doctor(s) or Family Physician(s) Min = Minimum  $(\min(s)) = Minute(s)$ MOHLTC = Ministry of Health Long Term Care N/A = Not AvailableNAPCRG = North American Primary Care Research Group NETSCC = National Institute for Health Research (NIHR) Evaluation, Trials and Studies **Coordinating Centre** NIHR = National Institute for Health Research NP(s) = Nurse Practitioner(s) NRT(s) = Nicotine Replacement Therapy(ies) NS = Nova ScotiaNSAIDS = Non-Steroidal Anti-inflammatory Drugs

PAD = Personalized Academic Detailing PBRN – Practice-Based Research Network

PBRN – Practice-Based Research Network

PDA = Personal Digital Assistant

PHM(s) = Pharmacist(s)

PrISM = Prescription Information Services of Manitoba

Q&As = Questions and Answers

RCT(s) = Randomized Control Trial(s)

RD(s) = Registered Dietitian(s)

REP(s) = Representative(s)

RPN(s) = Registered Practical Nurse(s)

RR = Relative Risk

SK = Saskatchewan

SMBG = Self Monitoring Blood Glucose

U of C = University of Calgary

URTI = Upper Respiratory Tract Infection

USB = Universal Serial Bus

UTI = Urinary Tract Infection

## **Declaration of Academic Achievement**

I, Margaret Yoklaan Jin, hereby declare that this research is original and the knowledge will be translated accordingly in publications, conferences, abstracts and posters.

Colleagues who have contributed to the contents of this thesis include Catherine Bednarowski, Janie Bowles-Jordan, Leslie Chappell, Dr. Antony Gagnon, Dr. Anne Mallin, Dr. Lisa McCarthy, Christine Rodriguez and Annette Vedelago.

### Chapter 1 <u>1.1 Background</u> 1.1.1 Drug costs in Canada

Medications are the second largest and fastest growing healthcare cost in Canada.<sup>1</sup> In 2010, there were 499.6 million prescriptions dispensed across Canada representing a total of \$23.3 billion.<sup>2</sup> While medications often produce extensive improvements in patient health and well-being, they have also been associated with many preventable adverse events.<sup>3,4</sup> In everyday practice, medications are often used at different dosages from those evaluated in clinical trials: used along with other medications in combinations not considered in clinical trials; or used in types of patients or conditions that were not included in clinical trials. These, along with additional areas of suboptimal prescribing, are contributing factors to drug-related morbidity and mortality.<sup>5</sup> In 2000, the estimated cost of drug-related morbidity and mortality resulting from drug-related problems exceeded \$177.4 billion US.<sup>6</sup> Hospital admissions accounted for nearly 70% (\$121.5 billion US) of total costs, followed by long-term-care admissions, which accounted for 18% (\$32.8 billion US).<sup>6</sup> In Canada, adverse drug reactions occur 7.5 per 100 hospital admissions<sup>7</sup>, are preventable  $(36.9\%)^7$  and prolong hospital stay by an average of 3.6 days.<sup>8</sup> Overall, the direct and indirect costs of drugs have become a heavy financial burden.

### 1.1.2 Academic Detailing

There have been a number of strategies evaluated to improve medication prescribing and use. An overview of 41 systematic reviews of interventions to change provider behaviour by Grimshaw et al<sup>9</sup> found that passive approaches were unlikely to effect changes in provider behaviour, while academic detailing (AD or educational outreach) was considered to be a promising approach, even when delivered as a single intervention. AD is defined as a process of outreach in which physicians are visited by a knowledgeable trained heath professional to discuss issues of drug use and (often) overuse in one-on-one or small group encounters.<sup>10,11</sup> Key components of academic detailing are that detailers (mostly pharmacists, sometimes nurses or other physicians) are not employed by the pharmaceutical industry and the academic detailing programs do not have any financial links to the pharmaceutical industry.

Some of the most important principles of academic detailing include (1) conducting interviews to investigate baseline knowledge and motivations for current prescribing patterns, (2) focusing on programs on specific groups of physicians and opinion leaders, (3) defining clear educational and behavioral objectives, (4) establishing credibility through a respected organizational identity, referencing authoritative and unbiased sources of information, and presenting both sides of controversial issues, (5) stimulating active physician participation in educational interactions, (6) using concise graphic educational materials, (7) highlighting and repeating the essential messages, and (8) providing positive reinforcement of improved practices in follow-up visits.<sup>12</sup> These principles have been used and implemented in academic detailing programs across the

world. The following is a summary of the evidence in academic detailing and the existing programs of academic detailing in Canada.

### **1.1.3 Evidence in Academic Detailing**

AD improves medication prescribing and use. AD has been employed to effect changes in prescribing practices based on the best available evidence to improve patient health outcomes. Some examples of improvements in the appropriate prescribing of antibiotics, <sup>13,14,15,16</sup> antidepressants<sup>17</sup>, benzodiazepines, <sup>18,19,20,21</sup> non-steroidal anti-inflammatory drugs (NSAIDs)<sup>22,23</sup> and diuretics for hypertension<sup>24</sup> by physicians have been observed. AD has also been employed to target behaviours related to the provision of preventive services or the general management of conditions commonly seen in general practice, such as the management of patients with diabetes, <sup>25</sup> patients with osteoporosis, <sup>26</sup> provision of smoking cessation advice, <sup>27</sup> or cancer screening. <sup>28,29</sup> A Health Council of Canada report by Sketris et al<sup>30</sup> supported these findings as part of a review of interventions to target suboptimal prescribing. AD was among one of the more highly rated interventions discussed by Sketris et al<sup>30</sup>, with some studies showing improvements ranging from 1% to 2%, to improve prescribing with a median improvement in physician performance of approximately 6.0%.<sup>11</sup> The positive results of AD has supported some provincial funding in Canada.

### 1.1.4 Academic Detailing in Canada

British Columbia, Saskatchewan and Nova Scotia have province-wide government-funded academic detailing programs. Other existing academic detailing programs include Prescription Information Services of Manitoba (PrISM) and the Hamilton Family Health Team. Other academic detailing pilot programs included the Alberta Health Services (Calgary) Academic Detailing and the Centre for Effective Practice academic detailing program in Ontario. The latter two programs were discontinued due to insufficient financial resources. Each organizational structure varies with the funding model and needs of the individual jurisdictions. (Table 1)

In 2003, the Canadian Academic Detailing Collaboration (CADC) was developed to represent the academic detailers of Canada. With the support of the Canadian Agency for Drugs and Technologies in Health (CADTH), representatives from each academic detailing program meet monthly to share experiences in academic detailing. The mission of CADC is to (1) promote the development and visibility of academic detailing in Canada, (2) collaborate in developing and disseminating evidence-informed interventions to optimize practice and (3) facilitate evaluation of academic detailing and research its impact on health outcomes in Canada.<sup>31</sup> The CADC meets regularly to support, facilitate and assist with the barriers and challenges of academic detailing across Canada.

Aspects of the AD program	British Columbia Provincial Academic Detailing Program	Alberta Health Services (Calgary), Academic Detailing	RxFiles (Saskatchewan)	Prescription Information Services of Manitoba (PrISM)	Hamilton Family Health Team (Ontario)	Dalhousie Academic Detailing Service (Nova Scotia)	Centre for Effective Practice (CEP) (Ontario)
Program start date	March 2008 (BC Community Drug Utilization Program, 1993- 2007)	Fall 2006 – July 2010 (ended)	May 1, 1997	February 1, 2003	January 1, 2008	August 2001	Sept 2007 – August 2008 (ended)
# of FTE detailers	9.0	1.4	3.0	0.3	0.3	1.8	2.0
# of FTE staff	2.5	0.5	0.8	0	0	1.0	1.5
# of MDs detailed (% of total MDS in region of coverage)	~ 800 (20%) with 5 FTEs	~ 175 (20%)	~350 (>50 %)	50-100 (5-10%)	69/69 (100%)	~370 (~55%)	125 (69%)
# of NPs or other HCPs detailed (% of NPs in region of coverage)	~50 NPs, ~200 PHM, ~150 other HCP (nurses, med/PHM students) (% N/A)	~75 HCP (% N/A) including PHM, RD, NP, RPN.	150 PHMs	100-200 PHMs, 10-20 NPs	12/12 (100%)	16 NPs 18 MD students 35 HCPs 150 PHMs (% N/A)	30 (18%) NPs, 25 (13%) family medicine residents
Additional support for AD (e.g., technology)	Laptop, webcam, blackberry, USB drive, library, microphone	Library access, internet, laptop, PDA	Varies depending on local need. Office expense reimbursement as necessary	Laptop, Cell Phones, Internet, University Library Access	University library access, laptop	Computers, PDAs, cellphones Library access	Library access, subscription to DIRC
Average time to book appointment	4 weeks (varies 1 day to 6 months)	3 weeks	1 – 12 weeks	Few days to 6 months	~4 weeks	~2-4 weeks	~2 -3 weeks
Average waiting room time	10 min	10 minutes	10min	10 min	0 min	10 min/visit	N/A
Average time – 1 detailing session (min)	43 min	40 minutes	25min	30 min	20 min	28 min/visit	30 min
Average # of f/u visits	0	0	0	0	0	0, 27 MDs request f/u	0, 44% request f/u
Average time f/u visit (min)	0	0	0	0	0	0	0
# of detailers went to basic training workshop (%)	11 (100%)	1 (50%)	9	2	8 PHMs (5.8FTE)	3 (100%)	5 (85%)
# of detailers attend advance training workshop (%)	10 (90%) – in Jan. 2011	0 (0%)	9	2	5 PHMs (4.8 FTE)	3 (100%)	N/A (no session during pilot)
# of topics detailed - 2010	2	2	2	1	2	2	1
Topic(s) detailed in 2010	Antibiotics in Community Practice (UTI, URTI); COPD	Alzheimer's; Insulin & Type 2 Diabetes (DM)	2010: Heart Failure, Osteoporosis	DM – Insulin Analogues	Hyper- tension, Depres- sion	DM – Insulin Analogues & SMBG, Opioids in CNCP	Type 2 DM
Annual Funding (2008)	\$2.25 million per year	\$225,000	2010 \$400,000	No Annual Funding – Project-based funding	0.2-0.4 FTE in kind	\$300,000	\$450,000

Table 1: Overview of Canadian Academic Detailing Programs - updated March 15, 2011

Aspects of the AD program	British Columbia Provincial Academic Detailing Program	Alberta Health Services (Calgary), Academic Detailing	RxFiles (Saskatchewan)	Prescription Information Services of Manitoba (PrISM)	Hamilton Family Health Team (Ontario)	Dalhousie Academic Detailing Service (Nova Scotia)	Centre for Effective Practice (CEP) (Ontario)
Evaluation of program effectiveness completed?	No	No	Pre vs post changes in prescribing for: psychotropics in elderly, NSAIDs. Physician survey – practice change	No	Yes; # of referrals for smoking cessation	No	No (time limits)
Recipient satisfaction / experience measured?	Yes – satisfaction questionnaire	Yes	Yes, Physician Survey	No	Yes, satis- faction question- naire	Yes	Yes
Cost effectiveness of program determined?	No, but is planned	No	No	No	No	No	No
Steering Committee (who is on it? MD, PHM, NP, government, etc.)	Advisory committee – 7 MDs – BCMD, BCPHM, 4 PHM, 0 NP, gvt reps = 3⁄4 PHMs, researchers, e- health, therapeutics initiative, CE development (MD), 3 secretariat	U of C CME Director, 3 MDs, 2 detailers, Regional Therapeutics Director, Chronic Disease Management Director, 1 Patient Care Manager	6 FP MDs, 1 specialist MD; 4 PHM, 1 administrator, 1 NP, 1 SK Health	No formal steering committee – informal guidance given by pharmacists, NPs and physicians.	1 MD, 3 PHM, 1 dietitian, 1 administra tor from HFHT, 1 social worker	4 family physicians from around the Province	Provincial reps, PHMs, MDs, program developers, AD programs leaders (National, International) academic/ faculty members & program staff
Topic Selection – how selected? Average time for upskilling	Suggestions from MDs, PHMs, academic detailers; 3-4 topic work-ups created & taken to advisory committee for discussion & recommendations 40 hours	Learning needs assessment, MD suggestions, resources, literature, CPG's, gaps in practice 60 to 80 hours	Physician surveys, practice gaps, current topics in news / Q&As, groups who identify practice gaps or current issues (e.g. HQC, CADTH, CADC) 48 hours	Detailer selected base on pragmatic assessment of resources available 60 to 80 hours	PHM, HFHT requests 20 hours	-Wish list from physicians -"Hot topics" -Suggestions from Drug Evaluation Unit of NS - CADTH topics Not documenting	Steering Committee recognized knowledge gaps in DM based on Ontario HQC findings of poor DM control. ~ 20 hours
each topic Average time to develop key messages and tools (hours)	~120 hours	20 to 30 hours	Not documented	40 hours (estimate)	20 hours	at present Not documenting at present	30 hours
Is there a process to update the information? How?	No formal process	No formal process	Yes: drug charts update regularly, publish online Q&As/trials, recent questions, presentations at medical/drug conferences.	No formal process	No formal process	No. Topics are repeated.	N/A
Is there a transparent systematic process used to review literature?	Yes. Use an external content expert. Peer reviewed materials (min. 2 MDs per topic).	No	Not specifically; rely on groups/ publications. (e.g. Cochrane, CADTH)	No	No	Yes, formal process	

Aspects of the AD program	British Columbia Provincial Academic Detailing Program	Alberta Health Services (Calgary), Academic Detailing	RxFiles (Saskatchewan)	Prescription Information Services of Manitoba (PrISM)	Hamilton Family Health Team (Ontario)	Dalhousie Academic Detailing Service (Nova Scotia)	Centre for Effective Practice (CEP) (Ontario)
Is there a process for tool review by members of the target audience prior to use?	Yes, newsletter is reviewed by minimum of 2 physicians (with at least 1 FP physician)	Yes, topic working group: 3 MD reviewers; 1- 2 MDs pilot detailing	Yes; informal review feedback & pilot detailing	Yes – informal review and feedback	Not for smoking cessation	Yes – planning committee & content expert review material	
Use of interactive video links for detailing?	Yes, but only a small number	No	Some but not routine	No	No	No for MDs, Yes for PHMs	
Website?	Yes	Yes	Yes	Yes	No	Yes	
Program website with tools?	No	Yes www.talksfor docs.com	Yes	Yes	None	Yes	
Target approach to prioritize who receives AD?	No	No.	No	No	No	No	
Prescribing profiles generated for each prescriber as ancillary behaviour change tool?	No	No	No	No	Yes (use EMR or patient records if MD is willing)	No	
Other comments			Updating process made possible through "not for profit" sale & online resources services; publish in CFP Journal; participation in CME, undergrad, post-grad training of PHMs/MDs				
* Information provided by individual programs and Canadian Academic Detailing Collaborative							

AD=academic detailing, BC=British Columbia, CADC=Canadian Academic Detailing Collaboration, CADTH=Canadian Agency for Drugs and Technology and Health, CEP=Centre for Effective Practice, CFP=Canadian Family Physician, CME=continuing medical education, CNCP = chronic non-cancer pain, CPGs=clinical practice guidelines, DIRC=drug information resource centre, EMR=electronic medical record, FP=Family Practice, FTE=full-time equivalent, f/u=follow up, gvt=government, HCP=health care professional, HQC=health quality council, MD(s)=medical doctor(s), min=minimum, (min)=minute, N/A=not available, NPs=nurse practitioners, PDA(s)=personal digital assistant, PHM(s)=pharmacist(s), NS=Nova Scotia, RD=registered dietitian, RPN=registered practical nurse, Q&As=questions and answers, Rep(s)=Representatives, SMBG = self monitoring blood glucose, U of C=University of Calgary, USB= Universal Serial Bus

### 1.1.5 Challenges in Academic Detailing

One of the main challenges in academic detailing is the low participation by family physicians in the academic detailing program. In the provinces (BC, SK, NS) which provide funding for academic detailing, all of the practicing family physicians are eligible for academic detailing services. However, many physicians (up to 50% in Nova Scotia) do not participate in the continuing medical education (CME) provided by the academic detailing program. (Table 1)

There are inherent challenges to the delivery of an AD intervention: 1) a relationship takes time to develop between the physician and academic detailer as their interactions are infrequent and 2) the material is 'generic', and is not applied to specific patients within the practice as detailers are typically outside the circle of patient care. In Nova Scotia, some factors that discourage the use of academic detailing include scheduling office time to see an academic detailer, physicians prefer to access CMEs in other ways, they do not want to spend office time doing CME, or they do not want to have CME provided by a non-physician.<sup>32</sup> Other barriers to academic detailing include physicians' doubts about the objectivity, the information was not new or they had other ways to obtain the information, time consuming, meant to cut expenses, politically coloured, and patronizing.<sup>33</sup> Although academic detailing has proven benefit in optimizing prescribing practices, academic detailing has limitations and barriers to some practicing family physicians. In Hamilton, Personalized Academic Detailing (PAD), a novel program, has been developed to offset some of the limitations of the conventional approach to academic detailing.

#### **1.1.6 Personalized Academic Detailing**

PAD is a new concept and has not been published in the literature. PAD is the merger of two professionals: the clinical pharmacist in primary care and the academic detailer. The following is a description of PAD and how it compares to conventional AD.

PAD uses the knowledge exchange approach of AD but takes advantage of existing relationships and roles within the healthcare team to enhance the strength and intensity of the AD approach. The healthcare in Canada and around the developed world has evolved to recognize the value of multidisciplinary team based care. Multidisciplinary care teams are used to provide quality care in a coordinated manner often from the same location or using the common patient medical record. In Ontario, interdisciplinary practice groups have manifested in a structure called Family Health Teams (FHTs). This has led to an increased involvement of allied healthcare professionals placed within family practice offices. For example, pharmacists integrated into primary care can foster components of chronic disease management, health promotion, illness prevention, or patient self-management interventions to optimize medication prescribing and use. Within FHTs, pharmacists are integrated within the family physicians' offices to provide care for the patient with respect to medication issues or chronic disease management such as diabetes, hypertension or hypercholesterolemia.

With the introduction of FHTs within Ontario, an opportunity exists to combine the benefits of AD (e.g., optimal prescribing practices, brief encounters, well-developed materials, and key messages that are practice and policy-relevant) with the benefits of a practitioner who is part of the collaborative interdisciplinary team and can reflect the AD learning points back to real-life patients who the physician cares for. In PAD, a trained healthcare professional integrated within the health team (e.g., the pharmacist) provides the general messages used in conventional AD but then also situates these messages within patient-specific case examples to promote better prescribing practices and delivers the messages in one-on-one, face-to-face encounters. These case examples are patients cared for by the physician they are working with. The clinical experiences between the physician and pharmacist are shared, and their relationship has already been established prior to the PAD session. The core role of PAD is to provide patient-specific, evidence-based information to physicians and other FHT members without any pharmaceutical influence. The word "Personalized" is used because the academic detailing message is "personalized" or patient-specific for the clinicians in whom the pharmacists have access to the patients' medical records. Table 2 compares conventional AD vs. PAD.

Conventional Academic Detailing	Personalized Academic Detailing
Academic Detailer does not work directly	Pharmacist works with the healthcare team
with the clinician	
1-2 visits per year per topic	Pharmacist works in the office at least once
	weekly. Professional relationship is more
	readily established
Academic Detailer provides evidence-	Evidence provided can be patient case-
based information that is generic, not	specific or generic
patient specific	
Answer drug information questions	Answer drug information questions
	Clinicians can refer patients to pharmacists
	Pharmacist has access to patient's medical
	record

Table 2: Conventional Academic Detailing vs. Personalized Academic Detailing

PAD, the merging of the roles of the academic detailer and primary care pharmacist, has theoretical advantages, but has not been formally evaluated. Evidence shows that AD has beneficial effects in improving medication prescribing and use.<sup>11</sup> Evidence also indicates that pharmacists in primary care has the potential to improve patient outcomes.<sup>34,35</sup> The goal of this thesis is to describe the feasibility of PAD in a FHT setting. The results of this study will be used for larger PAD studies.

### **1.2 Research Questions**

### 1.2.1 Main Research Question

Is PAD by primary care pharmacists to clinicians feasible with respect to time for the PAD coordinator to train the pharmacists, time for pharmacists to be trained in smoking cessation detailing, time for a PAD session, number and percentage of clinicians detailed within 3 and 6 months, and number of new patient referrals by the clinician for smoking cessation at 3 and 6 months?

### **1.2.2 Secondary Research Questions**

- 1. Did personalized academic detailing (PAD) by primary care pharmacists to clinicians (family physicians or nurse practitioners) increase the number of referrals for smoking cessation counseling to the pharmacist six months after the PAD session compared to no PAD service?
- 2. What is the administrative time (research in AD topic, identifying physician's patients time, discussion with physician time, documentation, travel time) for the PAD session?
- 3. Where are the PAD encounters taking place (e.g., physician office, hallway, lunchroom, etc.)?
- 4. What tools are used for the PAD sessions (e.g., presentation, handout, etc.)?
- 5. How many PAD sessions were one-on-one, clinician only group session, or multi-disciplinary group team education?

### Chapter 2 2.1 Methods

### 2.1.1 Design

### 2.1.1.1 Descriptive retrospective cohort pilot project

This descriptive retrospective cohort pilot project will assess the process, resources, management and scientific issues required for personalized academic detailing (PAD). A discussion of pilot studies, retrospective studies and alternate designs are provided below to provide more insight into the rationale for choosing a descriptive retrospective cohort pilot design.

### 2.1.1.2 Pilot or Feasibility Studies

The following is a brief summary of the various definitions of pilot or feasibility studies<sup>36,37,38</sup> and how it relates to this research project. Arain et al. distinguishes between "feasibility" and "pilot" studies and consider the National Institute for Health Research (NIHR) Evaluation, Trials and Studies Coordinating Centre (NETSCC) definitions to be most helpful and most closely mirror what investigators are doing.<sup>38</sup> According to NETSCC, feasibility studies are pieces of research done before a main study in order to answer the question "Can this study be done?".<sup>38</sup> They are used to estimate important parameters that are needed to design the main study. For instance:

- Standard deviation of the outcome measure, which is needed in some cases to estimate sample size;
- Willingness of participants to be randomized;
- Willingness of clinicians to recruit participants;
- Number of eligible patients;
- Characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure;
- Follow-up rates, response rates to questionnaires, adherence/compliance rates, or intracluster correlations (ICCs) in cluster trials

Feasibility studies for randomized controlled trials do not necessarily have to be randomized. If a feasibility study is a small randomized controlled trial, it does not need to have a primary outcome and power calculation is not necessary. Instead the sample size should be adequate to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision.<sup>38</sup> Also, feasibility studies do not need to evaluate the outcome of interest; this is left for the main study.

Using the NETSCC definition, pilot studies are a version of the main study that is run in miniature to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure recruitment, randomization, treatment, and follow-up assessments all run smoothly. It will therefore resemble the main study in many respects, including an assessment of the primary outcome. In some cases this will be the first phase of the substantive study and data from the pilot phase may contribute to the final analysis; this can be referred to as an internal pilot. Or at the end of the pilot study the data may be analyzed and set aside, a so-called

### external pilot.<sup>38</sup>

In the review articles written by Thabane et al and Teijlingen and Hundley, both articles do not distinguish between pilot or feasibility studies.<sup>36,37</sup> Thabane et al. provides many definitions of pilot studies from the web.<sup>37</sup> Hence, from the research literature, there is no clear definition of pilot or feasibility studies. However, pilot or feasibility studies are performed and published for various reasons. Some reasons for conducting pilot studies include:<sup>36</sup>

- Developing and testing adequacy of research instruments
- Assessing the feasibility of a (full-scale) study/survey
- Designing a research protocol
- Assessing whether the research protocol is realistic and workable
- Identifying logistical problems which might occur using proposed methods
- Estimating variability in outcomes to help determining sample size
- Collecting preliminary data
- Determining what resources (finance, staff) are needed for a planned study
- Assessing the proposed data analysis techniques to uncover potential problems
- Developing a research question and research plan
- Training a researcher in as many elements of the research process as possible
- Convincing funding bodies that the research team is competent and knowledgeable
- Convincing other stakeholders that the main study is worth supporting

Thabane et al. summarizes the main reasons for conducting pilot studies into four main components: process, resources, management and scientific.<sup>37</sup> A pilot study can assess the feasibility of the processes that are key to the success of the main study (e.g., recruitment rates). A pilot study can assess the time and resources that can occur during the main study (e.g., retention rates, refusal rates, adherence rates, eligibility criteria, understanding of data collection tools, etc.). A pilot study can determine some potential human and data management problems that may occur in the main study (e.g., determining capacity, process time, determining centre willingness and capacity, time commitments, management issues, etc.). And, lastly, a pilot study can assess the scientific component of the study, such as treatment safety, dose, response, effect and variance of the effect (e.g., sufficient data collection, all important data values considered, etc.).<sup>37</sup>

In summary, pilot or feasibility studies have various definitions in the literature. This retrospective cohort descriptive pilot study uses the four main components identified by Thabane et al.<sup>37</sup> to determine if this study is feasible in future PAD studies.

### 2.1.1.3 Retrospective studies

The following is a summary of retrospective studies and how it relates to this pilot study. A retrospective study looks back in time and examines information to answer the research question. In some cases, the information has been recorded for reasons other than research. A retrospective study is usually discouraged when a prospective study is feasible, but is particularly useful as a pilot study that is completed in anticipation of a prospective study. A retrospective study can help to focus the study question, clarify the hypothesis, determine an appropriate sample size, and identify feasibility issues for a prospective study.<sup>39</sup> There are three general types of observational research designs that can be carried out as a retrospective study: case-control, cohort and cross sectional studies.<sup>40</sup>

A case-control study is a study which involves identifying patients who have the outcome of interest (cases) and patients without the same outcome (controls), and looking back to see if they had the exposure of interest.<sup>39,40</sup> In a retrospective cohort study, the investigator identifies a group of subjects of interest, collect data about the predictor variables and subsequent outcomes from the past. A retrospective cohort study is only possible if adequate data about the risk factors and outcomes are available on a cohort of subjects that has been assembled for other purposes.<sup>39</sup> A cross-sectional study "is the observation of a defined population at a single point in time or time interval. The exposure and outcome are determined simultaneously."<sup>41</sup> Cross sectional studies can determine prevalence (the number of cases in a population at a given point in time) and infer causation.<sup>40</sup>

Other retrospective descriptive studies include case reports and case series. A case report is "a report on one patient with an outcome of interest."<sup>41</sup> A case series is "a report on a series of patients with an outcome of interest; no control group is involved."<sup>41</sup> Descriptive studies are useful in generating hypotheses, but cannot test the hypothesis and infer causation.<sup>40</sup>

### 2.1.1.3.1 Advantages and Disadvantages of Retrospective Studies

The advantages of retrospective studies include less resources and cost needed to conduct the study, uses existing records, allows for study of rare occurrences, easier to assess conditions where there is a long latency between exposure and disease, and can generate hypothesis that is then tested prospectively.<sup>39</sup> The disadvantages of retrospective studies include recall bias, lack of important data, difficult to control bias and confounders (no bias and no blinding), difficult to establish cause and effect, and the results are usually hypothesis-generating.<sup>39</sup>

### 2.1.1.4 Confounders and bias as it relates to this study

A confounding variable is one that is associated with the predictor variable and a cause of the outcome variable.<sup>42</sup> Confounding variables are prognostically linked to the outcome of interest and can be unevenly distributed between the study groups. In a non-randomized study, the imbalance of prognostic factors may lead to bias and affect the validity of the study. An example of confounding is to interpret the finding that people who carry lighters are more likely to develop lung cancer as evidence of an association between carrying lighters and lung cancer. Smoking is the confounding factor in this relationship – smokers are more likely to carry lighters and they are also more likely to develop lung cancer.<sup>43</sup> (Figure 1)





In this pilot project, confounding variables that are associated with both the PAD intervention and the outcome variables include education programs and related clinical services. Examples of education programs include pharmaceutical-sponsored individual one-on-one sessions with clinicians (e.g., Pfizer representative detailing Champix® to family physician), pharmaceutical-sponsored CME lunches or dinners, and Hamilton FHT nursing-led CME one-day session on smoking cessation. Examples of some related clinical services included local smoking cessation programs (e.g., St. Joseph's Hospital smoking cessation referral program), national smoking cessation programs (e.g., Canadian Cancer Society, Ottawa Model for Smoking Cessation in Primary Care), and FHT or pharmaceutical-sponsored chronic obstructive pulmonary disease (COPD) clinics lead by a respiratory therapist in the physicians' offices.

Bias due to confounding variables can be minimized during the design and analysis phases of the study. The following is a brief overview of strategies to minimize confounding in the design and analysis phases of the study.

### 2.1.1.4.1 Design Phase Strategies

In the design phase, randomization would reduce or eliminate confounding. In other observational studies, specification and matching are two design phase strategies used to cope with confounders.<sup>42</sup> Specification is the simplest strategy designed to include criteria that specify a value of the potential confounding variable and exclude everyone with a different value.<sup>42</sup> For example, clinicians who saw pharmaceutical representatives in their office would be excluded in this study to answer the research questions. In a case-control study, matching involves selecting cases and controls with matching values of the confounding variable(s). For examples, physicians who saw pharmaceutical representatives in their office and did not receive the PAD intervention (control group) would be compared to physicians who saw pharmaceutical representatives in their office and did receive PAD intervention (case group). Both specification and matching have advantages and disadvantages (Table 3). For future PAD studies, prospective randomization would be the ideal design to minimize bias.

Strategy	Advantages	Disadvantages
Specification	<ul> <li>Easily understood</li> <li>Focuses the sampling of subjects for the research question at hand</li> </ul>	<ul> <li>Limits generalizability</li> <li>May make it difficult to acquire an adequate sample size</li> </ul>
Matching	<ul> <li>Can eliminate the influence of strong constitutional confounders like age and sex</li> <li>Can increase precision (power) by balancing the number of cases and controls in each stratum</li> <li>May be a sampling convenience, making it easier to select the controls in a case-control study</li> </ul>	<ul> <li>May be time consuming and expensive; less efficient than increasing the number of subjects</li> <li>Decision to match must be made at the outset of the study and can have an irreversible adverse effect on the analysis and conclusions</li> <li>Requires an early decision about which variables are predictors and which are confounders</li> <li>Eliminates the option of studying matched variables as predictors or as intervening variables</li> <li>Require a matched analysis</li> <li>Creates the danger of overmatching (reduces power)</li> <li>Only feasible for case-control and multiple-cohort studies</li> </ul>

Table 3: Design Phase Strategies for Coping with Confounders<sup>42</sup>

### 2.1.1.4.2 Analysis Phase Strategies

During the analysis phase of the study, some strategies used to cope with confounding include stratification, statistical adjustment, propensity score adjustment, and instrumental variables.<sup>44</sup> A brief overview of these data-analytical techniques will be discussed. For this pilot study, data analysis techniques do not need to be performed to answer the research questions.

Stratification, similar to specification and matching, ensures that only cases and controls with similar levels of potential confounding variable are compared. It involves segregating the subjects into strata (subgroups) according to the level of a potential confounder and then examining the relationship between the predictor and outcome separately in each stratum.<sup>42,44</sup> The advantages of stratification includes clear interpretation and communication of results, direct warning when treatment groups do not adequately overlap on used covariates, and no assumptions about the relation between outcome and covariates (linearity).<sup>42</sup> The limitations of stratification include possible mismatching if more than two covariates are chosen and the continuous variables have to be classified using arbitrary criteria.<sup>42</sup> (Table 4)

Statistical adjustment such as multivariate adjustment can also be used to adjust for confounders. Commonly used multivariate models include multivariable linear

regression, logistic regression, and Cox proportional hazards regression (survival analysis). In these models, prognostic factors can be added to the analysis to adjust the treatment effect of these confounders. The main advantage of multivariate statistical techniques is that more prognostic variables can be used for adjustment. A ratio of 10-15 subjects or events per independent variable is suggested in the literature.<sup>45,46</sup> If there is not enough subjects of events per independent variable, then a multivariate model may not be the best way to express the data. The advantages and disadvantages of statistical adjustment are summarized in Table 4.

In some instances where the regression model does not fit, propensity scores can also be used to deal with confounding caused by nonrandomized assignment of treatments in cohort studies. D'Agostino found that "the propensity score for an individual, defined as the conditional probability of being treated given the individual's covariates, can be used to balance the covariates in observational studies, and thus reduce bias."<sup>47</sup> Each subject can be assigned a propensity score or predicted probability of treatment based on the measured covariates. The propensity score can be used as the only confounding variable in matched, stratified or multivariate analysis.<sup>42,44</sup> Alternatively, subjects who did and did not receive the treatment can be matched by propensity score, and outcomes compared between matched pairs.<sup>42</sup> The advantages of a propensity score is that it "may allow for unbiased estimates of treatment effects, improve the chances for generating valid causal inferences, and can complement conventional multivariable regression methods."48 One of the limitations of the propensity score is that it only relies on observed covariates available in the data set to balance treatment groups. It is possible that unobserved confounders may affect both the independent and dependent variable. Sensitivity analyses or instrumental variable methods may be used to test the robustness of the results or estimate the treatment effect, respectively. A summary of advantages and disadvantages of propensity score method is listed in Table 4.

Instrumental variables method is used for the estimation of treatment effects in observational studies and has the potential to adjust for all confounders (observed and not observed).<sup>44</sup> An instrumental variable is an observable factor associated with the actual treatment but not directly affecting outcome. This assumption is difficult to fulfill and practically untestable. One of the first examples of instrumental variables was by Permutt and Hebel<sup>49</sup>, who estimated the effect of smoking of pregnant women on their child's birth weight, using an encouragement to stop smoking as the instrumental variable. The difference in mean birth weight between the treatment groups was 92g and the differences in mean cigarettes smoked per day was -6.4. This led to an estimated effect of -15 (92/6.4), meaning an increase of 15g in birth weight for every cigarette per day smoked less.<sup>49</sup> The assumptions made for this method were that the encouragement to stop smoking does not affect birth weight other than through smoking behavior and that every women encouraged to stop smoking actually stopped smoking. These are strong assumptions and one of the major limitations of instrumental variable. A summary of advantages and disadvantages of instrumental variables is listed in Table 4.

Overall, there are many design methods and data-analytical techniques used to reduce bias due to confounding variables. For the purposes of this pilot study, these methods will not be used to answer the research questions.

	2-2 2	
Strategy	Advantages	Disadvantages
Stratification	Easily understood	Number of strata limited by sample
	Flexible and reversible: can	size needed for each stratum
	choose which variables can	<ul> <li>Relevant covariables must be</li> </ul>
	stratify upon after data collection	identified and measured
Statistical	Multiple confounders can be	Model may not fit
Adjustment	controlled simultaneously	Results may be hard to understand
	Information in continuous	Relevant covariables must be
	variables can be fully used	identified and measured
	Flexible and reversible	
Propensity	Multiple confounders can be	Results may be hard to understand
Scores	controlled simultaneously	Relevant covariables must be
	Information in continuous	identified and measured
	variables can be fully used	• Can only be done for exposed and
	Ennances control for controlling	unexposed subjects with overlapping
	treatment then get the outcome	propensity scores, reducing sample
	<ul> <li>If a stratified or matched analysis</li> </ul>	5120
	is used does not require model	
	assumptions	
	Flexible and reversible	
Instrumental	Adjusts for all confounders (both	Assumes instrumental variable only
Variables	observed and unobserved)	affects outcome by being a predictor
		for the treatment assignment and no
		direct predictor for the outcome
		<ul> <li>Treatment effect may not be</li> </ul>
		generalizable to a broader
		population
		Less useful for solving large
		confounding problems such as
		I contounding by indication

Table 4: Analysis Phase Strategies for Coping with Confounders<sup>42,44</sup>

### 2.1.1.5 Rationale for Descriptive Retrospective Pilot Project

A descriptive retrospective pilot project on PAD was chosen for various reasons, including minimal disruption to clinical care, the use of existing data, minimal cost, and to determine the feasibility of PAD for future PAD studies. The Hamilton Family Health Team (HFHT) did not want to randomize the clinicians to receive PAD (e.g., design-delay) because they wanted all clinicians to receive PAD as soon as possible and did not want to delay the intervention. As this was the first evaluation effort of PAD with the HFHT, it was important to start small and demonstrate that an evaluation could be done with minimal disruption to build the relationships and processes needed to set the stage for more sophisticated evaluations. The disadvantages of this study include recall and

selection bias. Recall bias can occur because some of the data required for the primary and secondary research questions were not collected during the PAD project on smoking cessation in 2008. The pharmacists will be asked to recall information from over 3 years ago. Selection bias may also occur as there is no control group for comparison.

### 2.1.1.6 Alternate designs

Alternative methodological designs were considered to answer the research questions, but were not chosen for various reasons. Experimental studies such as prospective randomized control trials (RCTs), cluster randomization, and prospective design-delay RCTs are some designs considered. Observational studies such as cohort, case-control and cross-sectional studies were not considered because there was insufficient resources to compare one group with the intervention against the "control" group. As well, the outcome of interest for this pilot project is based on the feasibility of the program with respect to the process, resources, management and scientific components of the study. Hence, cohort, case-control and cross-sectional studies were not considered as it does not adequately answer the research questions of this pilot study. Below is a brief discussion about other alternative designs considered for this research project.

### 2.1.1.6.1 Prospective Randomized Control Trial including Clustering

A prospective study usually involves taking a cohort of subjects and watching them over a period of time. In a prospective randomized control trial, the clinicians would be randomly assigned PAD or no PAD. Randomization balances the prognosis of the two study groups, thereby minimizing bias and confounding. The advantages of prospective randomized studies are the fewer potential sources of bias and confounding compared to observational studies. This design was not chosen because the Hamilton Family Health Team wanted all clinicians to receive PAD immediately.

A cluster randomization of comparing PAD in different family health teams across Ontario was considered for the research questions. The advantage of clustering is the minimal bias or contamination that can occur due to clinicians within a group practice receiving PAD and discussing the intervention (PAD) with his or her colleagues. For example, in cluster randomization, it is less likely that a family physician in the Hamilton Family Health Team would discuss PAD with another physician in the Thunder Bay Family Health Team. The disadvantage of cluster sampling is the homogeneity between the physicians and/or pharmacists groups. This similarity is expressed by the intracluster correlation coefficient (ICC) which compares the within-group variance with the between-group variance.<sup>50</sup> Mathematically, ICC is the between-cluster variability divided by the sum of the within-cluster and between-cluster variability. The calculation of ICC usually requires a pilot study. ICC is also necessary to calculate the effective sample size (ESS) in a cluster design. A cluster randomization was not chosen for this pilot study because an ICC was not readily available for the pharmacists and physicians in the Hamilton area. Additional resources would be required to determine the effects of PAD in a cluster randomized trial.

### 2.1.1.6.2 Prospective Design Delay

In a prospective design delay study, all pharmacists would be trained in academic detailing and the clinicians would be randomly assigned to PAD or no PAD at baseline. Within a certain timeframe, the second group that did not receive PAD (non-PAD group) would then receive PAD. In prospective design delay studies, the timeframe should be long enough to see a difference between the two groups (expect outcomes of interest to be measurable and outcome to show a difference), but short enough to retain the most up-to-date AD topic and short enough to complete the study based on available resources. Depending on available resources, it is estimated that the timeframe would be between 3-6 months before the non-PAD group receives PAD. The advantage of this study is that all clinicians would receive PAD, and there is minimal bias because of randomization and data is collected prospectively. This design was not chosen because the Hamilton Family Health Team wanted all clinicians to receive PAD immediately.

### 2.1.2 Inclusion/Exclusion Criteria

### 2.1.2.1 Inclusion criteria

Family Health Team (FHT) pharmacists willing to be trained in academic detailing and upskilling/education for smoking cessation were included. FHT clinicians (family physicians and nurse practitioners) willing to receive academic detailing service were also included.

2.1.2.2 Exclusion criteria

Participants who did not consent to be part of the study were excluded.

2.1.2.3 Setting

Primary Care Setting

2.1.2.4 Participants

Family Health Team pharmacists, family physicians, nurse practitioners and their patients

### 2.1.3 Intervention

In this pilot project, a complex intervention containing several interacting components was used. These components include (1) basic academic detailing training, (2) upskilling focused in the area of smoking cessation and (3) a 20-minute one-on-one session with the clinician (physician or nurse practitioner). Some dimensions of complexity include the number and interactions between components within the experimental and control interventions; the number and difficulty of behaviours required by those delivering or receiving the intervention; the number of groups or organizational levels targeted by the intervention; the number and variability of outcomes; and the degree of flexibility or tailoring of the interventions. In this pilot project, some of the complexities of this intervention include the behaviour changes required by the pharmacists delivering the messages, behaviour and/or prescribing changes by the

clinicians, and patient outcomes. The following is a more detailed description of the three components that make up the intervention for this pilot project.

### 2.1.3.1 Academic Detailing Basic Training Workshop

All pharmacists participated in a 3.5 days basic academic detailing workshop facilitated by the leaders of academic detailing in Canada and Australia. Two weeks prior to the workshop, pre-readings<sup>52,53,54,55,56,57,58,59,60,61</sup> were sent to the participants. The workshop consisted of didactic lectures and role-playing to understand the basic skills and knowledge required for an effective academic detailing session (Appendix A). The program content included an overview of academic detailing, structure for academic detailing visits, introductions in academic detailing visits, physicians speaking about pressures of current practice, trust and credibility, getting objectives clear and preparing key messages, management and use of detailing aids, challenging responses, closing the communication loop, preparing for the complete academic detailing visit and a "live" visit. At the end of the workshop, each participant detailed a family physician or nurse practitioner about "The management of sore throat in primary care practice."

### 2.1.3.2 Smoking Cessation Upskilling or education training to the pharmacists

Smoking Cessation reading materials<sup>62,63,64,65</sup> were provided to the pharmacists two weeks prior to the training session. The Academic Detailing Coordinator provided a summary (PowerPoint presentation) of the reading materials and handouts to the pharmacists. Each pharmacist was given the opportunity to practice detailing smoking cessation with their colleagues prior to detailing their clinicians.

The academic detailing trained-pharmacists reviewed an evidence-based smoking cessation (SC) education handout with the clinicians. The 2-page smoking cessation handout to be given to the clinicians was adapted from RxFiles (Appendix B).<sup>66</sup> Five key messages was emphasized: 1) refer patients to pharmacists for SC; 2) caution the use of varenicline in patients with psychiatric disorders; 3) combination therapy of bupropion and nicotine replacement therapy may be considered; 4) nicotine inhaler/lozenges are available in Canada; and 5) nortriptyline can be used for SC.

### 2.1.3.3 Personalized Academic Detailing session with the clinicians

Each pharmacist was encouraged to book a 20-minute one-on-one session with the clinician. Group sessions were discouraged. One-on-one sessions was preferred over large group presentations because evidence shows that large didactic lectures have no or minimal effect on prescribing changes.<sup>67,68</sup> Small group participatory educational meetings have been shown to be effective in some studies and appear promising, but further research is needed.<sup>69</sup> Each pharmacist also educated the rest of the office staff to have patients motivated to quit smoking to see the pharmacist for smoking cessation counseling. Each clinician referred patients motivated to quit smoking to the pharmacist for smoking to the pharmacist for smoking to the pharmacist for smoking cessation counseling.

### 2.1.4 Data collection

In this study, data will be collected both retrospectively and prospectively by busy clinicians. The following sections will review the benefits and limitations of retrospective and prospective data collection, a literature review of self-reporting by busy clinicians and the data that will be collected in this study.

### 2.1.4.1 Retrospective vs. prospective data collection benefits and limitations

Data can be collected retrospectively or prospectively. Both forms of data collection have benefits and limitations (Table 5).<sup>70</sup> Retrospective data collection involves looking back and retrieving data from medical records or subjects to answer the research question. The benefits of retrospective data collection include minimal cost, ability to retrieve data as far back as possible (e.g., years), and less workload. The limitations of retrospective data collection when it comes to medical records include missing data, ineligible hand-writing (e.g., paper charts), and reliability of the data inputted (human error, data entry errors). When asking questions regarding the past, there is also a potential for recall bias.

Prospective data collection involves collecting data over a period of time in the present. Data can be collected by the clinicians or trained research assistants. The benefits of prospective data collection is the potential for more reliable, valid, complete and accurate data to answer the research questions.<sup>71</sup> The limitations of prospective data collection are more cost, seasonal bias if the study is short, and possible attention bias or social desirable bias. Attention bias occurs because people who are part of a study are usually aware of their involvement and as a result of the attention received, may give more favorable responses or perform better than people who are unaware of the study's intent.<sup>72</sup>

Data collection	Benefits/Advantages	Limitations/Disadvantages
Prospective	Data is usually complete	More costly
-	More reliable data	Potential for social desirable bias (attention
	More valid data	bias)
		Can be seasonal data if collected only for a short period of time
		Busy clinicians may not provide accurate data
Retrospective	Less costly	Recall bias
	Can collect data for longer	Not all data may be available in medical
	period of time and avoid	records (incomplete)
	seasonal bias	Data may be entered incorrectly in the
	If using electronic medical	medical record or database
	record, can be very fast and	
	easy to retrieve data	

Table 5: Benefits and Limitations of retrospective and prospective data collection<sup>70,71</sup>

A retrospective study was chosen because of the ease of accessing data from the family health teams, minimal cost, less workload, and minimal resources allocated to this research project. However, there are challenges when retrieving data from busy clinicians.

#### 2.1.4.2 Self-reporting in a very busy environment

One of the major concerns about research based in busy practice settings is the completeness and accuracy of reporting.<sup>73</sup> A review of the literature was performed to understand and determine the differences in data quality (including reliability and validity) among different methods of data collection by clinicians working in primary care. Pubmed, Medline (1948 to April 2011), and EMBASE (1980-April 2011) were used with keywords including "retrospective studies", "prospective studies", "data collection", "information processing", "validity", "reliability", "reproducibility of results", "primary health care", or "primary medical care". Articles involving human and English were included. Other review articles<sup>74,75</sup> which focused on primary care were also scanned for relevant primary literature. Articles involving hospitals or data collection by patients were excluded. Only articles involving data collection by clinicians (e.g., physicians, nurses, etc.) in primary care were included. One article and one abstract were found that compared retrospective data collection versus prospective data collection by busy clinicians in primary care.<sup>76,77</sup>

In the Ambulatory Sentinel Practice Network (ASPN) miscarriage study, two individuals in each practice audited the information for each reported patient, comparing the study data with that of the medical record.<sup>76</sup> The overall error rate was 4.5%, for a total of 106 errors out of a possible 2361. Seventy percent of these errors came from 5 of the 34 participating practices, and 66% of the records were error free. Twenty-four percent of the miscarriages were not reported in the medical record. This raised the questions as to whether medical records should be used as gold-standard in practice-based research. In this case, self-reporting of miscarriages by clinicians may be more accurate than the medical record, and some practices were more accurate than others.<sup>76</sup>

Mitchell et al compared data reported prospectively by community-based providers on standardized case report forms versus data collected retrospectively by a research assistant based on data contained in the patient's medical record.<sup>77</sup> Prospectively, 104 AIDS-defining diagnoses were reported, in which 3 diagnoses was not reported retrospectively. Retrospectively, 111 AIDS-defining diagnoses were found; 10 were not reported prospectively. Mitchell et al concludes that retrospective data collection by trained research staff is more reliable than prospective data collection by community-based providers in primary care settings.<sup>77</sup> A combination of prospective data collection by a collection by providers with a retrospective chart review could insure completeness of clinical and laboratory data to yield the most complete and accurate data in observational data bases.<sup>77</sup>

Based on the current literature and results of the ASPN miscarriage study and Mitchell et al, it is difficult to assess the reliability or validity of data quality from busy clinicians in primary care. To enhance the quality of practice-based research, the Practice-Based Research Network (PBRN) suggests (1) use clear criteria for participation of practices and clinicians, (2) ensure that questions and methods fit the practice ecology, (3) provide easy to read protocols and appropriate training of clinicians and office staff, (4) compensate on-site staff for complex protocols that require obtaining patient consent, reviewing medical records, or implementing interventions, and (5) create a practice culture that values and supports research.<sup>75</sup> Other methods that have been used for better accuracy is computer-assisted programs<sup>78</sup>, secured websites/e-mail, and reminders (e.g., phone, e-mail, fax, etc.).

This study used some of the recommendations by PBRN along with secured emails and reminders to enhance the completeness and accuracy of the data collected.

### 2.1.4.3 Data collection

Data was collected according to Table 6. The availability of this data that was routinely collected as part of the PAD program will serve as the basis for data analysis in this pilot project. The PAD coordinator collected time for preparation of PAD tools, number of pages for PAD tools, and time required for topic updates on a daily basis up to six months after the last pharmacist was trained in smoking cessation academic detailing. (Appendix C) Each pharmacist documented the time of initial training, follow-up training and topic updates received on a daily basis. (Appendix D) The PAD coordinator collected the PAD topic pharmacist training data collection form. (Appendix D) The pharmacists collected data on the physician or nurse practitioner encounter or academic detailing session. (Appendix E) The PAD coordinator collected the Physician or Nurse Practitioner Encounter Data Collection Form. (Appendix E) Each pharmacist kept track of the number of smoking cessation referrals made by the clinicians and provide data to the PAD coordinator. (Appendix F)

Additional data such as pharmacist's demographics (e.g., credentials, sex, years since graduation, date started in a family health team) and clinician's demographics (e.g., sex, years since graduation) were also collected.

Data	Descriptive Analysis
Total number of pharmacists	Total number
Total Full Time Equivalent (FTE) for pharmacists	Total FTE
Total number of family physicians (MDs) to be	Total number at 3 and 6 months
detailed (maximum number of MDs to be	
detailed)	
Total number of nurse practitioners (NPs) to be	Total number at 3 and 6 months
detailed (maximum number of NPs to be detailed)	
Number of smoking cessation referrals at 3 and 6	Total number at 3 and 6 months
months	
Total number of smoking cessation referrals made	Total number 6 months prior to start
6 months prior to PAD session	of PAD session
# of MDs detailed	Total number and percentage
	detailed at 3 and 6 months
# of NPs detailed	Total number and percentage
	detailed at 3 and 6 months

Table 6: Data collection & descriptive analysis

Data	Descriptive Analysis
PAD Coordinator	
Total time to prepare for PAD tools	Total Time (min)
PAD tools – Total number of pages	Total Pages
Topic Updates	Total Time (min)
PAD Pharmacist	
Initial training time per pharmacist	Average (min), min-max
Number of follow up(s) per pharmacist	Average, min-max
Follow up training time per pharmacist	Average (min), min-max
Number of topic updates per pharmacist	Average, min-max
Topic update time per pharmacist	Average (min), min-max
Clinician encounter	
Total number of initial encounters	Total number
Total number of follow-up encounters	Total number
Number of refusals (list reason for refusal)	Total number (reasons listed)
Additional research time into AD topic per	Average (min), min-max
pharmacist	
Identifying physician's patients time per	Average (min), min-max
pharmacist	
Discussion time with physician per pharmacist	Average (min), min-max
Documentation time per pharmacist	Average (min), min-max
Travel time per pharmacist	Average (min), min-max
Total number of encounters in the physician's	Total number
office	
Total number of encounters in the hallway	Total number
Total number of encounters in the lunchroom	Total number
Total number of encounters elsewhere (list	Total number
location)	
Number of presentations used for tools	Total presentations
Number of RxFiles handout #1 used for tools	Total number
Total number of one-on-one sessions	Total number
Total number of group sessions (clinicians only)	Total number
Total number of group session (multidisciplinary)	Total number

(min)=minute(s), min=minimum, max=maximum

### 2.1.5 Outcomes

### 2.1.5.1 Main Outcomes

The criteria for the outcomes chosen in this pilot study were based on the process, resources, management and scientific reasons for conducting a pilot study.<sup>37</sup> The main outcomes are listed in Table 7.

Table 7. Main Oute	onics
Type of outcome	Main Outcomes
Management	Time for the PAD coordinator to train the pharmacists
Resources	Mean average time for pharmacists to be trained in smoking
	cessation detailing (upskilling)
	Mean average time for a PAD session
Process	Number and percentage of clinicians detailed within 3 and 6 months
Scientific	Number of new patient referrals by the clinician for smoking
	cessation counseling at 3 and 6 months after the PAD session

### Table 7: Main Outcomes

### 2.1.5.2 Secondary Outcomes

Secondary outcome was the comparison of new patient referrals to the pharmacists for smoking cessation counseling 6 months before and 6 months after the PAD session. Further secondary outcomes include administrative time, location of PAD encounters, tools used, and type of PAD session (e.g., one-on-one, clinician only group session or multi-disciplinary group team education). (Table 6)

### 2.1.6 Feasibility criteria

For this pilot study, criteria for success include:

- 1. Time for the PAD coordinator to train pharmacists < 40 hours,
- 2. Time for pharmacists to be trained in smoking cessation < 20 hours,
- 3. Time for PAD session (initial assessment < 60 minutes and follow up < 30 minutes),
- 4. At least 50% of clinicians detailed within 3 months of starting the smoking cessation program and at least 70% of clinicians detailed within 6 months of the program and
- 5. At least 5 patients per 1.0 FTE pharmacist referred to pharmacist for smoking cessation counseling within 3 months (approximately 30 patients) and 10 patients per 1.0 FTE pharmacist referred for smoking cessation after 6 months (approximately 60 patients).

2.1.6.1 Justification for feasibility criteria in this study

The feasibility criteria were based on the overview of Canadian Academic Detailing Programs (Table 1). The Centre for Effective Practice developed the overview of the Canadian Academic Detailing Program for a request for proposal of an Ontario AD program. Table 1 was updated during the CADC regular monthly meetings for the purposes of this thesis. Each representative of the CADC program put in their own data and the secretary of the CADC summarized the data into one table.

Table 8 summarizes the endpoints used to justify the feasibility criteria. The average time to develop key messages and tools can take as little as 20 hours in Alberta and up to 120 hours in British Columbia. The smoking cessation handout and tools used for this pilot study were developed from RxFiles, which saved time for the PAD coordinator from developing new material. The responsibilities of the PAD coordinator was to develop key messages, provide tools/handouts, background readings, develop evaluation forms, collect data, write an introductory letter about PAD to clinicians, and educate the pharmacists on smoking cessation. It was estimated that it would take less than 40 hours for the PAD coordinator to complete her responsibilities.

Smoking cessation is a topic that all pharmacists are familiar with as it is part of their undergraduate training. Across Canada, the minimum time for upskilling was 20 hours on diabetes (CEP) and up to 80 hours in Manitoba. Smoking cessation upskilling involved four background readings and a 90-minute didactic session by the PAD coordinator. It was up to the discretion of each individual pharmacist to read more on the evidence of smoking cessation pharmacotherapy in order to feel confident enough to provide academic detailing. It was estimated that it would take less than 20 hours for each pharmacist to learn about smoking cessation and the supporting evidence.

The average time for one academic detailing session across Canada can take as little as 25 minutes and up to 43 minutes. Since Hamilton pharmacists have never provided academic detailing services to the clinicians, it was estimated that the first academic detailing session would take less than 60 minutes. The academic detailing programs in Canada do not normally have follow up visits for the same topic, although some clinicians do request written follow up or ask questions via telephone or e-mail.<sup>79</sup> Since Hamilton pharmacists see the clinicians at least weekly, it was assumed that there would be more follow up visits on smoking cessation. It was assumed that each follow up visit would take less than 30 minutes.

The percentage of family physicians detailed in each province is as small as 5-10% in Manitoba and as high as 55% in Nova Scotia. The feasibility criteria for detailing clinicians in the Hamilton area is higher than the current provincial rates because of the readily established relationship each pharmacist has with the clinicians.

The final feasibility criteria is specific to pharmacists integrated in primary care. As one of the key messages, each clinician was encouraged to refer patients to pharmacists for smoking cessation counseling. It was estimated that for each 1.0 FTE pharmacist, at least 5 and 10 patient referrals for smoking cessation counseling at 3 and 6 months, respectively, would be made. This feasibility criteria was arbitrarily chosen as there was no data to support or refute this criteria.

Aspects of the AD program	British Columbia Provincial Academic Detailing Program	Alberta Health Services (Calgary), Academic Detailing	RxFiles (Saskatchewan)	Prescription Information Services of Manitoba (PrISM)	Dalhousie Academic Detailing Service (Nova Scotia)	Centre for Effective Practice (CEP) (Ontario)
Program start date	1993	Fall 2006 – July 2010 (ended)	May 1, 1997	February 1, 2003	August 2001	Sept 2007 – August 2008 (ended)
# of detailers (FTE)	9.0	1.4	3.0	0.3	1.8	2.0
# of FTE staff	2.5	0.5	0.8	0	1.0	1.5
Average time to develop key messages and tools	~120 hours	20 to 30 hours	Not documented	40 hours	Not documenting at present	30 hours
Average time for upskilling each topic	40 hours	60 to 80 hours	48 hours	60 to 80 hours	Not documenting at present	~ 20 hours
Average time for one detailing session	43 min	40 minutes	25min	30 min	28 min/visit	30 min
Average # of follow up visits per topic	0	0	0	0	0 27 MDs required written f/u	0 44% requested follow up
Average time for one follow up visit	0	0	0	0	0	0
# of MDs detailed (% of total MDS in region of coverage)	~ 800 (20%) with 5 FTEs	~ 175 (20%)	~350 (>50 %)	50-100 (5-10%)	~370 (~55%)	125 (69%)
# of NPs or other HCPs detailed (% of NPs in region of coverage)	~50 NP, ~200 PHM and ~150 other HCP (nurses, med/PHM students) (% N/A)	~75 HCP (% N/A) including PHM, RD, NP, RPN.	150 PHMs	100-200 PHMs, 10-20 NPs	16 NPs 18 Med students 35 HCPs 150 PHMs (% N/A)	30 (18%) NPs, 25 (13%) family medicine residents

Table 8: Aspects of the Canadian Academic Detailing Programs

FTE=full-time equivalent, HCP=health care professional, MD(s)=medical doctors, Med=medical, NP(s)=nurse practitioner(s), PHM(s)=pharmacist(s), RD=registered dietitian, RPN=registered practical nurse

### 2.1.7 Sample Size

This pilot study aimed for a feasibility sample of approximately 20 clinicians expected to provide a reasonable opportunity to assess success of the primary outcome of number of new patient referrals to the pharmacists for smoking cessation counseling at 3 and 6 months after the PAD session. A formal sample size calculation was not carried out.<sup>37</sup>

### 2.1.8 Analysis

As outlined in Table 6 and 9, descriptive statistics including mean, median, standard deviation, totals, proportions, minimums and maximums will be calculated using Microsoft Excel for Mac 2011 Version 14.0.2.

Missing data will be documented and assessed relative to the feasibility of data collection methods for the study. However, strategies to input missing data will not be part of the analysis.

Question	Outcome	Comparison	Method
Was PAD by primary care	Time for PAD	40 hours	Descriptive
pharmacists to clinicians feasible	coordinator to train		
with respect to time for the PAD	the pharmacists		
coordinator to train the pharmacists?			
Was PAD by primary care	Average time for	20 hours	Descriptive
pharmacists to clinicians feasible	pharmacists to be		
with respect time for pharmacists to	trained in smoking		
be trained in smoking cessation	cessation detailing		
detailing?			
Was PAD by primary care	Average time for an	60 minutes for initial	Descriptive
pharmacists to clinicians feasible	initial PAD session.	PAD session	
with respect to time for a PAD	Average time for a	30 minutes for follow	
session?	follow up PAD	up PAD session	
	session		
Was PAD by primary care	Number &	50% of clinicians	Descriptive
pharmacists to clinicians feasible	percentage of MDs	detailed within 3	
with respect to number and	and NPs receiving	months, 70% of	
percentage of clinicians detailed	PAD within 3 and 6	clinicians detailed	
within 3 and 6 months?	months	within 6 months	
Did personalized academic detailing	# of smoking	# of smoking	Descriptive
(PAD) by primary care pharmacists	cessation patient	cessation referrals 6	
to clinicians (family physicians or	referrals at 6	months prior to the	
nurse practitioners) increase the	months after the	PAD training on	
number of referrals for smoking	first PAD session	smoking cessation	
cessation counseling to the	with clinician		
pharmacist six months after the PAD			

### Table 9: Summary of Analyses

Question	Outcome	Comparison	Method
session compared to no PAD			
service?			
Was PAD by primary care	# of new referrals	5 patients per 1.0 FTE	Descriptive
pharmacists to clinicians feasible	within 3 months and	PHM (~30 patients)	
with respect to number of new	6 months	within 3 months	
patient referrals by the clinician for		10 patients per 1.0	
smoking cessation within 3 and 6		FTE PHM (~60	
months?		patients) within 6	
		months	

### 2.1.9 Ethics

Consent was obtained from the participating pharmacists, physicians, and nurse practitioners to use their data for data analysis. (Appendix G) To maintain confidentiality, consent forms and data collection forms were stored in a secured office and locked cabinet. Data stored on the computer had a secured password protection. A coding system was used to protect identifiable information when transferring paper files into the Microsoft Excel worksheet (e.g., Pharmacist name = Code "A"). The code was isolated from the study data and stored in a secure manner.

### Chapter 3 <u>3.1 Results</u> 3.1.1 Characteristics of participants

Eight pharmacists (5.8 FTE) received basic academic detailing training in November 2008 and all were trained in smoking cessation personalized academic detailing in February 2008.(Table 10) The maximum number of eligible family physicians and nurse practitioners (clinicians) to be detailed were 54 and 10, respectively. Twenty-six male and 31 female clinicians consented to be part of this study.(Table 11,12)

Table 10: Characteristics of pharmacists

Characteristics	Results
Total Number of pharmacists	8
Total Full Time Equivalent (FTE) (min, max)	5.8 (0.2, 1.0)
Credentials	3 – BScPhm, PharmD
	4 – BScPhm
	1 – BSc Biology, BScPhm
Sex (male, female)	1 Male, 7 Females
Years practicing as a pharmacist, mean (min, max)	17.4 (6, 35)
Years practicing in Family Health Team, mean (min, max)	1.2 (0.4, 2.5)
Number of physicians per pharmacist, mean (min, max)	7 (3, 11)
Number of nurse practitioners per pharmacist, mean (min, max)	1 (0, 2)

### Table 11: Eligible clinicians

	Family Physicians (MDs)	Nurse Practitioners (NPs)
Total eligible for PAD	54	10
# received PAD	50	10
Reason for not	2 refused (not interested in topic)	Not applicable
receiving PAD	2 unable to schedule appointment	
# consent	48 (88.9%)	9 (90.0%)
Reason for no consent	2 refused PAD (above)	0 refused
	2 did not receive PAD (above)	1 no longer with FHT &
	2 no longer with FHT & unable to contact	unable to contact

### Table 12: Characteristics of clinicians

Characteristics	MDs	MDs	NPs	NPs
	(consent)	(no consent)	(consent)	(no consent)
Total Number	48	6	9	1
Mean average years since graduation, mean average (min, max)	25 (6, 46)	22 (11, 39)	7 (1, 13)	Not available
Sex, (male, female)	25 M, 23 F	2 M, 4 F	1 M, 8 F	1 F

### 3.1.2 Outcomes & Analysis

### 3.1.2.1 Main Outcomes

Table 13 summarizes the results and analysis of the main outcomes. The PAD coordinator prepared the reading package<sup>62-65</sup> (1 hour), handouts (1 hour), key message summary (6 hours), updated the RxFiles handout (2 hours), and continued to review any additional research (e.g., attended local CE events, medline search, Google scholar, Health Canada review, US FDA review) (6 hours), provided smoking cessation PAD training (3 hours) and updated the pharmacists via e-mail (5 min) during the PAD program for a total of 29.1 hours.

Among 7 pharmacists (4.8 FTE), the median time to read the package was 1 hour (min=1, max=3 hours). The PAD upskilling training session included one PowerPoint presentation (60 minutes) and observing one mock PAD session (30 minutes) between the PAD coordinator and a pharmacist acting as a clinician. Only one pharmacist was not able to observe the practice PAD session (most communication was via e-mail and phone). The PAD upskilling training session was completed early February 2008. Two of the 5 pharmacists researched and read more than the reading package provided by the PAD coordinator (1 and 2 hours of additional readings, respectively).

Eight pharmacists started their very first PAD session as early as February 11, 2008 and as late as May 27, 2008. At 3 and 6 months, 42/54 (76.4%) MDs and 8/10 (80.0%) NPs, and 48/54 (87.3%) MDs and 9/10 (90.0%) NPs received PAD on smoking cessation, respectively. The median average time for a PAD session or discussion with the clinician was 15 minutes (min=5, max=60). Only 1 follow-up visit was recorded, which took a total of 25 minutes of the pharmacist's time (research time = 15 min, discussion with physician time = 5 min, documentation time = 5 min).

Overall, the criteria for success was met for all main outcomes. (Table 13)

Main Outcomes	Results	Criteria for Success	Was criteria for success met?
Mean average time for the PAD coordinator to train the pharmacists, hours	29.1 hours	< 40 hours	Yes
Median average time for upskilling, hours (min, max)	Total: 3.1 hours (1.7, 6.2)	< 20 hours	Yes
Median average time for a	Initial visit: 15 min (5, 60)	Initial visit: < 60 min	Yes
PAD session, minutes, (min,	Follow-up visit: 5 (only 1	Follow-up visit: < 30 min	
max)	follow up visit recorded)		
Number (%) of clinicians	3 months: 50/64 (78.1%)	3 months: > 50%	Yes
detailed within 3 and 6 months	6 months: 57/64 (89.1%)	6 months: > 70%	
Number of new patient	3 months: 66 patients	3 months: 5 pts/1.0 FTE	Yes
referrals by the clinician for	6 months: 200 patients	PHM (29 pts)	
smoking cessation counseling	(0, 77)	6 months: 10 pts/1.0 FTE	
at 3 and 6 months after the		PHM (58 pts)	
PAD session (min, max)			

Table 13: Results and analysis of Main Outcomes

### 3.1.2.2 Secondary Outcomes

Six months prior to the PAD smoking cessation sessions, 5/8 (62.5%) of the pharmacists had zero referrals for smoking cessation counseling (max=24). Within six months after the PAD session, 7/8 (87.5%) pharmacists had at least one smoking cessation referral (median=9, min=0, max=77) from the clinicians. One pharmacist did not have any referrals as the team decided that they should refer the patients to the nurse practitioner for smoking cessation counseling; 3 patients were referred to the NP for smoking cessation counseling. Overall, six months after the PAD smoking cessation session, there was an increase of 156 smoking cessation referrals to the pharmacists in the family health team.

The majority of the PAD encounters occurred in the physician's office (42/57, 73.7%)), one-on-one (46/55, 80.7%) using the RxFiles handout (55/57, 96.5%). The median average time for all administrative tasks for each encounter was 25 min (min=5, max=60), including the time for discussion with each physician (median average=15 min, min=5, max=60). (Table 14)

Secondary Outcomes	Results		
Total number of new patient referrals by the clinician for smoking cessation	44 patients (0, 24)		
counseling 6 months prior to the PAD session (min, max)			
Total number of new patient referrals by the clinician for smoking cessation	200 patients (0, 77)		
counseling 6 months after to the PAD session (min, max)			
Administrative data for each initial PAD session			
Mean average time for additional research into AD topic, minute (min, max)	6.5 (0, 30)		
Mean average time in identifying physician's patient time, minute (min, max)	0.8 (0, 5)		
Mean average documentation time, minute (min, max)	2.3 (0, 5)		
Mean average travel time, minute (min, max)	0		
Location of PAD session for each initial PAD encounter			
Physician's Office, number (%)	43/57 (75.4%)		
Pharmacist Office, number (%)	4/57 (7.0%)		
Hallway, number (%)	2/57 (3.5%)		
Lunchroom, number (%)	4/57 (7.0%)		
Team room, number (%)	2/57 (3.5%)		
Other: Restaurant	2/57 (3.5%)		
Tools Used			
RxFiles	55/57 (96.5%)		
PowerPoint Presentation	12/57 (21.1%)		
Other (EMR form)	3/57 (5.3%)		
Method of encounter			
One-on-one, number (%)	46/57 (80.7%)		
Group of prescribing clinicians only, number (%)	4/57 (7.0%)		
Group of clinicians and allied health (non-prescribing clinicians), number (%)	7/57 (12.3%)		

#### Table 14: Descriptive Results of Secondary Outcomes

### Chapter 4: <u>4.1 Discussion</u>

A pilot of personalized academic detailing has not been tested before in a Canadian setting. The main outcomes indicate that this pilot study is feasible with respect to the management, resources, process and scientific components. Compared to other existing Canadian Academic Detailing programs, there is a higher attrition rate of clinicians with similar administration times for the PAD coordinator and pharmacists. In PAD, the pharmacists in primary care may potentially have less administration time compared to conventional academic detailers as there is zero travel time and zero waiting time in the "waiting room". This pilot study showed that pharmacists in a primary care setting, with formal academic detailing training, have the ability to provide education or academic detailing to clinicians on smoking cessation.

Although the effect of group vs. one-on-one academic detailing in prescribing behaviour varies<sup>80,81,82</sup>, the PAD coordinator encouraged one-on-one encounters with the clinicians. Hence, it was expected that all of the PAD sessions would be one-on-one. Of the 57 clinicians, 7 (12.3%) requested a group discussion with other allied health care professionals and 4 (7.0%) requested group academic detailing with another clinician (MD/NP). The request for group academic detailing by the clinicians was to increase team building in the practice and to develop an organized system of referring patients to the pharmacist or other allied health care professional for smoking cessation counseling. A priori, this study did not set out to analyze the difference of smoking cessation referrals between group and one-on-one academic detailing. Group vs. one-on-one PAD may be explored in future studies.

There was also an increased number of smoking cessation referrals after the PAD session (from zero cases prior to PAD session up to 77 cases six months after the PAD session). Although the clinical impact of smoking cessation counseling is not analyzed in this study (e.g., the actual number of patients who quit smoking after a PAD session), there is a potential for more patients to quit smoking. Evidence shows that physicians who give patients brief advice on smoking cessation are more likely to quit smoking compared to usual care, relative risk (RR) 1.66, 95% confidence interval (CI) 1.42 to 1.94 in increasing the rate of quitting).<sup>83</sup> More intensive interventions by physicians had a higher quit rate than usual care (RR 1.84, 95% CI 1.60 to 2.13).<sup>83</sup> Although data is limited, pharmacists in the community pharmacies (drug stores) may also be effective in smoking cessation counseling and assist in helping patients quit smoking.<sup>84</sup> The combination of the clinician and the pharmacist actively trying to assist the patient to seek smoking cessation counseling can potentially increase smoking cessation rates.

At this time, there is no existing literature of PAD or pharmacist in primary care providing academic detailing to the clinicians on a one-on-one basis. This pilot project shows that PAD is feasible in a primary care setting.

Some limitations of this retrospective cohort pilot study include recall and selection bias. Most of the data was collected prospectively as part of a quality assurance program. The training time for each pharmacist and a few physician encounters were collected retrospectively. There did not seem to be a difference between the retrospective

and prospective data. Selection bias may occur since this pilot study was completed in the Hamilton area; the results of this study may not reflect other family health teams or primary care sites.

However, the results of this study may be beneficial for a larger PAD study on smoking cessation. In Ontario, the Ministry of Health Long Term Care (MOHLTC) has given the Local Health Integration Networks (LHINs) free nicotine replacement therapy (NRTs) to give to their patients. In family health teams (FHTs) with pharmacists, they can act as a conduit to the NRTs. At this time, the MOHLTC is determining the logistics of providing the NRTs to each FHT. If possible, a larger prospective randomized study of PAD on smoking cessation would be optimal once NRTs become free to the patients to determine the impact of PAD compared to no PAD. In the larger RCT on PAD, one of the main outcomes of interest would be the clinical impact of smoking cessation.

Other future research in PAD is to compare PAD versus conventional AD versus usual care (no AD), group vs. one-on-one PAD, surveys to pharmacists or clinicians on their viewpoint of PAD, qualitative analysis on PAD (e.g., why clinicians do or do not participate in PAD), topic selection, and evaluation tools for PAD.

In summary, pharmacist in a family health team can help with prescribing practices and work with the healthcare team to also assist patients with smoking cessation counseling.

### 4.2 Knowledge Translation

The results of this study will be presented to the Canadian Academic Detailing Collaboration (CADC), Continuing Medical Education (CME) Congress, North American Primary Care Research Group (NAPCRG), pharmacy organizations, and other primary care organizations. Submission for publication will be sent to the Canadian Family Physician (CFP).

### **4.3 Update on PAD in the Hamilton area**

Since 2008, the Hamilton Family Health Team pharmacists have detailed clinicians on hypertension (January 2009) and depression (December 2009). The next topic will be on opioid use for non-cancer chronic pain.

# Appendix

### Appendix A - AD Basic Training Workshop

Program Schedule	Objectives
<ol> <li>Introduction         <ol> <li>a. Welcome and housekeeping details</li> <li>b. An overview of academic detailing</li> <li>c. Getting to know you</li> </ol> </li> </ol>	<ul> <li>To provide a welcome and general overview of what the workshop entails</li> <li>To cover housekeeping issues (e.g. Parking, location of amenities, etc.)</li> <li>To provide participants with a general overview of academic detailing</li> <li>To outline evidence about the effectiveness of educational visiting as a mechanism for supporting and positively influencing community medical practice</li> <li>To help participants and faculty get to know each other</li> <li>To develop a rapport between workshop participants</li> <li>To find out what participants are expecting to gain from the workshop and what they bring with them. By gleaning this information, faculty will be in a better position to meet their needs.</li> </ul>
<ul> <li>2. Workshop outline and structure of an academic detailing visit <ul> <li>a. Overview of the workshop program</li> <li>b. Theoretical background to the workshop</li> <li>c. Structure for academic detailing visits</li> </ul> </li> </ul>	<ul> <li>To introduce participants to procedural matters they need to know for the workshop</li> <li>To orient participants to the structure of the workshop</li> <li>To highlight the structure of an academic detailing visit by working through each step in the order in which it sometimes will occur</li> <li>To show how an individual's thoughts (attitudes, values and beliefs), feelings and behaviour (including communication), influence one another</li> <li>To show that we need to keep an open mind and avoid prejudice, in order to communicate effectively with others</li> <li>To explain that educational visitors need to have an attitude of respectful caring in order to be of use to physicians</li> <li>To discuss in more detail the structure of an academic detailing visit</li> <li>To provide participants with a model by which they can follow the process of a visit</li> <li>To provide participants with a demonstration of a videotaped visit, so that they can understand what the finished product can look like</li> </ul>
<ol> <li>Introductions in academic detailing visits         <ul> <li>Essentials for introductions</li> </ul> </li> </ol>	<ul> <li>To each participants how to:         <ul> <li>create a suitable space for the visit</li> <li>attend to the immediate needs of the physician</li> <li>define their own and the physician's availability</li> </ul> </li> </ul>

### Overall Program Schedule and Objectives

Program Schedule	Objectives
<ul> <li>b. Presentation and practice of skills required for a successful introduction</li> <li>c. Exploration of approaches to</li> </ul>	<ul> <li>To make participants aware of:         <ul> <li>The need for small talk to establish rapport</li> <li>Body language that show attentiveness in an anglo-franco-celtic culture</li> </ul> </li> <li>For participants to explore different ways of explaining to the abusistic the substantiation.</li> </ul>
approaches to introductions d. Values, attitudes and beliefs e. Barriers to communication f. Identifying communication barriers	<ul> <li>physician the purpose of the visit</li> <li>For participants to practice the process of introducing themselves to a physician and getting to know the physician and their practice</li> <li>For participants to explore techniques covered in the previous session for introducing themselves to the physician</li> <li>For participants to: <ul> <li>Realize that there are many different ways of approaching the task of introducing themselves to the physician</li> <li>Learn the effects of those approaches</li> <li>Identify their particular approach</li> <li>Identify some of their communication barriers</li> </ul> </li> <li>To explore and make overt some of the commonly held beliefs and attitudes about physicians, academic detailers and patients</li> <li>To demonstrate how values and beliefs are expressed and influence the process and outcome of the interaction</li> <li>To explore the ways in which perceptions can be changed by punctuating the communication cycle in different places</li> <li>For participants to become aware of their values and beliefs and how they impact on their interactions</li> <li>To demonstrate that when you are aware of how you behave and the impact of your behaviour on others, you can exert better control over both your behaviour and its effects</li> </ul>
4. Physicians speaking about	<ul> <li>For the participant to understand the pressures operating on a</li> </ul>
<ul> <li>pressures of current practice</li> <li>a. Primary care</li> <li>physicians speak</li> <li>b. Reflections</li> <li>c. Identifying and eliciting</li> <li>needs: The concepts of</li> <li>needs</li> </ul>	<ul> <li>For the participant to understand the pressures operating off a primary care physician in a typical day</li> <li>For the participant to understand more about the structure of a primary care physician's practice</li> <li>To discover how physicians think an academic detailer might be of assistance to them</li> <li>For the participant to gain an appreciation of the viewpoint of physicians in relation to their perceptions of the practical value of differing types of continuing medical education</li> <li>For the participant to understand that the needs of each individual physician may not be the same, in order to provide a helpful service, they will need to establish what the physician's needs and adapt their communication style and presentation accordingly</li> <li>To share reflections on the experiences of the guest primary</li> </ul>

Program Schedule	Objectives
	<ul> <li>care physicians</li> <li>To explore consonance and dissonance which exists between the information and views of the guest primary care physicians and our own beliefs and views</li> <li>For participants to understand the importance of needs which people have, specifically with regard to a product or service</li> <li>For participants to realize how a sales interaction is rendered successful when the needs of a customer are met</li> <li>For participants to perceive a visitor-physician relationship as a sales interaction, in that the academic detailer is selling the physician ideas for a suggested change in practice</li> <li>To highlight some professional needs of the physician and for eliciting needs, to show participants the usefulness of closed and open questions, minimal encouragers, and reflecting skills for facts, feeling and for summarizing content</li> </ul>
<ul> <li>5. Trust and credibility <ul> <li>a. Building trust and credibility</li> <li>b. Putting the skills together</li> <li>c. Wrap Up</li> </ul> </li> </ul>	<ul> <li>For participants to identify strategies that, from their own experience, build trust and establish credibility</li> <li>For participants to be able to observe such strategies in use, in the context of an academic detailing visit</li> <li>For participants to develop their understanding and appreciation of such strategies through discussion</li> <li>For participants to develop the skills of a successful introduction through role-play</li> <li>For participants to learn ways of overcoming the problems they and others experienced while they were in the role of "detailer"</li> <li>To allow reflection on the role-play experience of introduction</li> <li>To explain the format for the next day and review of the sore throat topic materials</li> </ul>
<ul> <li>6. Getting objectives clear, and preparing key messages <ul> <li>a. Getting your objectives clear for the visit</li> <li>b. Identifying resources needed to achieve your objectives</li> <li>c. Making summaries of the issues</li> <li>d. Preparing key messages from preworkshop materials</li> </ul> </li> </ul>	<ul> <li>To elaborate and explore differences in detailing interactions which occur from time to time in office based clinical practice</li> <li>To remind participants of the variety of barriers to communication which result from differing approaches to one-to-one detailing</li> <li>To help participants to see the importance of successful assessment of barriers to behaviour chance which exist for different physicians as a result of different types of visiting programs</li> <li>To introduce and explore the limitations and strengths of the use of printed materials in persuasive communication</li> <li>To demonstrate the importance of gaining a sound understanding of the subject matter to be discussed</li> <li>To provide some techniques for preparing summaries of critical issues</li> <li>To provide an opportunity for participants to extract key</li> </ul>
7. Management and Use of	To provide participants with the opportunity to critically review

Program Schedule	Objectives
Detailing Aids a. Critical analysis of educational aids b. Using your materials – Role plays c. Debriefing session	<ul> <li>printed educational aids which have been used in other educational and commercial visiting programs</li> <li>To provide an opportunity to practice an educational visit using printed educational aids with improved communication skills and an assessment of barriers to communication and behaviour change</li> <li>To discuss amongst all participants the experience of the role play</li> </ul>
<ul> <li>8. Challenging responses <ul> <li>a. Handling challenging responses</li> <li>b. Practicing verbal skills</li> <li>c. Practicing verbal and non-verbal skills in handing challenging responses</li> <li>d. Debrief</li> </ul> </li> </ul>	<ul> <li>To present theory on dealing with challenging responses in an academic detailing encounter</li> <li>For participants to identify the nature of the challenging responses presented</li> <li>For participants to think through potential ways of responding to these challenging responses, and the likely consequences of acting in those ways</li> <li>For participants to improve their ability to identify and deal with challenging responses by role-playing challenging encounters, discussing their experiences with others and brainstorming solutions to difficulties experienced during the role-plays</li> <li>For participants to improve their ability to identify and deal with challenging responses by role-playing challenging encounters, discussing their experiences with others and brainstorming solutions to difficulties experienced during the role-plays</li> <li>For participants to improve their ability to identify and deal with challenging responses by role-playing challenging encounters, discussing their experiences with others and brainstorming solutions to difficulties experienced during the role-plays</li> <li>To discuss amongst all participants the experience of the role play</li> </ul>
<ul> <li>9. Closing the communication loop <ul> <li>a. Understanding</li> <li>closures in academic</li> <li>detailing visits</li> </ul> </li> <li>b. Exploring closures in practice – Role play</li> <li>c. Debrief</li> </ul>	<ul> <li>To teach participants how to conclude the visit by obtaining acknowledgement of the points made and commitment to act (e.g. closing the communication loop)</li> <li>For participants to begin to learn, through role-play, how to close the communication loop as well as to effectively use educational aids</li> <li>For participants to learn more about the process of closing the communication loop by discussing their role-play experiences with one-another and joining together to seek solutions to problems experienced by "detailers" during role-play</li> <li>To explore problems and successes in closure which occurred in the role plays</li> </ul>
<ul> <li>10. Preparation for the complete academic detailing visit <ul> <li>a. Practicing your audiovisual recording</li> <li>b. Reviewing the structure of the academic detailing visit</li> <li>c. Practice of a complete visit – Role play</li> </ul> </li> </ul>	<ul> <li>To provide participants with a clear view of the requirements for the final academic detailing visit of the workshop</li> <li>To help participants to consolidate, discuss and reflect on what they have learned over the course of the workshop</li> <li>To prepare participants for the recorded role-play</li> <li>To allow participants to perform a complete academic detailing visit with their group facilitator acting as the "physician" in preparation for the final recorded interview with an unfamiliar primary care practitioner</li> </ul>

Program Schedule	Objectives
11. A "live" visit and workshop conclusion	<ul> <li>To introduce the primary care physicians whoa re going to participate in the recorded academic detailing visit</li> </ul>
<ul> <li>a. Introduction to the recorded session</li> <li>b. Recording a complete</li> </ul>	<ul> <li>To give the participants an opportunity to practice the skills they have learned during the workshop, in order to prepare them for the role of the academic detailer</li> </ul>
academic detailing encounter with a primary care physician	<ul> <li>To provide the experience of an academic detailing session with a "friendly" primary care physician</li> <li>To provide take-home material for further analysis with another</li> </ul>
c. Plenary session with the primary care physicians	<ul> <li>participant of the workshop</li> <li>To learn the views of the primary care physicians and their experiences with the academic detailers</li> </ul>
12. Summary and final debrief a. Wrap-up	<ul> <li>For participants to reflect on their experiences over the duration of the workshop</li> </ul>
	To provide participants with further guidance on the use of their audiovisual recording
	<ul> <li>To provide participants with the opportunity to provide evaluative feedback on their experience of the workshop</li> </ul>

### Appendix B - Smoking Cessation Handout - RxFiles

(next 2 pages)

(The original document was formatted and laminated to fit 2 pages and given to the family physician or nurse practitioner.)

2 pages to be inserted

### Appendix **B**

### **Smoking Cessation Handout – RxFiles**

Page 1 of RxFiles to be inserted

### Appendix **B**

### **Smoking Cessation Handout – RxFiles**

Page 2 of RxFiles to be inserted

### Appendix C - PAD Coordinator Data Collection Form

PAD Coordinator time associated with research, preparation, training of the pharmacist {*The original data collection form (2 pages) was reformated for thesis requirements*}

Preparation of PAD Tools	Time (min)
Research	
Preparation of reading package	
Preparation of handout(s)	
PAD Tools	Number of pages
Reading Package	
Key Message Summary	
Handout 1 =	
Handout 2 =	
Topic Updates	Time (min)
Additional Research	
Reading Package changes	
Handout changes	
Key Message Summary Changes	
Initial Training	Time (min)
RxFiles Training	
PAD training	
Documentation	
Travel time	
Follow-up training	
Contact with pharmacist?	Yes/no?
If yes, telephone calls?	Yes/no?
Number of telephone calls	
Total time (min) for telephone calls	
If yes, e-mails?	Yes/no?
Number of e-mails?	
Total time (min) for e-mails	
If yes, face-to-face meeting(s)?	Yes/no?
Number of face-to-face meetings?	
Total time (min) for face-to-face	
Topic Updates Received?	Yes/no?
If yes, number of topic updates received?	
Additional communication with pharmacist via:	
Telephone call(s)?	Yes/no?
Number of telephone call(s)?	
Total time (min) for telephone	
E-mail(s)?	Yes/no?
Number of e-mail(s)	
Total time for e-mail(s)	
Face-to-face meeting(s)	Yes/no?
Number of face-to-face meeting(s)	
Total time (min) for face-to-face	

### **Appendix D - Pharmacist Training Data Collection Form**

Pharmacist time associated with research and preparation for implementation of each personalized academic detailing topic

{The original data collection form was reformatted for thesis requirements}

Pharmacist name: \_\_\_\_\_

PAD Topic:

Initial Preparation	Time (min)
Reading package	
PAD training session with PAD Coordinator	
Preparation of PAD tools	
Documentation	
Travel time	
Follow-up preparation	
Contact with PAD coordinator?	Yes/no
If yes, contact via	
Telephone call(s)	Yes/no
Number of telephone call(s)	
Total time (min) for telephone	
E-mail(s)	Yes/no
Number of e-mail(s)	
Total time (min) for e-mail(s)	
Face-to-face meeting(s)	Yes/no
Number of face-to-face meeting(s)	
Total time (min) for face-to-face	
Topic Updates Received	Yes/no
If yes	
Number of topic update(s) received	
Additional research time (min)	
Changes to materials for physicians (time [min])	
Topic updates provided to physicians (time [min]	

### **Appendix E - Clinician Encounter Data Collection Form**

Pharmacist time associated with researching and implementing each academic detailing topic for each physician {*The original data collection form was reformated for thesis requirements*}

Date of encounter:\_\_\_\_\_ Physician or Nurse Practitioner name:\_\_\_\_\_ Detailing Topic:\_\_\_\_\_

### **Reason for refusal:**

(to be completed if physician refused to participate in AD topic – check one below)  $\Box$ No time available

 $\Box$ Not interested in AD topic

□Unable to schedule appointment

Other:

### **Type of encounter:**

□Initial □Follow-up

Administrative Data	Time (min)
Research into AD topic	
Identifying physician's patients	
Discussion with physician	
Documentation	
Travel time	

### **Encounter Details**

Location (check one below)

Physician Office 
Hallway 
Lunchroom 
Other:

Method (check one below)

 $\Box$ One-on-one meeting

Group discussion meeting with NP/MD(s) only

Group discussion meeting with NP/MD(s) AND other allied health/staff

### Appendix F - Data Collection form at 3 and 6 months

(after first detailing session)

Pharmacist name: FTE status: Total number of family physicians (MDs) to be detailed: Total number of nurse practitioners (NPs) to be detailed:

	At 3 months	At 6 months
# of smoking cessation referrals		
# of MDs detailed		
# of NPs detailed		



Appendix G - Information and Consent Form



Inspiring Innovation and Discovery

### A Study about Personalized Academic Detailing – Pilot Project on Smoking Cessation

### **Investigators:**

Principal Investigator: Dr. Margaret Jin, BScPhm PharmD Hamilton Family Health Team 10 George Street, 3<sup>rd</sup> floor Hamilton, ON L8P 1C8

> (416) 453-8516 E-mail: margaret.jin@hamiltonfht.ca

Co-Investigator(s): Faculty Supervisor:

Dr. Lisa Dolovich, BScPhm PharmD MSc Research Director & Associate Professor, Dept of Family Medicine, McMaster University McMaster Innovation Park 175 Longwood Road South, Suite 201A Hamilton ON L8P 0A1 (905) 521-2100 x28500 E-mail: Idolovic@mcmaster.ca

Dr. Lehana Thabane, BSc MSc PhD

Dr. Antony Gagnon, BScPhm PharmD

Research Sponsor: None

### **Purpose of the Study**

This pilot study will assess the feasibility of conducting a large study to determine the effect of a personalized academic detailing (PAD) session in primary care on smoking cessation management. This study is being conducted as part of a thesis for Health Research Methodology Master's Program at McMaster University. A feasibility or pilot study tests the methods and procedures to be used on a larger scale. The specific feasibility objectives of this study are to evaluate the process (percentage of clinicians willing to participate), the resources (pharmacist's time, time of personalized academic

detailing session), management (time to train pharmacists), and scientific process (number of referrals made to detailer).

Personalized academic detailing (PAD) is the merging of two roles, the academic detailer and the pharmacist in primary care. Academic detailing or education outreach programs is a type of continuing education in which a pharmacist meets with a clinician (family physician or nurse practitioner) in their practice setting to provide a one-on-one evidencebased information with the intent of optimizing their practice. PAD is a new initiative in which pharmacists integrated within the Family Health Team provides academic detailing service to clinicians in their practice site. A PAD session is usually a 15-20 minute oneon-one visit between the pharmacist and the clinician during office hours.

You are invited to take part in this study as a participant to help us determine the feasibility and applicability of the study.

### Procedures involved in the Research

As a pharmacist, you were trained in academic detailing to detail family physicians and nurse practitioners on smoking cessation. As a family physician or nurse practitioner, you were asked by the pharmacist for approximately 20 minutes of your time to review the material on smoking cessation and key learning messages. This consent asks you to allow the data collected routinely as part of the PAD program to be analyzed as part of a research thesis project.

### Potential Harms, Risks or Discomforts:

It is not likely that there will be any harms or discomforts associated with taking part of this study. You may be asked questions about the data collected. You do not need to answer questions that you do not want to answer or that make you feel uncomfortable. And you can withdraw (stop taking part) at any time. The steps taken to protect your privacy are described below.

### **Potential Benefits**

The research will not benefit you directly. The medical, pharmacy and academic community will learn more about the feasibility of personalized academic detailing in primary care.

### Confidentiality

Your name or any information that would allow you to be identified will not be used. No one but the members of the research team, the group of pharmacist detailers, and selected management personnel at the Hamilton Family Health Team will know whether you participated in this study unless you choose to tell them.

The information/data you provide will be kept in a locked desk/cabinet where only the research team will have access to it. Information kept on a computer will be protected by a password. Once the study has been completed, the data will be destroyed. Once the

study is complete, an archive of the data, without identifying information, will be deposited.

### Participation and Withdrawal

Your participation in this study is voluntary. It is your choice to be part of the study or not. If you decide to be part of the study, you can decide to stop (withdraw), at any time, even after signing the consent form or part-way through the study. If you decide to withdraw, there will be no consequences to you. In cases of withdrawal, any data you have provided will be destroyed unless you indicate otherwise. If you do not want to answer some of the questions you do not have to, but you can still be in the study. Your decision whether or not to be part of the study will not affect your continuing access to services.

### Information about the Study Results

This study will be completed by the end of 2011. You can request to receive a brief summary of the results.

### Questions about the Study

If you have questions or require more information about the study itself, please contact Margaret Jin at 416-453-8516.

This study has been reviewed by the McMaster University Research Ethics Board and received ethics clearance. If you have concerns or questions about your rights as a participant or about the way the study is conducted, please contact the Office of the Chair of the Hamilton Health Sciences/Faculty of Health Sciences Research Ethics Board at 905-521-2100, ext 42013

### CONSENT

### SIGNATURE OF RESEARCH PARTICIPANT

I have read the preceding information thoroughly. I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I will receive a signed copy of this form.

Name of Participant

Signature of Participant

Date

### PERSON OBTAINING CONSENT

I have discussed this study in detail with the participant. I believe the participant understands what is involved in this study.

Name and title

Signature

Date

I would like to receive a summary of the study's results. Please send them to this email address: \_\_\_\_\_\_ or to this mailing address:

\_\_\_\_No, I do not want to receive a summary of the study's results.

This study has been reviewed by the Hamilton Health Sciences/McMaster Faculty of Health Sciences Research Ethics Board (HHS/FHS REB). The REB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call The Office of the Chair, HHS/FHS REB at 905.525.2100 x 42013.

# References

<sup>1</sup> Canadian Institute for Health Information. Drug Expenditure in Canada. Canadian Institute for Health Information. Accessed at <u>https://secure.cihi.ca/estore/productFamily.htm?pf=PFC1428&lang=en&media=0</u>, January 7, 2011

<sup>2</sup> Campeau L. Top RxDrugs of 2010. Pharmacy Practice. 2011;February/March:32-36

<sup>3</sup> Hanlon JT, Artz MB, Pieper CF et al. Inappropriate medication use among frail elderly inpatients. Ann Pharmacother 2004;38:9-14.

<sup>4</sup> Piecoro LT, Browning SR, Prince TS, Ranz TT, Scutchfield FD. A database analysis of potentially inappropriate drug use in an elderly medicaid population. Pharmacother 2000;20:221-8.

<sup>5</sup> Lau E, Dolovich L. Drug-related problems in elderly general practice patients receiving pharmaceutical care. Int J Pharm Pract 2005;13:165-77.

<sup>6</sup> Ernst FR and Grizzle AJ. Drug-related morbidity and mortality: Updating the cost-ofillness model. J Am Pharm Assoc 2001;41:192-9.

<sup>7</sup> Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, et al. The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada. CMAJ. 2004;170(11):1678-86

<sup>8</sup> Canadian Institute for Health Information. Hospital Morbidity Database 2000/01 Tabular Reports. 2002, <u>http://secure.cihi.ca/cihiweb/products/HospitalMorbidityTabularReports2000-2001.pdf</u>

<sup>9</sup> Grimshaw JM, Shirran L, Thomas R et al. Changing provider behavior: An overview of systematic reviews of interventions. Med Care 2001;39:I12-I45.

<sup>10</sup> Knowledge Translation Program. Glossary of terms in knowledge translation and continuing education. 2006. Knowledge Translation Program.

<sup>11</sup> O'Brien MA, Rogers S, Jamtvedt G et al. Educational outreach visits: Effects on professional practice and health care outcomes (review). Cochrane Database Syst Rev 2007;(4):CD000409.

<sup>12</sup> Soumerai SB, Avorn J. Principles of Educational Outreach ("Academic Detailing") to Improve Clinical Decision Making. JAMA. 1990;263:549-56.

<sup>13</sup> Coenen S, Van Royen P, Michiels B, Denekens J. Optimizing antibiotic prescribing for acute cough in general practice: A cluster-randomized controlled trial. J Antimicrob Chemother 2004;54:661-72.

<sup>14</sup> Seager JM, Howell-Jones RS, Dunstan FD, Lewis MAO, Richmond S, Thomas DW. A randomised controlled trial of clinical outreach education to rationalise antibiotic prescribing for acute dental pain in the primary care setting. Br Dent J 2006;201:217-22.

<sup>15</sup> Solomon DH, Van Houten L, Glynn RJ et al. Academic detailing to improve use of broad-spectrum antibiotics at an academic medical center. Arch Intern Med 2001;161:1897-902.

<sup>16</sup> Ilett KF, Johnson S, Greenhill G, Mullen L, Brockis J, Golledge CL, Reid DB. Modification of general practitioner prescribing of antibiotics by use of a therapeutics adviser (academic detailer). British Journal of Clinical Pharmacology. 2000;49:168-73.

<sup>17</sup> Van Eijk ME, Avorn J, Porsius AJ, de Boer A. Reducing prescribing of highly anticholinergic antidepressants for elderly people: randomized trial of group versus individual academic detailing. BMJ 2001;322:654-7.

<sup>18</sup> Berings D, Blondeel L, Habraken H. The effect of industry-independent drug information on the prescribing of benzodiazepines in general practice. Eur J Clin Pharmacol 1994;46:501-5.

<sup>19</sup> de Burgh S, Mant A, Mattick RP, Donnelly N, Hall W, Bridges-Webb C. A controlled trial of educational visiting to improve benzodiazepine prescribing in general practice. Aust J Public Health 1995;19:142-8.

<sup>20</sup> Schmidt J, Claesson CB, Westerholm B, Nilsson LG, Svarstad BL. The impact of regular multidisciplinary team interventions on psychotropic prescribing in Swedish nursing homes. J Am Geriatr Soc 1998;46:77-82.

<sup>21</sup> Midlov P, Bondesson A, Eriksson T, Nerbrand C, Hoglund P. Effects of educational outreach visits on prescribing of benzodiazepines and antipsychotic drugs to elderly patients in primary health care southern Sweden. Family Practice 2006;23:60-64.

<sup>22</sup> Newton-Syms FA, Dawson PH, Cooke J, Feely M, Booth TG, Jerwood D. The influence of an academic representative on prescribing by general practitioners. Br J Clin Pharmacol 1992;33:69-73.

<sup>23</sup> Pit SW, Byles JE, Henry DA, Holt L, Hansen V, Bowman DA. A Quality Use of Medicines program for general practitioners and older people: A cluster-randomised controlled trial. Med J Aust 2007;187:23-30.

<sup>24</sup> Stafford RS, Bartholomew LK, Cushman WC, Cutler JA, Davis BR, Dawson G, et al. Impact of the ALLHAT/JNC7 Dissemination Project on Thiazide-Type Diuretic Use. Arch Intern Med 2010;170(10):851-8.

<sup>25</sup> Feder G, Griffiths C, Highton C, Eldridge S, Spence M, Southgate L. Do clinical guidelines introduced with practice based education improve care of asthmatic and diabetic patients? A randomised controlled trial in general practices in east London. BMJ 1995;311:1473-8.

<sup>26</sup> Solomon DH, Polinski JM, Stedman M et al. Improving care of patients at-risk for osteoporosis: A randomized controlled trial. J Gen Intern Med 2007:362-7.

<sup>27</sup> Young JM, D'Este C, Ward JE. Improving family physicians' use of evidence-based smoking cessation strategies: A cluster randomization trial.

<sup>28</sup> Kim CS, Kristopaitis RJ, Stone E, Pelter M, Sandhu M, Weingarten SR. Physician education and report cards: Do they make the grade? Results from a randomized controlled trial. Am J Prev Med 2002;35:572-83. Med 1999;107:556-60.

<sup>29</sup> Walsh JM, Salazar R, Terdiman JP, Gildengorin G, Perez-Stable EJ. Promoting use of colorectal cancer screening tests. Can we change physician behaviour? J Gen Intern Med 2005;20:1097-101.

<sup>30</sup> Sketris I, Langille E, Lummis H. Optimal prescribing and medication use in Canada: Challenges and opportunities. Health Council of Canada; 2007 May.

<sup>31</sup> Private communication with CADC members, January 15, 2011

<sup>32</sup> Allen M, Ferrier S, O'Conner N, Fleming I. Family physicians' perception of academic detailing: a quantitative and qualitative study. BMC Medical Education. 2007 7:36

<sup>33</sup> Janssens I, De Meyere M, Habraken H, Soenen K, van Driel M, Christiaens T, Bogaert M. Barriers to academic detailers: a qualitative study in general practice. Eur J Gen Pract 2005;11(2):59-63.

<sup>34</sup> Nkansah N, Mostovetsky O, Yu C, Chheng T, Beney J, Bond CM, Bero L. Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns. Cochrane Database of Systematic Reviews 2010, Issue 7. Art. No.: CD000336. DOI: 10.1002/14651858.CD000336.pub2

<sup>35</sup> Glynn LG, Murphy AW, Smith SM, Schroeder K, Fahey T. Interventions used to improve control of blood pressure in patients with hypertension. Cochrane Database of

Systematic Reviews 2010, Issue 3. Art. No.: CD005182. DOI: 10.1002/14651858.CD005182.pub4

<sup>36</sup> van Teijlingen ER, Hundley V. The importance of pilot studies. Social Research Update 2001, Issue 35, http://sru.soc.surrey.ac.uk/SRU35.html

<sup>37</sup> Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, et al. A tutorial on pilot studies: the what, why and how. BMC Medical Research Methodology 2010, 10:1 http://www.biomedcentral.com/1471-2288/10/1

<sup>38</sup> Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. BMC Medical Research Methodology 2010;10:67 <u>http://www.biomedcentral.com/1471-2288/10/67</u>

<sup>39</sup> Hess DR. Retrospective Studies and Chart Reviews. Respir Care 2004;49(10):1171-4.

<sup>40</sup> Mann CJ. Observational research methods. Research design II: cohort, cross sectional, and case-control studies. Emerg Med J 2003;20:54-60

<sup>41</sup> Glossary of EBM Terms, <u>http://ktclearinghouse.ca/cebm/glossary#glossary\_c</u>, accessed March 17, 2011

<sup>42</sup> Hulley SB, Cumming SR, Browner WS, Grady DG and Newman TB. Designing Clinical Research. 3<sup>rd</sup> Edition, 2007.

http://www.collemergencymed.ac.uk/CEM/Research/technical\_guide/biasconfound.htm, accessed April 14, 2011

<sup>44</sup> Klungel OH, Martens EP, Psaty BM, et al. Methods to assess intended effects of drug treatment in observational studies are reviewed. J Clin Epidemiol 2004;57:1223-1231

<sup>45</sup> Peduzzi P, Concato J, Feinstein AR, et al. Importance of events per independent variable in proportional hazards regression analysis. II. Accuracy and precision of regression estimates. J Clin Epidemiol 1995;48:1503-10

<sup>46</sup> Peduzzi P, Concato J, Kemper E et al. A simulation study of the number of events per variable in logistic regression analysis. J Clin Epidemiol 1996;49:1373-9

<sup>47</sup> D'Agostino RB Jr. Tutorial in biostatistics: propensity score methods for bias reduction in the comparison of a treatment to a non-randomized control group. Stat Med 1998;17:2265-81.

<sup>43</sup> 

<sup>48</sup> Newgard CD, Hedges JR, Arthur M, et al. Advanced Statistics: The Propensity Score – A Method for Estimating Treatment Effect in Observational Research. Acad Emerg Med 2004;11(9):953-61.

<sup>49</sup> Permutt T, Hebel JR. Simultaneous-equation estimation in a clinical trial of the effect of smoking on birth weight. Biometrics 1989;45:619-22.

<sup>50</sup> Killip S, Mahfoud Z, Pearce K. What is an intracluster correlation coefficient? Crucial concepts for primary care researchers. Ann Fam Med 2004;2:204-8.

<sup>51</sup> Craig P, Dieppe P, Macintyre S, et al. Medical Research Council. Developing and evaluating complex interventions: new guidance. www.mrc.ac.uk/complexinterventionsguidance

<sup>52</sup> Thomson O'Brien MA, Oxman AD, Davis DA, Haynes RB, Freemantle N, Harvey EL. Educational outreach visits: effects on professional practice and health care outcomes. The Cochrane Database of Systematic Reviews 1997, Issue 4. Art. No.: CD000409. DOI: 10.1002/14651858.CD000409

<sup>53</sup> Avorn J and Soumerai SB. Improving drug-therapy decisions through educational outreach – A randomized controlled trial of academically based "detailing". N Engl J Med. 1983;308(24):1457-1463

<sup>54</sup> May FW, Rowett DS, Gilbert AL, et al. Outcomes of an educational-outreach service for community medical practitioners: non-steroidal anti-inflammatory drugs. MJA 1999;170:471-4.

<sup>55</sup> Freemantal N, Nazareth I, Eccles M, et al. A randomised controlled trial of the effect of educational outreach on prescribing in UK general practice. British Journal of General Practice. 2002;290-5.

<sup>56</sup> Centor RM and Cohen SJ. (editorial) Pharyngitis Management – Focusing on where we agree. Arch Intern Med. 2006;166.

<sup>57</sup> Bisno AL, Gerber MA, Gwaltney MJ et al. Practice guidelines for the diagnosis and management of Group A Streptococcal pharyngitis. CID. 2002;35:113-125.

<sup>58</sup> McIsaac WJ, Kellner JD, Aufricht P, et al. Empirical validation of guidelines for the management of pharyngitis in children and adults. JAMA. 2004;291:1587-95.

<sup>59</sup> Singh S, Dolan JG and Centor RM. Optimal management of adults with pharyngitis – a multi-criteria decision analysis. BMC Medical Informatics and Decision Making. 2006;6:14 doi:10.1186/1472-6947-6-14 <sup>60</sup> Gonzales R, Bartlett JG, Besser RE, et al. Principles of appropriate antibiotic use for treatment of acute respiratory tract infections in adults: background, specific aims, and methods. Ann Intern Med. 2001;134:479-486

<sup>61</sup> Linder JA, Chan JC, and Bates DW. Evaluation and treatment of pharyngitis in primary care practice – The difference between guidelines is largely academic. Arch Intern Med. 2006;166:1374-9.

<sup>62</sup> Smoking Cessation Guidelines, found at <u>http://www.smoke-free.ca/pdf\_l/smoking\_guide\_en.pdf</u>, accessed online January 2008

<sup>63</sup> Smoking Cessation, <u>http://www.healthknowledgecentral.org/onepagers/smoking.pdf</u> accessed January 2008

<sup>64</sup> Stack NM. Smoking Cessation: An Overview of Treatment Options with a Focus on Varenicline. Pharmacotherapy 2007;27(11):1550-7.

<sup>65</sup> Crane R. The most addictive drug, the most deadly substance: Smoking Cessation Tactics for the busy clinician. Prim Care Clin Office Pract 2007(34):117-35.

<sup>66</sup> www.rxfiles.ca, accessed online January 2008

<sup>67</sup> Oxman AD, Thomson MA, Davis DA, Haynes RB. No magic bullets: A systematic review of 102 trials of interventions to improve professional practice. CMAJ 1995 Nov 15;153(10):1423-31

<sup>68</sup> Forsetlund L, Bjørndal A, Rashidian A, Jamtvedt G, O'Brien MA, Wolf F, Davis D, Odgaard-Jensen J, Oxman AD. Continuing education meetings and workshops: effects on professional practice and health care outcomes. Cochrane Database of Systematic Reviews 2009, Issue 2. Art. No.: CD003030. DOI: 10.1002/14651858.CD003030.pub2

<sup>69</sup> Grol R, Wensing M. Selection of strategies. In: Grol R Eccles M, Wensing M, editors. Improving Patient Care: The implementation of change in clinical practice. Edinburgh: Elsevier Butterworth Heinemann, 2005.

<sup>70</sup> World Health Organization, <u>http://apps.who.int/medicinedocs/en/d/Js2289e/4.3.html</u>

<sup>71</sup> Michel P, Quenon JL, de Sarasqueta AM, et al. Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. BMJ. 2004;328:1991-5

<sup>72</sup> Krishna r, Maithreyi R, Surapeneni KM. Research Bias: A review of medical students.
Journal of Clinical and Diagnostic Research [serial online] 2010 April [cited: 2010 April 5]; 4:2320-4.

<sup>73</sup> Green LA, Hames CG Sr, Nutting PA. Potential of practice-based research networks: experiences from ASPN. Ambulatory Sentinel Practice Network. J Fam Pract. 1994;38:400-6.

<sup>74</sup> Kutner, JS, Main DS, Westfall JM, et al. The Practice-based Research Network as a Model for End-of-Life Care Research: Challenges and Opportunities. Cancer Control. 2005;12(3):186-95

<sup>75</sup> Green LA, Curtis G, Hames Sr, et al. Potential of practice-based research networks: experiences from ASPN. (Ambulatory Sentinal Practice Network. Journal of Family Practice. 1994;38:400-7.

<sup>76</sup> Green LA, Reed FM, Miller RS, Iverson DC. Verification of data reported by practices for a study of spontaneous abortion: a report from ASPN. Fam Med 1988;20:189-91.

<sup>77</sup> Mitchell T, Abrams DI, child CC, Townley D. Data collection methods in primary care settings: minimizing problems of missing data in observational data bases. The Community Consortium. Int Conf AIDS. 1992;Jul 19-24;8:C329 (abstract no. PoC 4509)

<sup>78</sup> Lamont S, Murphy P, Sington S. Data collection barriers can be overcome by schemes such as MEDICS. BMJ. 2001;322;674

<sup>79</sup> Canadian Academic Detailing Collaboration meeting, March 17, 2011

<sup>80</sup> Figueira A, Sastre I, Tato F, et al. One-to-One Group Sessions to Improve Prescription in Primary Care. A Pragmatic Randomized Controlled Trial. Med Care 2001;39:158-67

<sup>81</sup> Van Eijk MEC, Avorn, J, Porsius AJ, et al. Reducing prescribing of highly anticholinergic antidepressants for elderly people: randomized trial of group versus individual academic detailing. BMJ 2001;322:1-6

<sup>82</sup> Simon SR, Majumdar SR, Prosser LA, et al. Group versus individual academic detailing to improve the use of antihypertensive medications in primary care: a cluster-randomized trial. Am J Medicine. 2005;118(5):521-8.

<sup>83</sup> Stead LF, Bergson G, Lancaster T. Physician advice for smoking cessation. Cochrane Database of Systematic Reviews 2008, Issue 2. Art. No.: CD000165. DOI: 10.1002/14651858.CD000165.pub3

<sup>&</sup>lt;sup>84</sup> Sinclair HK, Bond CM, Stead LF. Community pharmacy personnel interventions for smoking cessation. *Cochrane Database of Systematic Reviews* 2004, Issue 1. Art. No.: CD003698. DOI: 10.1002/14651858.CD003698.pub2.