PRIMARY CARE DIABETES: ISSUES FACING FAMILY DOCTORS

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By

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ABSTRACT

This thesis describes some of the prominent issues facing primary care practitioners regarding diabetes care. Type 2 diabetes (T2DM) is a common metabolic disturbance among Canadians, now reaching worldwide epidemic proportions. Alarmingly, diabetes prevalence is expected to increase significantly in future years. This increase in diabetes will lead to corresponding increases in the rates of complications, which place a burden on the health care system. However, interventions could prevent or delay T2DM and thus decrease morbidity and mortality associated with its complications if individuals at risk of developing diabetes are detected early.

The first paper describes a systematic review to determine the effectiveness of T2DM screening methods using community or family practice-based systematic screening approaches compared to opportunistic family practice-based approaches. The second paper describes a novel community health initiative, the Community Health Awareness of Diabetes (CHAD) Program. It reports participant characteristics and satisfaction with the community-wide diabetes awareness demonstration project. The third paper examines whether the CHAD program was effective in increasing detection of diabetes. As routine diabetes care remains largely a family practice activity, and something that all family doctors participate in, the fourth paper reports on the current state of diabetes care in 96 Ontario family practices.. The final paper reports the findings

of a qualitative study examining family physicians' approach to insulin prescribing in older patients. Current prevalence figures estimate that 16% of people over 65 years have diabetes and family practitioners look after these individuals and their diabetes.

Finally, recommendations are made as to how screening and care for diabetes in primary care could be improved. In summary, policies supporting community initiatives partnering with primary healthcare should be promoted in an effort to share the burden of screening for diabetes, and also to target appropriate screening to populations that need it the most.

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On a personal note, my children, Milan Singh and Mira Singh have tried to be extremely patient during times of stress with this thesis, and my mother Mrs Margaret Agarwal and father, Dr Rishi Agarwal have supported me throughout the course of the work. Also, Sheri Burns, longtime friend and colleague has helped me with layout and formatting.

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PREFACE

This PhD thesis, which has been written for the Health Research Methodology program, consists of a series of related papers. Five manuscripts, written according to Uniform Requirements for Manuscripts Submitted to Biomedical Journals,[1] are included. One manuscript has been published, and from the remaining four, two have been submitted for publication and are under consideration at the time of writing. An introductory section is included to frame the context of the work and the overall theme, and a concluding section seeks to summarize the findings of the preceding papers.

All five papers are based on studies in which the student was the principal investigator. Data came from two separate studies. The student wrote the grant proposals required to perform the studies, with guidance and supervision of the supervisor, and led the studies, performed all data analyses, and wrote the papers included in this thesis with guidance from the co-investigators and supervisory committee. The final paper mentions co-authors, who provided assistance; but the main body of work (research question, design, analysis and write up) is the student's own unique work, in entirety.

The five papers in order of presentation in the thesis are entitled:

1) Systematic review to determine the effectiveness of T2DM screening methods when using community or family practice based systematic screening approaches, compared to opportunistic family practice based approaches

2) Community Health Awareness of Diabetes (CHAD): Description of participant characteristics and satisfaction with community-wide diabetes awareness demonstration project
3) Is a community-based diabetes awareness program effective at increasing detection of diabetes?
4) Care for patients with type 2 diabetes in a random sample of community family practices in Grimsby, Ontario
5) GPs' approach to insulin prescribing in elderly patients: A qualitative study

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1. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication. *www icmje org* 2007 February 1;Available at: URL: www.icmje.org.

Introduction

Prevalence and Incidence of Diabetes in Canada

Type 2 diabetes (T2DM) and prediabetes [impaired fasting glucose (IFG); impaired glucose tolerance (IGT); and / or both IFG and IGT] are common metabolic disturbances in Canada and worldwide, reaching close to epidemic proportions (1). According to the National Diabetes Surveillance System, in 2009, over 2 million Canadians (over the age of 1) were estimated to have T2DM; a prevalence of T2DM 6.4% (2). As many as one in six people over the age of 65 years are currently estimated to have diabetes (3). Adults from lower income groups are twice as likely to have diabetes as those in the highest income groups (3). Estimates suggest that over 5 million Canadians had prediabetes in 2004; a prevalence of 23% for ages 40 to 74 years (4). The prevalence of IFG is more frequent in women but both IFG and IGT increase in prevalence with age (5). Over a 6 years period a 31% increase in yearly incidence occurred in Canada, from 6.6 per 1,000 in 1997 to 8.2 per 1,000 in 2003 (6). The diabetes epidemic is not restricted to Canada, as 1 in 10 adults in the USA now have diabetes (7). Global estimates indicated there were 171 million people in the world with diabetes in the year 2000 (8).

Predicted increase in numbers of people with diabetes

Alarmingly, diabetes prevalence is expected to increase significantly, to 2.4 million people with diabetes and 6.3 million with prediabetes by 2016 (5,8).

One out of every ten Canadians is predicted to develop T2DM between 2007 and 2017 (9). A recent report predicts that the number of new diabetes cases each year will increase from eight per 1,000 people in 2008, to 15 per 1,000 in 2050 in the USA (7). The report estimated that the number of Americans with diabetes will range from 1 in 3 to 1 in 5 by 2050. The global rate of diabetes was projected to increase to 366 million by 2030 (8).

This increase in diabetes, will lead to corresponding increases in the rates of serious macrovascular and microvascular complications (1,11,12). Indeed, T2DM is associated with a 2-4-fold higher risk for cardiovascular disease (13) and those with IFG, and particularly IGT, are at increased risk of cardiovascular disease (11,12,14). This already places a tremendous burden on the health system.

Progression of prediabetes to diabetes

Individuals with prediabetes are estimated to progress to type 2 diabetes at a rate of 10-12% per year - in total up to as much as 70% will progress (15-17). Furthermore, individuals with both IFG and IGT develop type 2 diabetes at approximately twice the rate as those who have only one of these impairments (18). The speed at which prediabetes progresses to diabetes has serious implications for adequate healthcare provision to the adult Canadian population aged 40 and over (which represented approximately 50% of the Canadian population in the 2006 census) (19).

Since diabetes is a multi-system metabolic chronic disorder, it causes complications that affect many organs including eyes, nerves and kidneys as well as other health related consequences. Specific complications of diabetes include macrovascular (i.e. coronary artery disease), and microvascular (i.e. renal damage, nerve damage and retinal damage) (20). Treatment for diabetes consists of dietary and lifestyle changes, oral medication and injected insulin (20). The healthcare system will be stretched having to care for an epidemic of people with diabetic complications.

However, pharmacological and lifestyle interventions could prevent or delay T2DM and thus decrease morbidity and mortality associated with its complications if individuals at risk of developing diabetes are detected early (21). Unfortunately, only 49% of Canadians over 40 years old report ever having a diabetes screening blood test sometime during their life (22) and much diabetes and prediabetes remains undiagnosed (23). Future treatment costs could possibly be avoided by increasing prevention and screening efforts.

Diagnosis of diabetes

Prediabetes and diabetes can be diagnosed with inexpensive fasting blood tests [either a fasting plasma glucose (FPG) level or a 75-gram oral glucose tolerance test (OGTT)]. The WHO 2006 diagnostic criteria provide the appropriate cut-off points for blood tests interpretation (see Table 1) (24). The FPG test is commonly used by Canadian physicians to identify those with

prediabetes and diabetes (22). Measurement of only a FPG misses 15% or more of people with IGT (25,26); but, using the diagnostic criteria for IFG identifies a different and smaller group of people compared to using criteria for IGT (27,28). Although the oral glucose tolerance test (OGTT) is the diagnostic gold standard, cost and impracticality limit its use as a screening test (overnight fasting and a 2-hour laboratory wait are required).

Screening for diabetes

Screening for diabetes can be approached in 3 different ways; opportunistic, risk-based or universal. Opportunistic screening occurs where a health care practitioner will screen as part of routine medical care, whether this is part of a physical examination or other arising medical interaction (29). Risk-based screening focuses on screening individuals at high risk of developing diabetes due to a health related trait that they have, such as obesity, age, positive family history (30). Universal screening would screen everyone irrespective of characteristics (30) or just use age and gender criteria for screening.

Since the OGTT is the gold standard, including it in any screening program for diabetes and prediabetes may therefore be an important strategy (31), though impractical for universal screening. The challenge is how to improve the overall accuracy of diabetes screening, and to incorporate OGTT at a reasonable cost, by incorporating it as part of a multi-stage screening process. This two-step approach has already been tested and proven in Finland, and is now being

implemented across many European countries as an emerging best practice. Literature demonstrates that non-laboratory based questionnaires (e.g. the FINRISK) to pre-identify individuals at risk of T2DM and prediabetes can be successful (32,33). Screening questionnaires have similar diagnostic accuracy to laboratory screening tests and are inexpensive, simple to use and can also be used as educational tools for patients undergoing screening (32,33,34). They can be used in conjunction with laboratory testing for universal screening.

Role of family practitioners

In light of the evidence for early treatment of diabetes, in the 2003 and 2008 versions of the Canadian Diabetes Association (CDA) clinical practice guidelines (35,36), there was a clear recommendation that individuals at high risk for developing diabetes should be screened to determine their dysglycemic status, in an attempt to be able to recommend changes to lifestyle which may prevent or delay the onset of diabetes. 'High risk' is defined as a person whose first degree relatives have diabetes, and/or who have other diabetes risk factors such as ethnic origin, obesity and dyslipidemia, and who have a FPG of 5.7-6.9 mmol/L. Though not explicitly stated, the implementation of this screening recommendation is the responsibility of family doctors, since traditionally they are the first point of access to health care in Canada. Family doctors usually have the opportunity to detect diabetes in their patients at annual health checks as long as the patient has a physical exam. However, at least 15% of the Canadian

population does not have a family doctor and will not receive a physical (37). Therefore, opportunistic screening in this way may not be the best approach to effectively identify the individuals with diabetes. Other strategies may be more appropriate, but few have been tested or rigorously evaluated in family practice.

Once patients are diagnosed, family physicians are usually the main clinicians managing T2DM. Indeed, in Canada, primary care practitioners are the sole care providers for most patients with diabetes (77%) (38). Family physicians aim to reduce or prevent future complications of diabetes in their patients. However, since diabetes is a chronic condition influenced by many other factors, this can be challenging.

Effective management of diabetes and adherence to guidelines are recommended to family physicians as necessary for the care of patients with diabetes (36). Indeed, the first set of diabetes management guidelines were produced in Canada in 1992 (39). Once guidelines are produced, family physicians have the task of implementing them. However, literature describes the primary care physicians' challenge of balancing the multiple goals of ideal diabetes care and the realities of patient adherence, expectations, and circumstances (40). Physicians perceive many challenges in the care of their patients with diabetes. In the UK, an extensive survey of 20% of GP practices showed that getting patients to alter their lifestyles was perceived as causing the most difficulty in managing patients, followed by lack of time, patients' nonattendance, non-compliance with medical regimens and poor communication

with secondary care (41). Also, the greatest barriers to practices providing desirable care were lack of time/under-funding and keeping up to date in the area of diabetes, followed by lack of space, inadequate chiropody, dietetics, ophthalmology and access to secondary care (41).

From patients' perspectives, behavioural change depends on social and economic priorities. Some patients might understand that they need to make the changes their family doctors recommend; but, cannot make them because they are unemployed, have no benefits, or eat food culturally different from that discussed with the dietitian (42). Despite challenges that are met by family doctors in the care of their patients with diabetes, they are nonetheless expected to meet certain guidelines for diabetes care. Evidence shows that they have fallen short of these guidelines (38).

The increasingly larger elderly population, in whom the prevalence of diabetes is higher, can be a particularly difficult group to clinically manage. In this group, tighter control, including greater use of insulin and combination therapies, is more and more important in ensuring better outcomes and fewer complications (43–47). However, there is evidence that in the elderly, insulin is under-prescribed (48). In 1999, only 11% of seniors in Ontario were prescribed insulin (compared to approximately 40% on diet only or oral hypoglycemics) (49). Other research has suggested that physicians hold personal beliefs about the nature of diabetes in the elderly and that these subsequently influence treatment decisions (50). One belief is that aggressive treatment of chronic hyperglycemia

in elderly people with diabetes is not imperative because of their reduced life expectancy and the inevitability of developing diabetes-related complications (50-53).

Physicians often have a negative view of insulin as a treatment for people with T2DM (48,50,51,54-57). In particular, they are wary of the potentially damaging side effects of insulin, fear treatment refusals, complaints and overall non-compliance due to an insulin-induced decrease in quality of life, and may mention using insulin therapy more as a threat (58). Some specialists believe that family physicians may fuel patient resistance to insulin (56). Delays in the initiation of insulin therapy in elderly people with diabetes validate the opinion that providers frequently delay the use of insulin for as long as possible, despite high plasma glucose levels (59). Furthermore, studies show that elderly patients pay particular attention to their family physician's attitude, often valuing the perspective of the physician's above their own (58,60).

Thesis objectives

This thesis examines several aspects of diabetes screening and care in primary care/family practice in Ontario, with a particular focus on the issues facing family practitioners (i.e. screening for diabetes, adherence to clinical guidelines for diabetes care and use of insulin the elderly) as well as the description and initial evaluation of a novel community diabetes risk assessment program.

Paper 1 overview: Systematic review to determine the effectiveness of T2DM screening methods using community or family practice based systematic screening approaches compared to opportunistic family practice based approaches

Type 2 Diabetes is rapidly increasing in prevalence worldwide. Earlier identification could be beneficial in terms of reducing complications of diabetes. The Canadian Diabetes Association recommends diabetes-screening for all individuals 40 years of age and older. However, widespread community-based diabetes-screening programs for the general population are controversial. There are different approaches to screening: community-based screening in which the screening is offered to everyone or systematic family practice based screening in which the screening is offered to everyone in family practice as a separate specific exercise; or opportunistic screening in which it is offered as part of routine care.

A comparative assessment of the yields of the different types of programs as well as the differences in sensitivity, specificity and positive predictive value (PPV) of the different screening methods is unknown. This systematic review attempts to synthesise the evidence concerning whether community based diabetes-screening programs are effective in the diagnosis of diabetes. The objective of this paper was to determine the yield, sensitivity, specificity and PPV of T2DM screening methods (where possible) when identified using a) community or family practice based systematic screening approaches, or b)

opportunistic family practice based approaches and (if possible) to compare these approaches.

A systematic review of the relevant databases was carried out. Broad areas covered by the search terms were: diabetes; community screening programs; risk assessment and screening; and intervention studies or randomized controlled trials (RCTs). To identify studies in which specific systematic community or family practice based screening strategies were used to identify patients with diabetes. These were those in which screening was a multi-stage approach consisting of diabetes risk assessment questionnaires or questions, with or without ancillary capillary blood glucose testing, followed by an oral glucose tolerance test. To be included screening had to have been based in, or instigated by, the family practice or have taken place in community settings. RCTs, cross sectional studies, time series studies and case control studies were all included. To identify studies in which opportunistic family practice based screening identified patients with diabetes, studies had to identify prevalent cases of T2DM. Methodological quality was independently assessed, using established criteria. The primary outcomes were the yield, sensitivity, specificity and PPV of each screening method. If not reported, these values were then calculated where possible, using the information reported in the study.

Paper 2 overview: *Community Health Awareness of Diabetes (CHAD): Description of participant characteristics and satisfaction with community-wide diabetes awareness demonstration project*

Due to the alarming increase in diabetes globally, developing and testing effective strategies to increase detection of diabetes in the community is an important primary care and population health issue. Current screening tests are too costly and inconvenient to be offered at a population level in the form of a screening program. Furthermore, the organization of primary care in Canada is poorly designed to cope with the initiation and management of comprehensive diabetes screening for everyone over 40 years of age, as recommended by the Canadian Diabetes association. However, sequential and selective screening of high-risk groups could increase efficiency and reduce workload and screening costs for the healthcare system.

The Community Health Awareness Diabetes (CHAD) program was designed to be a two-stage community program to increase awareness of diabetes and identify high-risk individuals for subsequent diabetes screening by their family doctors. This paper describes and evaluates the CHAD program. The outcomes examined were the numbers and characteristics of participants, numbers found at risk and satisfaction of participants.

Participants of the CHAD program were residents of Grimsby, Ontario and the surrounding areas, who were over 40 years old. They were invited to the

program by a local media campaign or by their family physician. All participants were instructed not to eat or drink anything other than water for 8 hours prior to risk-assessment attendance to allow valid blood testing.

Each 3 hour CHAD session took place in a local pharmacy. All attendees consented to participation and then completed a diabetes risk-assessment questionnaire with the assistance of a volunteer staff member (peer health educator/PHE). Scores for each individual risk were interpreted and assigned a risk score according to a validated algorithm. Following this, participants self-administered the capillary blood glucose and glycosylated hemoglobin tests. At the end, participants received a simplified copy of their assessment. Upon participants' consent, risk-assessment results were also sent to participants' family doctors. If indicated, formal screening was suggested by the risk assessment result for those individuals scoring at a 'high risk' of developing or having diabetes.

All sessions were delivered by trained volunteer PHEs who had already participated in a similar community health awareness program focused on hypertension. All were older individuals (55 years of age and older), including some ex-healthcare professionals. Their role was to assist attendees in self-completing the risk-assessment questionnaire, and to guide attendees through the process of the self-testing.

The objective of this paper is to describe and evaluate the CHAD program, focusing on characteristics of the attendees, numbers found to be at risk of diabetes and

participants' satisfaction with the program. This report does *not* describe the effectiveness of the intervention at detecting diabetes, which is described elsewhere.

Paper 3 overview: *Is a community-based diabetes awareness program effective at increasing detection of diabetes?*

(Submitted to Annals of Family Medicine: April 2011)

Diabetes is a chronic condition, which is increasing in prevalence. Over the past ten years, the prevalence of T2DM in Ontario has increased at a much faster rate than anticipated. Up to one third of the people with diabetes are estimated to be undiagnosed. People with diabetes or dysglycemia are at increased risk of developing cardiovascular disease; therefore, there is the potential for a huge amount of healthcare resources to be consumed by people developing diabetes. In Canada, it is recommended that those over the age of 40 should be screened for diabetes every 3 years. Though family doctors are currently aptly placed to be able to provide this service, they are a scarce resource and overwhelmed with other primary care issues.

Evidence regarding the effectiveness of screening programs at actually detecting diabetes in primary care populations is sparse. However, rather than a universal screening program of everybody over the age of 40 years, selective screening of subgroups at high risk of having the disease may reduce the workload and cost of diabetes screening. With this in mind, the CHAD Program

was developed and piloted. To determine the effectiveness of the CHAD program, this study aimed to answer the following questions:

1. In family practice patients aged 40 years or more who were diabetes free, did the availability of diabetes risk assessment program in the community increase the detection of diabetes regardless of whether people attended or did not attend the program?

2. In the same population, did attendance at a diabetes risk assessment program increase the detectable annual incidence (rate) of diabetes compared to patients from the same practices that did not attend the program?

a) Accounting for the age/gender differences and physician differences between attendees and non attendees, did exposure to the CHAD diabetes risk-assessment program lead to an increase in the diagnosis of diabetes 1 year before compared to 1 year after the program, as noted in the charts of a sample of the population of eligible patients compared to usual practice?

b) Assuming there were different diabetes incidence rates in the two groups, when comparing those who attended the CHAD program and those who did not, were there differences in characteristics of the patients' physicians, which could account for different incidence rate ratios?

3. What type of risk information from the CHAD diabetes risk assessment program, when presented to family physicians, was associated with the subsequent diagnosis in a population of patients who had attended the CHAD program?

The study was a retrospective observational chart audit comparing incidence rates of diabetes during one year before and one year after the introduction of the CHAD program, in attendees of the CHAD program and non-attendees of the CHAD program. Two separate analytical techniques, either at the physician level (paired t-test) or at the individual patient level (multi-level regression modeling), were used. The difference in rates of diabetes diagnosis before and after the program was calculated per physician.

Paper 4 overview: *Care for patients with type 2 diabetes in a random sample of community family practices in Grimsby, Ontario*
(Submitted to Canadian Family Physician: May 2011)

Routine diabetes care remains largely a family practice activity and something that all family doctors participate in. In Canada, standards for the care of people with type 2 diabetes have been set by the regularly updated Canadian Diabetes Association (CDA) guidelines since 1999 and continuing thereafter. These guidelines form part of the principles of diabetes care that all family doctors are aware of and are considered to be markers of primary care quality. Previous work has examined family physicians management of patients with diabetes in Canada. Generally, management was found to fall short of the guidelines. It is not currently known how well family physicians are performing at following the most current and appropriate CDA guidelines in their regular

patients in Ontario. This knowledge could help family physicians target certain areas of diabetes care of in service planning for the future.

The goals of this study were to examine a small group of family physicians' management practices in following the current CDA guidelines and achieving targets in clinical care in the following areas: glycemic screening, control and management strategies, documentation and counselling for lifestyle habits, prevalence of co-morbidities, screening for hypertension, hyperlipidemia and use of appropriate recommended preventive medications.

Data was used from a retrospective chart audit of 96 charts from 18 physicians in Grimsby and its surrounding area. Practices provided lists of names of all patients who were rostered to each family physician and who were over the age of 40, and therefore eligible for diabetes screening. As part of this sampling strategy, a number of charts of people with diagnosed diabetes were unintentionally randomly sampled (n=96). This random sample of patients with diabetes formed the sample for study in this paper.

The charts were examined regarding diabetes care during a one year period. Information was extracted from these charts by chart auditors, concerning the routine family practice diabetes care that they received between February 1st 2004 and February 1st 2005. The chart auditors consisted of 2 health research assistants, both with extensive experience of chart auditing in a number of settings. The data extracted by the chart auditors was based upon the CDA 2003 guidelines (which were the current ones at the time of chart review), which

recommended that the following factors needed to be checked on an annual or more regular basis: glycosylated haemoglobin (A1c), lipid values, blood pressure values, lifestyle, diet and exercise factors, smoking and alcohol consumption, and use of medications.

In addition, data concerning the demographics of the physicians and their actual practices was collected by a direct questionnaire to each physician. Physician variables included practice, gender, years in practice and certification status with the College of Family Physicians of Canada. Physician and patient demographic data were summarised using descriptive statistics.

Data was analysed at the patient level. Univariate analysis was performed to look at the proportions of patients who had specific clinical characteristics. To take into account clustering due to the potential similarities of patients attending a particular physician, the intra cluster correlations (ICCs) and their 95% confidence intervals were calculated.

Paper 5 overview: *GPs' approach to insulin prescribing in older patients: a qualitative study*

(Published in British Journal of General Practice: August 2008)

Current prevalence figures estimate that 16% of people over 65 years of age have diabetes. The number of people aged 65 and over with type 2 diabetes (T2DM) in the developed world will double by 2025. As healthcare provision shifts from secondary to primary care T2DM management continues to be a

growing part of the general practitioners' (GPs) role. In an increasingly ageing population of people with T2DM, tighter control, including greater use of insulin and combination therapies, will be important in ensuring better outcomes and less complications; however, there is evidence that in the elderly, insulin is under-prescribed.

Some specialists believe that GPs fuel patient resistance to insulin and postpone its use despite high patient plasma-glucose levels. This study fills an important gap by exploring the process and rationale for prescribing decisions of GPs regarding insulin, when treating older adults with T2DM.

Qualitative research methods were used. Potential participants were randomly selected from a list of actively practicing GPs within a 1 hour driving radius of Hamilton, Ontario. Letters of invitation that outlined the study requirements were mailed to eligible physicians and those that expressed an interest in participating were contacted and consented by a research assistant. An experienced, trained interviewer conducted the in-person interviews. Participant demographic information was collected and interviewing continued until no new ideas emerged and theoretical explanations of emerging phenomena were evident. Interviews were transcribed verbatim.

Data were analysed using a grounded theory approach, and investigators independently read all transcripts and discussed the findings with the research team, ensuring that emerging themes received adequate opportunity for discussion

to allow the developing theory to become saturated. Investigators validated themes by referring back to the original transcripts.

In summary, these 5 papers all demonstrate the importance of family medicine in the identification and management of people with diabetes in the community. Some unique issues are highlighted and discussed in the course of this thesis as they pertain to family medicine.

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Table 1: Diagnostic Criteria for Diabetes and Prediabetes (1, 7, 8)

	Fasting Plasma Glucose (mmol/l)	2 hour Post 75g Glucose Load (mmol/l)
T2DM	≥7.0	≥11.1
Isolated IGT	<6.1	7.8-11.0
Isolated IFG	6.1 – 6.9	<7.8
IGT and IFG	6.1 – 6.9	7.8-11.0
Normal	<6.1	<7.8

Systematic review to determine the effectiveness of T2DM screening methods when using community or family practice based systematic screening approaches, compared to opportunistic family practice based approaches

Abstract:

Background:

Though the Canadian Diabetes Association has recommended diabetes-screening for all people over the age of 40 years, provision of community-based diabetes-screening programs remains controversial. Here, an attempt is made to synthesise evidence concerning whether community based diabetes-screening programs can make an impact on the diagnosis of diabetes.

Method:

A systematic review of adult diabetes-screening programs in a community or family practice context and opportunistic screening in a family practice context was conducted. English-language articles from Medline, Embase, CINAHL and the Cochrane Central Register of Controlled Trials were included. Two independent reviewers assessed methodological quality and extracted data.

Results:

Of 1101 potentially relevant studies, based on assessment by two raters (kappa=0.69), 25 were fully reviewed. Methodological quality between all studies varied. Screening efforts varied, ranging from oral glucose tolerance tests to questionnaires. A community or family practice based systematic diabetes screening approach was utilized in 5 studies; the yield rates of confirmed diabetes

diagnosis among those screened, ranged from 0.066 – 0.017. Opportunistic diabetes screening methods in family practice were utilized in 21 studies; 3 described incidence of new diabetes and 18 described prevalent diabetes; yield rates ranged from 0.010 – 0.126. Neither sensitivity nor positive predictive value could be calculated for either group of studies.

Conclusions:

Though community-based diabetes-screening programs were described in the literature, few had been well evaluated. Studies found were not comparable and methodological quality of the designs was poor. The current literature provides no reliable evidence either for or against community or family practice-based screening. Careful future research is needed in this area and any future program development must include rigorous program evaluation.

Introduction

Evidence shows that the prevalence of type 2 diabetes (T2DM) is rapidly increasing worldwide(1). Though T2DM can often remain undiagnosed and asymptomatic in its early stages(2), once diagnosed, it can be treated with lifestyle modification and medication, and some elements of the disease process may be reversible(3,4,5). In light of this, early T2DM detection may be beneficial to both patients and society(6). Screening may also detect people at high risk of developing diabetes; and thereby, determine the likelihood that a person may have a positive diagnosis of diabetes.

Although the Canadian Diabetes Association recommends diabetes-screening for all individuals 40 years of age and older, widespread community-based diabetes-screening programs for the general asymptomatic non-pregnant population remain controversial(7). However, community-oriented diabetes risk-assessment programs have the potential to identify people at increased risk of prediabetes or diabetes in whom subsequent diagnostic screening can be recommended. Organized systematic community or family practice based screening for diabetes is also a controversial issue. Although opportunistic family practice-based screening, which is offered during routine care, is recommended, its effectiveness has been questioned. Instead, targeted and more focused risk-based screening has been suggested in family practice and in the community. As screening is not diagnostic, patients still need diagnostic tests to confirm the presence (or absence) of the disease.

The yield of patients found to have true diabetes out of all those screened (the ability of a program to detect undiagnosed cases)(8), is a useful crude measure of the feasibility and effectiveness of a screening method, though sensitivity, specificity and positive predictive value remain the best values for epidemiological comparison(9,10). The yield rate refers to the number of those found with a gold standard diagnosis of diabetes out of all those screened, BUT the PPV is the number of those with a gold standard diagnosis of diabetes out of all those found to have diabetes or a risk of diabetes by screening - therefore they are quite different. Nevertheless, a comparative assessment of the yields of the different types of programs as well as the differences in sensitivity, specificity and positive predictive value (PPV) of the different screening methods is unknown. Until this is determined, it is difficult for policy makers and public health professionals to advocate for the optimal screening approach in community and/or family practice settings in terms of effectiveness and cost-effectiveness.

In this paper, an attempt has been made to identify and synthesise the evidence regarding the value or effectiveness of using community or family medicine based systematic diabetes-screening programs versus opportunistic family practice based approaches.

Objective:

To determine the yield, sensitivity, specificity and PPV of T2DM screening methods (where possible) when identified using a) community or family

practice based systematic screening programs, or b) opportunistic family practice based approaches and (if possible) to compare these approaches.

Methods

A systematic review of MEDLINE, Cumulative Index to Nursing & Allied Health Literature (CINAHL), Cochrane Central Register of Controlled Trials (CCTR) and EMBASE from their inception to September 19th 2008 was carried out. To examine all the relevant literature, two separate searches, which were appropriate to each part of the question, were carried out.

Search strategy

The search strategy included the mesh terms listed in Table 1. The search combined 'content' terms (MeSH and Emtree) identified through related reviews and test searches, 'design' terms (e.g., intervention studies) and 'free-text' terms likely to appear in relevant articles. Broad areas covered were: diabetes; community screening programs; risk assessment and screening; and intervention studies or randomized controlled trials (RCTs). The bibliographic reference lists of all included studies or relevant review articles were also screened for articles that may require inclusion. All searches were limited to those written in the English language, and studies conducted on humans.

Inclusion and exclusion criteria

Initially, to identify studies which used systematic community or family practice based diabetes screening only the most rigorous design (randomized controlled trials (RCTs)) was included in the search. However, because no RCTs

were found, the search criteria based on design were relaxed to include cross sectional studies, time series studies and case control studies as well. Participants in the included studies had to be over 40 years of age, previously undiagnosed with diabetes, and regular patients (rostered/registered/identified as regular patients) with a community family practitioner or resident in a community in which the intervention was being delivered (so that a standardized screening instrument was available to all eligible candidates).

Screening strategies included those in which screening was a multi-stage approach consisting of diabetes risk assessment questionnaires or questions, as outlined in the Finnish Diabetes Risk Score(11) and the American Diabetes Risk Score(12), with or without ancillary capillary blood glucose testing, followed by an oral glucose tolerance test. To be included, screening had to have been based in, or instigated by, the family practice or have taken place in a community setting. Those studies that did not report oral glucose tolerance test results (OGTT) or fasting blood glucose (FBG) results, those in whom participants were already diagnosed with diabetes and/or were residing in an institution or long term care facility were excluded. The FBG and OGTT used for diagnosis as per the WHO/CDA guidelines(7,13) were considered gold standards. Two reviewers (GA and TK) independently pre-screened titles or abstracts for relevance and assessed potentially eligible full-text reports for this section of the review.

To identify studies which used opportunistic family practice based diabetes screening several methods were used. First, studies had to identify

prevalent cases of T2DM. In this context 'prevalent diabetes' was defined as undiagnosed diabetes and newly detected diabetes together, found in family practice. Second, published chart audits, retrospective studies and cross-sectional studies conducted on family practice records that reported prevalence of diabetes were included. Lastly, for the study to be included, T2DM had to have been detected by usual practice methods (this was assumed to be either 2 sequential OGTTs, or FBGs or one of each according to the WHO guidelines/Canadian Diabetes Association Guidelines)(7,13). Therefore, the gold standard was physician diagnosis of diabetes in the primary care chart. Where special or novel screening methods were employed the study was excluded. Population prevalence studies were also excluded since they did not detect a prevalence estimate that could be attributable solely to opportunistic family practice screening methods. One reviewer (GA) assessed the eligibility for this section.

Data collection and statistical analysis

Data review and extraction was undertaken independently by two authors (TK, GA) for the first section of the review, using a pre-developed, pilot-tested form. A consensus process was used to make decisions and interpretations based on the study reports. A qualitative analysis of the studies' data to summarize the information was carried out. Data collected included characteristics of study design, details and demographics of the population that was screened, the method of diabetes diagnosis utilized, the numbers of those diagnosed with diabetes as a

result of intervention-based screening tests and the numbers of those diagnosed by definite gold standard tests.

Information was actively sought regarding the yield[1], sensitivity[2], specificity[3] and PPV[4] of the screening or diagnostic tests, and if not reported, then these values were calculated where possible, using the information reported in the study, as defined in the diagram below.

Diagram to show definitions for values used in calculations

		True diagnosis (gold standard)		
		Diabetes present	Diabetes absent	
Test results	Positive	True positive (tp) - those who had a positive diagnosis in the primary care chart (assumed gold standard) or who had gold standard testing	False positive (fp)	People identified by screening as having disease (D) = tp+fp - all those who screened or were identified as diabetic
	Negative	False negative (fn)	True negative (tn)	
TOTALS				All those who underwent screening (S) = tp+tn+fp+fn - population who was screened, or the number out of which the prevalence or incidence was quoted (usually 1000)

[1] **Yield** = number of true positives with diabetes (tp)/total number who underwent screening (S) [this differs from the positive predictive value in which the denominator is that number which is used as the numerator in the yield calculation]

[2] **Sensitivity**=number of true positives (tp) /number of true positives (tp) + false negatives (fn) (9)

[3] **Specificity**=number of true negatives (tn)/number of true negatives (tn) + false positives (fp) (9)

[4] **Positive predictive value** = number of true positives with diabetes (tp)/ tp + fp OR number of those identified at risk of diabetes (D) (10)

Where information regarding the numbers of those newly diagnosed with diabetes or diabetes prevalence was given in the studies for multiple time points, the most recent was used for the purposes of describing the rates for the review, and because more recent rates would be more relevant and up to date.

Methodological quality

The methodological quality of each relevant article was independently assessed, using established criteria. RCTs were scored using the Jadad scale (1996)(14) and additional criteria from Verhagen (1998)(15). Combined criteria from Mallen et al (2006)(16) and Downs & Black (1998)(17) were applied to observational designs.

Outcomes

The primary outcomes were the yield, sensitivity, specificity and PPV of each screening method. The gold standard (known as the true positive in the sensitivity calculation) for diabetes diagnosis for all screening methods was defined by the WHO guidelines/Canadian Diabetes Association Guidelines (7, 13), which utilized either 2 sequential OGTTs, or FBGs or one of each. Where studies did not quote confidence intervals, these were calculated (18). Calculated data were indicated within the tables.

Results

A total of 1101 studies were identified by the full literature search (see Figure 1) (19-43). Finally, 25 studies were finally found to be relevant to the

questions posed; 5 studies for one question and 21 studies for the other; one study was found to be common to both questions therefore a total of 25 studies were included (see Tables 2, 3 and 4[*]). The included studies were conducted in Europe and North America; two each from the Netherlands, Denmark and the U.S.A and 19 from the U.K. All studies were observational in design, and were very heterogeneous in aspects of design. No RCTs were found. A qualitative narrative meta-synthesis approach was used because the substantial diversity in study designs, interventions and outcomes prevented pooling of quantitative data for meta-analysis(44). None of the studies reported sensitivities, specificities or PPVs of the screening methods or the information needed to calculate them.

Methodological Quality

Agreement between reviewers on potentially relevant articles, based on title review, for the studies pertaining to systematic diabetes screening methods in the community, was moderate (kappa 0.69, $p<0.000$, SE=0.073). Since no RCTs were found and all studies reviewed were observational in nature, criteria from Mallen et al (2006)(16) and Downs & Black (1998)(17) were used to assess methodological quality (see Figure 2). Methodological quality varied for the 25 studies (see Table 5), ranging from 3 to 15, with a mean of 9.72 out of 15 (SD=3.26). The main methodological failure was that in most of the studies, compliance with the screening method was not reported (n=22); in many, loss to follow up was also not reported (n=21) and uptake rate for screening was also not

[*] Tables 2, 3 and 4 present different information since information was not available on all types of studies consistently.

described (n=19). Five studies scored less than half of the total methodological score possible.

Data reported in studies and calculations possible

In the systematic screening group, yield was not reported. However, all studies reported the numbers of people who were screened; a few reported numbers of true positives (by OGTT) and most reported numbers of those who had a diagnosis of diabetes after undergoing screening. Therefore, it was possible to calculate a yield.

In the opportunistic screening group, there were also no reports of yield. Studies reported prevalence of diabetes per 1000 patients or annual incidence of diabetes per 1000 patients in primary care. These values had been extracted from the primary care charts by study researchers. It was assumed that WHO/CAD guidelines would have been adhered to in diagnosing diabetes in primary care; therefore, prevalence and incidence values can be considered to be 'true positives'. A yield was calculated assuming that the prevalence per 1000 was equivalent to true positives per 1000 of the population screened.

Community or family practice based screening for diabetes using a systematic screening approach

Of the 469 studies identified through the literature review for diabetes screening using a systematic approach, five were included in the review (see Table 6).

The yield rates of diagnosis from the screening methods ranged from 0.017 – 0.066. The highest (0.066) was found in the study that assessed screening in an Eskimo population only(25). The next highest yield rates, ranging from 0.035- 0.037, were found in the two studies that were lifestyle modification studies to prevent diabetes(23,37), and had been designed primarily as RCTs; but, the portion of data examined for the purpose of the systematic review was cross sectional, and part of screening prior to RCT entry. The yield rates generated from these 2 studies seem consistent with each other, probably due to the fact that the same type of population self-selected to participate in this type of lifestyle study. Two of the studies had been designed to test step-wise diabetes screening methods in general practice, one in the UK (34) and one in Denmark(21). The British study(34) had a lower sample size. Both had the lowest yield rates, (0.06-0.02). There was no obvious pattern linking the methods of screening used and the yield rates found.

Screening for diabetes in general practice using opportunistic methods

Of the 632 studies identified, 21 were included in the review (see Table 7 and 8). Of these, 3 specifically identified the numbers of those with newly diagnosed diabetes, and the remaining 18 identified prevalent diabetes rates. All of these were cross-sectional in design and were conducted in the UK, except for one, which was conducted in the Netherlands. Data were extracted in two ways; 15 studies used practice collated diabetes registers and three audited the electronic records. All practices had relied on the existing methods of diabetes detection.

The practices used in the studies were heterogeneous; some were small (a single practice with 7 GPs) and others reported on large collations of data from 8970 practices. The diabetes prevalence figures were a combination of T1DM and T2DM, unless otherwise stated, and all studies used a general practice population, not restricted by age or gender. They were all conducted at different times; the earliest prevalence was from 1989 and the most recent from 2004. Six out of the 18 studies scored less than half of the methodological score. Papers reviewed did not clearly report whether or not diabetes diagnoses had been established using gold standard testing methods; therefore, it was not possible to report or calculate sensitivities, specificities or PPVs. However, yield rates were calculated and ranged from 0.010- 0.026. The 3 studies using electronic medical records had higher yield rates and those using diabetes registers seemed to have lower yield rates.

Two of the studies extracting newly diagnosed diabetes rates used diabetes registers and one used electronic medical records (Table 8). All scored high on methodological quality and were conducted within a 4 year period of time. The yield rates of screening methods used in all 3 studies was 0.02.

Discussion

The studies reviewed in both groups were very different, utilizing different study populations and methods of recording positive screening tests. Therefore, it was not possible to directly compare sensitivities, specificities or

PPVs between groups. Overall, the data were poor and it was difficult to draw meaningful conclusions from the review. Differences in the yield rates are also questionable due to the difference in study methodologies and screening tests. Looking at the studies that did have comparable populations(21,34) the systematic annual screening yield rate ranged from 0.06 to 0.017, compared to approximately 0.010 from opportunistic family practice screening(27,28,42,43). Thus, systematic screening appeared to identify more people with diabetes. However, there are other factors to consider in a systematic approach to screening such as the frequency of screening, cost, burden to the system and resource use in general. More research is required on these factors.

Previous literature has shown that yields of diabetes screening programs vary according to the screening test cut-off points and have ranged from 4% – 72% (8). These values are not directly comparable with the yield rates obtained from this review, since here, the number of new cases potentially identified within a certain timeframe was extracted.

In the studies reviewed, the detected diabetes would likely have been undiagnosed prevalent diabetes and therefore yield rates calculated from such programs at the time point reported here may be higher than subsequent yield rates at later times. Using time intervals between screenings would allow detection of newly arising diabetes, depending on the time intervals chosen. It was not possible to determine from these studies what the exact recommended interval should be.

The main limitation of this review was the fact that the studies were so heterogeneous and thus not directly comparable in a meaningful way. In the opportunistic screening in the family practice group of studies, although a diagnosis of diabetes may have been recorded, it was not certain that a gold standard method was always, or even ever, used. In family practice, diagnoses may have been made without fully following guidelines; therefore, FBG and/or OGTT may not have been utilized. It was not possible to verify this for the studies reviewed here. It was also not possible to calculate specificities since the figures were not available from the papers for the numbers of patients who had true negative testing for diabetes.

Few studies looked at systematic diabetes screening in a robust way, with a design that would allow for confounding factors. This is likely to be due to the fact that such an RCT involving matched communities, though robust, would be costly and difficult to coordinate. There were also no studies that included a control group or time series measurement to assess effectiveness of screening methods in comparison with other existing measures; all were observational.

The studies looking at systematic screening methods were difficult to interpret as a whole. The populations of the studies were different and ranged from a specific ethnic group, to a general practice population. The purposes of the studies were also different and therefore different populations may have been attracted to the studies thus introducing self selection bias, particularly for the

lifestyle prevention studies. Moreover, the time periods over which the screening programs were conducted varied significantly.

Most of the studies reviewed for the family practice opportunistic screening group were based on prevalence estimates from the UK. Literature shows that in the UK, practice registers are only able to identify 60.4% of all patients with diabetes(45). Therefore, it is possible that the estimates presented are not an accurate representation of true prevalence, and that with systematic screening or improved screening approaches a further 40% could be identified.

Conclusion

This systematic review showed that there were differences in yield rates for different screening methods used in family practice and the community, depending upon the population screened and method used. However, data were difficult to interpret since the studies were of poor methodological quality and not directly comparable. The current literature provides no reliable evidence either for or against community or family practice-based diabetes screening. Before being adopted widely, screening methods and intervals would need to be investigated more rigorously and further careful research would be needed in several different communities or family practice populations.

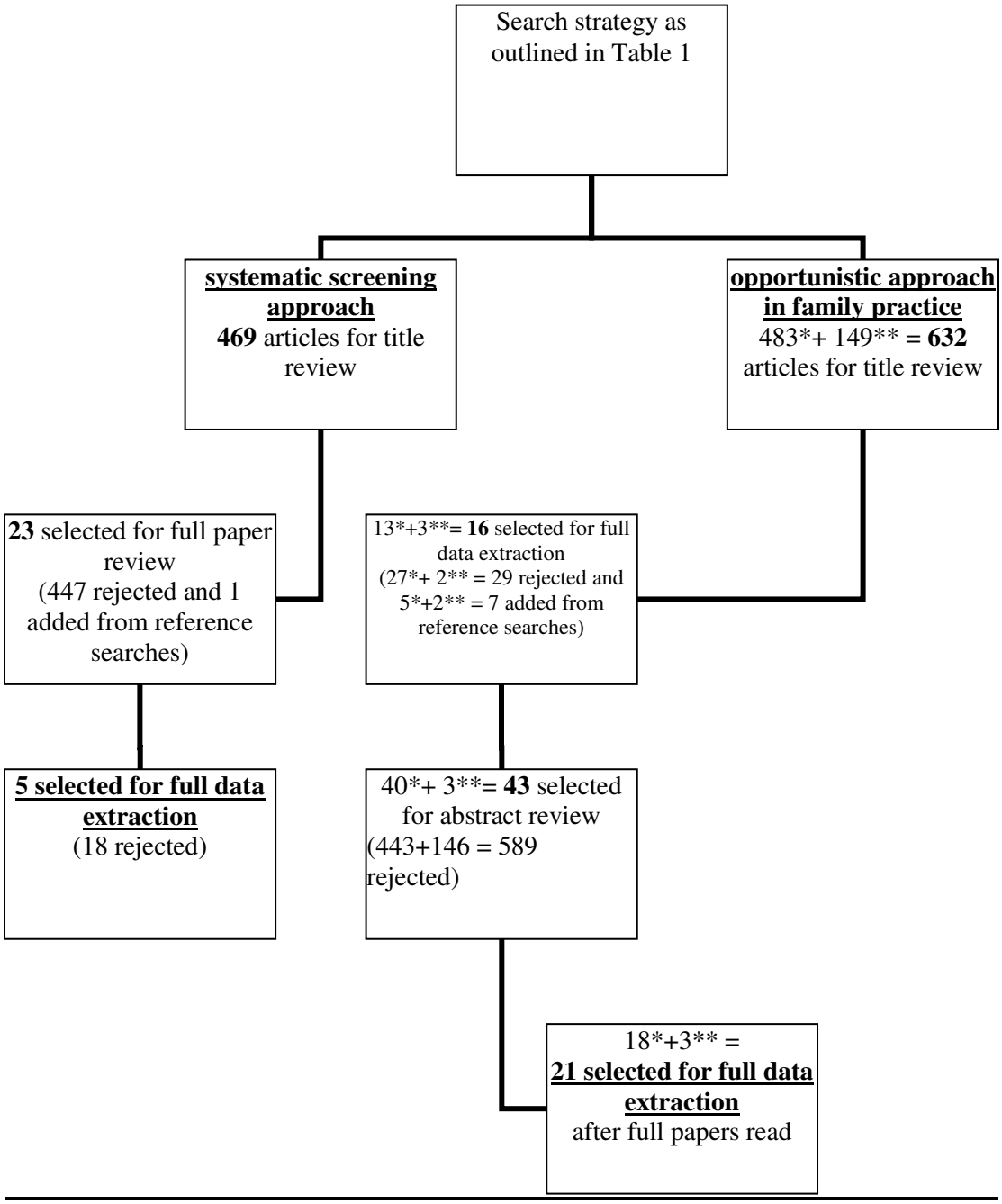
Table 1: Search strategies used

Group A
1 diabetes.mp.
2 diabetes mellitus, Type 2/
Group B
3 family practice.mp.
4 family practice/
5 general practice.mp.
Group C
6 prevalence.mp.
7 prevalence/
8 incidence
Group D
9 chart audit.mp.
10 chart review.mp.
11 retrospective studies/
Group E
12 screening.mp
13 mass screening/
14 community screening.mp.
15 community-based screening.mp.
Group F
16 programme.mp.
17 program.mp.
Group G
18 community-based.mp.
19 population based.mp.
Group H
20 risk prevelance.mp.
21 risk assessment.mp.
22 diagnosis.mp.
Group I
23 Intervention.mp. or intervention studies/
24 Randomized Controlled Trials/ or RCT.mp.

Each group of terms was combined using 'OR'.
Different groups were then combined using 'AND' as follows:

Search strategy to determine the prevalence of type 2 diabetes within the community or family practice when identified using:
a) a systematic screening approach used A and B and C and D.
b) an opportunistic approach used A and B and (E or F or G) and (H or I).

Figure 1: Flow chart of articles identified



* articles pertaining to prevalence
** articles pertaining to incidence (NOTE: one article stated prevalence and incidence and therefore has been included in this diagram twice)

Figure 2: Evaluation of Observational Designs

Based on Mallen et al (2006)(16); refinements/headings informed by Downs & Black (1998)(17)

1. Type of study stated (list: quasi-experimental, before & after, etc)
2. Is the hypothesis/aim/objective clearly described? (D&B)
3. Sufficient power to detect a clinically important effect? (D&B)
4. Accurate and appropriate outcome (intervention) measures
5. Outcomes measured for all participants
6. Participants characteristics described
7. Potential confounders described
8. Adjustment for confounding
9. Response/uptake rate described
10. Loss to follow-up (appropriate level)
11. Was compliance with the intervention/s reliable? (D&B)
12. Were the statistical tests used to assess the main outcomes appropriate? (D&B)
13. Clear inc/exc criteria for all designs
14. Main findings described
15. Conclusions supported by findings

OVERALL SCORE: _____/ 15

Table 2: Studies using a systematic screening approach (n=5)

Author, journal, year and study	Design and study purpose	Date	Population	Recruitment from (community vs. family practice)	Sample size	Intervention description and location
Diabetes Prevention Program, Diab Care, 2005 DPP study	Cross sectional No control Study to identify people with diabetes and then to start a lifestyle intervention in them and see the effects of the intervention	Early 2000	US population	Community recruitment via special DPP clinics and use of media, radio, newspaper to attract participants as well as physicians, work place clinics and health fairs	158,183 made contact with the study of which 79,190people were eligible for screening	Pre-screening questions and capillary blood test in DPP study centres to identify people needing to have screening for diabetes with OGTT for recruitment into lifestyle intervention arm of study
Christensen et al, Diabetologica 2004 ADDITION study	Cross sectional To test stepwise diabetes screening in general practice	2001-2002	88 general practices in Denmark	Patients of general practices aged 40-69	60,926	Pre-screening questions self-administered, then random blood glucose and HbA1c, then fasting BG, then OGTT
Ebesson, Int J of Circumpolar Res, 2005	Cross sectional study	1994	Northwestern Alaska	People from 3 Eskimo ethnic groups	899 eligible individuals, 454 participated in screening	Interview and then FBG/OGTT
Mensink et al, Diab Res and Clin Pract, 2003	Lifestyle intervention study primarily, but included a portion at the beginning where people were screened for diabetes in order to recruit them for the trial	1999-2000	Dutch over 40 year olds – unclear where the population was selected from – says it was form an existing community study (the Maastricht SLIM study)	Not reported	Not reported	Not reported

Author, journal, year and study	Design and study purpose	Date	Population	Recruitment from (community vs. family practice)	Sample size	Intervention description and location
Lawrence et al, BMJ, 2001	Cross sectional population study to assess stepwise screening methods in general practice	2000	Over 45 year olds registered to a particular general practice in the UK	Letter sent to all over 45 year old in the practice not known to have diabetes already	2481 patients	Recruitment letter invited attendance at the practice for a screening test (capillary blood glucose) and questionnaire after fasting for 8 hours, from this patients were stratified into being sent for an OGTT, or repeat FBG

Table 3: Studies using an opportunistic screening approach (n= 18)*

Author, journal and year	Type of population of study	Sample size	Date	Identification of people with diabetes	Intervention description	Age adjusted preva-lence
Fleming et al, BJGP, 1994	British General practices registered as sentinel practices in a network	48 general practices	1993	Practices but NOT clear exactly how	Chart audit	
Gatling et al, Diab Res and Clin Pract, 2001	Poole, UK, registered to GPs in study	24 General practices	1996-1998	At the study start, those already in the practice registers were verified with the local hospital register [1996 prevalence of diagnosed diabetes 1.59 (CI 1.53 – 1.56)]	Those patients with newly diagnosed diabetes who did NOT attend any screening programs (WHO 1985 def'n) identified if they had been to DM education groups, hospital, clinics	
Gibbins et al, JRCGP, 1989	Powys, Gwent, Wales, registered to GPs in study	6 large group general practice, with 29 GPs	1988	Register identified by each GP from memory and also diabetes prescriptions	Chart audit of all those identified by the register	
Howitt et al, BMJ, 1993	Tunbridge Wells, UK	41 practices in Tunbridge Wells,	1993	Practice registers and memories of practitioners	Questionnaire of all participating practices	
Kemple et al, BMJ, 1991	Bristol, UK	1 group practice with 7 grps	1990	Diabetes register started in 1983	Retrospective chart audit	

Author, journal and year	Type of population of study	Sample size	Date	Identification of people with diabetes	Intervention description	Age adjusted preva-lence
Khunti et al, BJGP, 1999	UK	259 general practices in the UK, part of multi-practice audit group	1994	Diabetes registers in practices	Data collection form to be filled out by practices	
Lusignan et al, BMC Family Practice, 2005	England and Wales	74 practices, part of the Doctor's Network database	1994-2000	Practice registers	Electronic data collection and collation from EMRs	
Meadows et al, Diab Med, 1995	Bristol, UK	8 general practices	1992-1993	Practice register	Observation data from practices	1.51% (1.31% - 2.51%)
Millett et al, J R Soc Med, 2007	England and Scotland	8970 general practices	2004	Practice registers	Electronic data collection and collation from EMRs	
Morgan et al, Diab Med, 2000	Wales	74 general practices	1996	Practice registers	Chart audit	
Morris et al, BMJ, 1997	Tayside, Scotland	8 general practices	1996	Practices registers	Chart audit	
De Grauw et al, J of Fam Pract, 2002	Nijmegan, Netherlands	10 family practices	1993 and 1999	Practice registers	Electronic data collection and collation from EMRs	
Gatling et al, Diab Med, 1998	Poole, UK	10 general practices	1983 and 1996	Practice registers	Chart audit	'83- 0.97% '96- 1.55%

Author, journal and year	Type of population of study	Sample size	Date	Identification of people with diabetes	Intervention description	Age adjusted preva-lence
Carney et al, BJGP, 1995	Tynedale, Northumberland, UK	12	1991	Practice registers	Chart audit confirmation of register	
Dunn et al, BJGP, 1996	Poole, UK	36	1992-93	Practice registers	Chart audit	
Williams et al, Diab Med, 1990	Norwich, UK	8 general practices	1987	registers	Chart audit, prescriptions and case ascertainment	
Higg s et al, Diab Med, 1992	Trowbridge, UK	?	1992	Practice registers	Chart audit and confirmation of records	
Benett et al, Diab Med, 1994	Manchester, UK	64	1993	Practice registers	Chart audit	

*studies documented prevalence of diabetes as an outcome

Table 4: Further studies an using opportunistic screening approach (n= 3)*

Author, journal and year	Type of population of study	Sample size and age	Date	Identification of people with diabetes	Intervention description	Time interval	Age adjusted incidence
Ryan et al, Public Health, 2005	208 general practices form the General Practice research database in UK	1.3 million All ages included	1994 and 1998	From diabetes registers in each practice;	Data analysis form the data in the database, no chart audit verification for all	1 year	Age and sex specific and also individual year specific are reported in the text
Ubink-Veltmaat, Eur J of Epidemiology, 2003	8 general practices from a working group Netherlands	155,774 All ages	1998 and 1999	From diabetes registers and also chart records which were reviewed to back the information up	GPs who were part of the working group included in the study had access to research staff who would perform these tasks	1 year	For women; 22.5 [22.2-22.7] For men; 21.6 [21.3-21.8]
Gatling, Diab Res Clin Pract, 2001**	Poole, UK, registered to GPs in study	24 General practices	1996-1998	At the study start, those already in the practice registers were verified with the local hospital register (1996 prevalence of diagnosed diabetes 1.59 [CI 1.53 – 1.56])	Those patients with newly diagnosed diabetes who did NOT attend any screening programs (WHO 1985 defn) identified if they had been to DM education groups, hospital, clinics	186,889	Age adjusted annual incidence for the UK 1.67 per 1000 (1.49-1.84)

*Studies documented incidence of diabetes as an outcome

** This study is included in the prevalence studies as well since it quoted BOTH prevalence AND incidence of diabetes

Table 5: Methodological Quality of Studies Reviewed n=25)

Author, journal and year	Type of study stated (list: quasi-experimental, before & after,	Is the hypothesis/aim/objective clearly described?	Sufficient power to detect a clinically important effect?	Accurate and appropriate outcome (intervention) measures	Outcomes measured for all participants	Participants characteristics described	Potential confounders described	Adjustment for confounding	Response/uptake rate described	Loss to follow-up (appropriate level)	Was compliance with the intervention/s reliable?	Were the statistical tests used to assess the main outcomes	Clear inc/exc criteria for all designs	Main findings described	Conclusions supported by findings	Score Out of 15
Benett et al, Diab Med, 1994 (19)	0	1	1	1	1	0	0	0	0	0	0	0	0	1	1	**6**
Carney et al, BJGP, 1995 (20)	0	1	1	1	1	1	1	0	0	0	0	1	1	1	1	**10**
Christensen et al, Diabetologica, 2004 (21)	0	1	1	1	0	1	1	1	1	1	1	1	1	1	1	**13**
De Grauw et al, J of Family Practice, 2002 (22)	1	1	1	1	1	1	1	1	0	0	0	1	1	1	1	**12**
Diabetes Prevention Program, Diab Care, 2005 (23)	1	1	1	1	1	1	1	0	1	1	0	1	0	1	1	**12**
Dunn et al, BJGP, 1996 (24)	1	0	1	1	1	1	1	0	0	0	0	0	0	1	1	**8**
Ebesson, Int J of Circumpolar Research, 2005 (25)	1	1	0	1	1	0	0	0	1	0	0	1	0	1	1	**8**
Fleming et al, BJGP, 1994 (26)	0	0	1	0	1	1	0	0	0	0	0	1	0	1	1	**6**
Gatling et al, Diabetic Medicine, 1998 (27)	1	1	1	1	1	1	1	1	0	0	0	1	1	1	1	**12**
Gatling et al, Diab Res Clin Pract, 2001 (28)[††]	1	1	1	1	1	1	1	1	0	0	0	1	1	1	1	**12**
Gibbins et al, JRCGP, 1989 (29)	0	0	1	0	1	1	0	0	0	0	0	1	0	1	1	**6**
Higg s et al, Diab Med, 1992 (30)	0	0	1	0	0	0	0	0	0	0	0	0	0	1	1	**3**
Howitt et al, BMJ, 1993 (31)	1	1	1	1	0	1	1	0	1	0	0	1	1	1	1	**11**
Kemple et al, BMJ, 1991 (32)	0	1	0	1	1	1	0	0	0	0	0	0	0	1	1	**6**
Khunti et al, BJGP, 1999 (33)	0	1	1	1	1	1	0	0	0	0	0	1	1	1	1	**9**
Lawrence et al, BMJ, 2001 (34)	1	1	0	1	1	1	1	0	1	1	1	1	1	1	1	**13**
Lusignan et al, BMC Family Practice, 2005 (35)	0	1	1	1	1	1	1	1	0	0	0	1	1	1	1	**11**

[††] This paper was reviewed for two outcomes – once for prevalence and once for incidence

Table 5: Methodological Quality of Studies Reviewed n=25)

Author, journal and year	Type of study stated (list: quasi-experimental, before & after,	Is the hypothesis/aim/objective clearly described?	Sufficient power to detect a clinically important effect?	Accurate and appropriate outcome (intervention) measures	Outcomes measured for all participants	Participants characteristics described	Potential confounders described	Adjustment for confounding	Response/uptake rate described	Loss to follow-up (appropriate level)	Was compliance with the intervention/s reliable?	Were the statistical tests used to assess the main outcomes	Clear inc/exc criteria for all designs	Main findings described	Conclusions supported by findings	Score Out of 15
Meadows et al, Diab Med, 1995 (36)	1	1	1	1	1	1	1	1	0	0	0	1	1	1	1	**12**
Mensink et al, Diab Res and Clin Pract, 2003 (37)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	**15**
Millett et al, J R Soc Med, 2007 (38)	1	1	1	1	1	1	1	1	0	0	0	1	1	1	1	**12**
Morgan et al, Diabetic Medicine, 2000 (39)	1	1	1	1	1	1	1	1	0	0	0	1	1	1	1	**12**
Morris et al, BMJ, 1997 (40)	1	1	1	1	1	0	0	0	0	0	0	1	0	1	1	**8**
Ryan et al, Public Health 2005 (41)	1	1	1	1	1	1	1	1	0	0	0	1	1	1	1	**12**
Ubink-Veltmaat, Eur J of Epidemiology 2003 (42)	0	1	1	1	1	1	1	1	0	0	0	1	1	1	1	**11**
Williams et al, Diab Med, 1990 (43)	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	**3**

Table 6: Yield from systematic screening approaches (n= 5)

Author, and year	Screening methods used														# total screened, age and gender, sample charact-eristics	# screened positive (D)	# with OGTT diagnosis of T2DM (Gold standard or tp)	Yield of screening program = tp/total screened (calculated)	Time frame of program (months)	Methodological score
	Gestational M	MedicationD	Age	Sex	Ethnicity	FHx DM	BMI /height+weight	PHx HT	Lifestyle	Smoking	BP	CBG	Random ?Fasting BG	HbA1c						
Diabetes Prevention Program, 2005			•	•	•	•	•					•			79,190 Overweight individuals >25yrs invited for lifestyle modification study, form clinics and employment health groups	30,383	2,753	2,753/79,190 = **0.035** *[0.034-0.036]	1999-2002 2 2/3 yrs 28months	12
Mensink et al, 2003			•			•	•								6108 People aged >40yrs, both male an female invited to attend study for monitoring health and disease	2715	226	226/6108= **0.037** *[0.033-0.042]	March 1999-June 2000 15months	15
Ebesson, 2005		•		•	•	•			•	•	•		•		454 Eskimo population from 1 village area, >25 yrs, all genders	Not reported	30	30/454= **0.066** *[0.047-0.093]	April/May 2004 months	8

Christensen et al, 2004	•		•	•		•	•	•	•				•	•	60,926, From 88 general practices in Denmark, males and females 40-69 yrs, excluding severe mental, debilitating chronic illness	11,243	361	361/60926= **0.06** *[0.053-0.066]	Not reported	13
Lawrence et al, 2001			•			•	•	•		•	•	•			876 Males/females aged >45 From single practice in the UK (n=2481)	495	15	15/876= **0.017** *[0.011-0.028]	2000 12 months	13

Table 7: Yield from opportunistic screening approaches (n= 18)*

Author, journal and study	Method of data extraction	Age and gender	Stated Crude T2DM Prevalence per 1000 patients out of practice population [95% CI]	Yield of screening program = tp/total screened (calculated)	Year	Methodological Score
Fleming et al, BJGP, 1994	Diabetes registers	All ages/gender	**16** *[15.6-16.5]	0.016	1993	6
Gatling et al, Diab Res Clin Pract, 2001	Diabetes registers	Al ages/gender	**23** [CI 22-23]	0.023	1998	12
Gibbins et al, JRCGP, 1989	Diabetes register	All ages and gender	**10** *[9.2-11.1]	0.010	1989	6
Howitt et al, BMJ, 1993	Diabetes registers	All in the practice	**12** *[11.0-12.3]	0.012	1993	11
Kemple et al, BMJ, 1991	Diabetes register	All ages/gender	**17** *[14.8-19.2]	0.017	1990	6
Khunti et al, BJGP, 1999	Diabetes registers	All ages/gender	**15** *[14.1-15.2]	0.015	1995	9
Meadows et al, Diab Med, 1995	Diabetes register – validated form charts (Both types of diabetes)	All ages/genders	***14** *[13.2-14.9]	0.014	1992/1993	12
Millett et al, J R Soc Med, 2007	Diabetes registers	All and both	**33** *[31.9-34.9]	0.033	2004	12
Morris et al, BMJ, 1997	Diabetes registers	All ages and genders (T2DM only)	**18** *[16.8-19.5]	0.018	1996	8
Gatling et al, Diab Med, 1998	Diabetic registers (Both types of DM)	All ages and genders in the practices – Poole, UK	**19** [CI = 18-20]	0.019	1996	12
Carney et al, BJGP, 1995	Diabetes registers	All ages and both genders	**13** *[11.7-13.5]	0.013	1991	10

Author, journal and study	**Method of data extraction**	**Age and gender**	**Stated Crude T2DM Prevalence per 1000 patients out of practice population [95% CI]**	**Yield of screening program = tp/total screened (calculated)**	**Year**	**Methodological Score**
Dunn et al, BJGP, 1996	Diabetes register	All ages and gender	**16** *[15.6-16.6]	0.016	1991	8
Williams et al, Diab Med, 1990	Diabetes registers, but validated from charts	All ages and genders Norwich, UK	**13** *[11.8-13.9]	0.013	1989?	3
Higgs et al, Diab Med, 1992	GP registers, semi rural Trowbridge, UK	All ages, genders	**13** *[11.9-14.4]	0.013	1992	3
Benett et al, Diab Med, 1994	GP registers	All ages/genders	**12** *[11.7-12.5]	0.012	1993	6
Lusignan et al, BMC Family Practice, 2005	Electronic databases		**27** [26-28] **23** [22-24] *Both genders; 26 [25-28]	0.026	2000	11
De Grauw et al, J of Fam Prac, 2002	Electronic medical records audit (T2DM only)	All ages and genders in the practices	**19** *[17.3-19.8]	0.019	1999	12
Morgan et al, Diab Med, 2000	Electronic chart audit	All ages, both males and females	**16** *[15.2-16.0]	0.016	1996	12

* confidence interval calculated using prevalence (denominator 1000)

Table 8: Yield from opportunistic screening approaches (n= 3)*

Author, journal and study	Data extraction	Time (months)	Age and gender	Crude Annual Incidence per 1000 patients of diabetes out of practice population [95% CI]	Yield of screening program = tp/total screened (calculated)	Year	Methodological Score
Ryan et al, Public Health, 2005	Chart audit of electronic records	24	All ages, males and females included	**2** [2.1-2.3]	0.02	1996-1998	12
Ubink-Veltmaat, Eur J of Epidemiology 2003	Diabetes registers	36	All ages, males and females included	**2** [2.1-2.2]	0.02	1998-2000	11
Gatling et al, Diab Res and Clin Prac, 2001	Diabetes registers	Not reported	All ages, males and females included	**2** [2.2-2.3]	0.02	1998	12

* confidence interval has been calculated using quoted incidence of diabetes rate (denominator was 1000)

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Community Health Awareness of Diabetes (CHAD): Description of participant characteristics and satisfaction with community-wide diabetes awareness demonstration project

Abstract

Background: Developing and testing effective strategies to screen for and detect diabetes in the community is an important population health issue. The Community Health Awareness Diabetes (CHAD) program was designed to be a community program to identify high-risk individuals for subsequent diabetes screening by their family doctors.

Objectives: This paper describes the CHAD program and evaluates its success.

Methods: Participants, who were residents of Grimsby, Ontario and over 40 years old, were invited to self risk-assess for diabetes using a validated questionnaire and 2 near patient blood tests (capillary blood glucose and glycosylated hemoglobin). Some participants were self-selected, having seen advertising for the program, and others had been invited by a letter from their family doctor. No participants had pre-existing diabetes. The outcomes examined were the numbers and characteristics of participants, numbers found at risk and satisfaction of participants.

Results: There were 588 participants in CHAD; of these, the majority had received invitation letters, were seniors and females; 526 did not have pre-existing diabetes; and 16% of participants (n= 84/526) were identified as being at high risk

for diabetes. Those at high risk of diabetes had significantly more modifiable risk factors, including higher fat, fast food and salt intake, and higher systolic blood pressure. Satisfaction with the program was high.

Conclusion: Use of a two-stage screening process may be useful in identifying community-based individuals who are at risk of diabetes or pre-diabetes.

Introduction

Alarmingly, adult diabetes-prevalence in Ontario rose by 80%, from 5% in 1995, to 9% in 2005(1). Current estimates suggest that people with diabetes use five-times as many health resources as those without(2). Therefore, developing and testing effective strategies to increase detection of diabetes in the community, is an important primary care and population health issue. An effectively screened population will have diabetes diagnosed 5–6 years earlier than a population without an organized screening program(3), offering opportunities for delaying diabetes and related complications(4). Hence, the Canadian Diabetes Association recommends that all Canadians over 40 years old should be screened for diabetes with fasting plasma glucose (FPG) or oral glucose tolerance tests (OGTT) every 3 years, or annually in the presence of risk factors(5).

These current screening tests are too costly and inconvenient to be offered at a population level in the form of a screening program. Furthermore, the organization of primary care in Canada is poorly designed to cope with the initiation and management of comprehensive diabetes screening for everyone over 40 years of age(6). Existing diabetes prevention and lifestyle programs, designed for research and not community application, have unrealistic program costs, since they require all participants to have OGTTs(7,8). However, sequential and selective screening of high-risk groups could increase efficiency(9) and reduce workload and screening costs for the healthcare system by reducing the

number of individuals requiring a 'gold standard' diagnostic test, as compared to universal screening(10,11).

The Community Health Awareness Diabetes (CHAD) Program was designed to be a practical, feasible, low-cost community program to increase awareness of diabetes and identify high-risk individuals to be targeted for subsequent diabetes-screening by their family doctors.

The objective of this paper is to describe and evaluate the CHAD program, focusing on characteristics of the attendees, numbers found to be at risk of diabetes and participants' satisfaction with the program. This report does *not* describe the effectiveness of the intervention at detecting diabetes, which is described elsewhere.

Methods

Participants, setting and program description

Participants of the CHAD program were residents of Grimsby, Ontario and the surrounding areas, who were over 40 years old. Participants were invited to the program in two separate ways. Firstly, a local media campaign (local paper advertisements, radio announcements and local news television appearances) advertized the program and listed the eligibility criteria. Secondly, family physicians (recruited to the program by personal contact from the principal investigator) agreed to either hand out advertisements/invitations to suitable patients for risk assessment sessions opportunistically, or to send invitations through the mail to all patients over 40 years old without diabetes. All participants

were instructed, by letter or advertising, not to eat or drink anything other than water for 8 hours prior to risk-assessment attendance to allow valid blood testing.

Each CHAD session took place in one of 5 local pharmacies and consisted of a 3 hour period accommodating 15 - 30 people. All attendees consented to participation and then completed a diabetes risk-assessment questionnaire with the assistance of a volunteer peer health educator (PHE). The risk-assessment questionnaire included questions (shown in Table 1) which had been previously validated(12,13). Scores for each individual risk score were interpreted as high risk for diabetes if they were > 15 for the Finnrisk or >0.199 for the Cambridge risk score. Following this, two near patient tests were self-administered by participants (the capillary blood glucose - CBG and glycosylated-hemoglobin - HbA1c). Performance characteristics of these screening tests compared to the gold standard are presented in Table 2.

After the session, participants received a simplified copy of the assessment, and, if warranted by the assessment, were invited to attend a session for counseling, provided locally, around modifiable risk factors. Upon consent, a risk-assessment result was also sent to participants' family doctors. These results were formatted to resemble a laboratory test and included attendance date, and a risk-assessment for diabetes described as low, moderate or high according to the literature. An algorithm which combined the Finnrisk Questionnaire scoring(12), the Cambridge Diabetes risk assessment questionnaire(13), HbA1c lab cutoff values(14) and FBG values(15) was used to report on these results, which also

suggested further management and follow-up strategies using the adapted CDA guidelines(5) (see Table 3). Formal screening was suggested for those individuals scoring at a 'high risk' of developing or having diabetes.

All sessions were delivered by volunteer PHEs who had been recruited from a pool of interested older adults, who had already participated in a similar community health awareness program focused on hypertension. All were older individuals (55 years of age and older) and included some ex-healthcare professionals. They were trained in 2 two-hour long sessions by a public health nurse and family physician (GA), including hands-on experience with the risk-assessment questionnaire and CBG and HbA1c testing. The PHEs assisted attendees in self-completing the risk-assessment questionnaire, and guided attendees through the process of the CBG and HbA1c self-testing. PHEs were not required to touch the attendees' soiled lancets or blood-stained items at any time, as they instructed attendees to dispose of their own biological waste in appropriate containers that were provided.

Outcomes

The program was evaluated based on the following outcomes:

1. attendance rates and characteristics of participants;
2. numbers of participants who had been identified as being at high risk for diabetes and specific numbers of individuals who were high risk for the different components of the CHAD program (Finnrisk, Cambridge Risk score, CBG, HbA1c);

3. the presence of modifiable or non-modifiable lifestyle risk factors; and

4. participants' satisfaction with the program.

At the end of each session, exit self-evaluation surveys were administered by the PHEs. Participants were asked 12 questions (see Table 4) about whether the tests that they had undergone were suitable and acceptable, whether the timing and location of the clinics was satisfactory, their opinions of the importance of diabetes screening, the need for a screening program and the operational aspects of the program. Responses were assessed on a 5-point Likert scale ranging from strong disagreement to strong agreement with each item. In addition, free space was given for participants to write comments of their own. The questionnaire was not validated, but had been piloted for face validity on a small convenience sample prior to use.

Analysis

All data was statistically analyzed using SPSS version 16.0 (16) to generate descriptive statistics.

Characteristics of participants were compared to data drawn from Census Canada 2001(18), where possible, and examined for differences by method of referral to program. Risk assessment scores and their components were summarized descriptively. Satisfaction with the program was analyzed descriptively and comments on the surveys were analyzed with thematic analysis(17).

Results

Attendance and characteristics of attendees

In 2005, between February 26th and April 28th, 62 CHAD sessions were held in 5 community-based pharmacies in Grimsby, Ontario. Twenty five PHEs and 10 family physicians (n=10/32) were recruited to the program. At the time of the study, Grimsby had a population of approximately 36,000 individuals over 40 years of age(18). The majority of participants (46%) had received an invitation letter from their family doctor (of whom 58% were female, 51% seniors); 40% responded to media advertisements (of whom 64% were female; 61% seniors); and 14% just walked in off the street (of whom 66% were female and 49% seniors).

In total, 526 patient participants without pre-existing diabetes attended the CHAD clinics. The participants' mean age was 66 years (std. deviation 12), 56% were 65 years of age or older (age range 40- 99 years), and 62% were female. Of those who answered the post program satisfaction questionnaire (n=202), 95% (n=194) answered a question about their educational attainment status; a third (37%) were educated to high school, less were educated to college level (19%), and about the same amount (approximately 13% each) were educated to university, trade/apprenticeship or less than high school level.

Comparing the attendees to data about Grimsby residents as reported by the 2001 Census, the educational status of attendees was slightly higher than that of the local population; there were more high school graduates (36.6% CHAD

attendees vs. 25.6% from Census data) and fewer elementary school-only graduates (12.9% CHAD vs. 24.2% Census). The age distribution of the attendees was also different; there were fewer 45-54 years olds (13.5% CHAD vs. 40.2% Census) and more 65-74 year olds (34.2% CHAD vs. 18.6% Census). The attendees represented approximately 5% (526/12,390) (18) of the adult population in the Grimsby/West Lincoln area eligible to participate in the program (over 40 years of age).

Risk status

Using a combination of the Finnrisk Score (very high risk/high risk; scores of >15), Cambridge risk score (high risk; scores > 0.199), HcA1c (>0.63%) and CBG (> 6.1mmol/l), 16% of attendees (n= 84/526) were identified as potentially high risk for diabetes and the results of the risk-assessment were sent to their family doctor. Separate test risk scores are shown in Table 5. Those with a high diabetes-risk, as identified by the risk-scoring, had *significantly* higher self-reported prevalence of modifiable-risk-factors when compared to those with low risk of diabetes (Table 6). This group had a higher fat and fast food intake (45.8% vs. 30.3% [p= 0.006]), reported higher salt consumption (45% vs. 32% [p = 0.021]), were more likely to require medication for high blood pressure (54.8% vs. 33.3% [p,0.000]), but were less likely to adhere to the medication (44.0% vs. 65.6% [p<0.000]), and were more likely to have a higher mean systolic BP (140mmHg vs. 135mmHg [p=0.037]). The trend towards self-reporting a higher

cholesterol measurement (51.2% vs. 40.0% [p=0.061]) was also exhibited in the 'at risk' group.

Presence of Risk factors

Modifiable risk factors that are part of the diabetes risk assessment themselves (either in the Finnrisk or Cambridge scores) were expected to be different in the high risk and other groups. The 'at-risk' participants were less active (only 14% were active for 30 minutes a day compared to 83% in the low risk group [p=0.024]), more overweight (77% had a body mass index over 25 vs. 62% in the low risk group, [p=0.012]), and had a higher naval waist circumference (81% vs. 68%, [p=0.021]). They did not report a lower vegetable consumption (10% did not eat vegetables fruits and berries vs. 5.3% [p=0.12]), and they were less likely to report smoking (2.4% vs. 8.6% [p=0.14]) (see Table 6). Non-modifiable risk factors were not significantly different in the 'at risk' group (see Table 7). The demographics of the 'at-risk' population was significantly different from those not 'at-risk' in that they were more likely to be male (38.8% vs. 36.0% [p=0.027]), and there was a greater number of 55-64 year olds (28.6% vs. 18.5% [p=0.025]) (see Table 8).

Participants' assessment of and satisfaction with the program

Thirty five percent (204 participants) completed a questionnaire after a risk assessment-session (35% were males; ages ranged from 42 to 88; 72% were over 65; and 51% stated their health was either very good or excellent).

Specific satisfaction-related factors worth mentioning are as follows; Ninety percent thought pre-attendance fasting was easy. Only 7% (n=15) felt the blood test had been too painful. Overall, 84% (n=172) thought the risk-assessment clinics had been worthwhile. Just below half (n=97) were going to change their lifestyle as a result of the clinic. Just under half had had a glucose test and lipid test at their family practice within the preceding year. The thematic analysis of open comments on the post attendance questionnaires revealed 29 positive comments, mostly about the informative nature and value of the clinics, the ease of the location, what was expected of participants and helpfulness of the volunteer staff.

Discussion

The CHAD program performed a risk assessment prior to inviting individuals to attend their family doctor for more conclusive screening; 16% were at risk for diabetes and could have been tested further by their family physician. Literature shows that many diabetes screening programs have been developed and tested; but, have generally produced disappointing results(7) and there have been problems with generalizability, implementation and impracticality(8, 19, 20). Literature demonstrates that community screening can identify less than 1% of participants as having diabetes(7); but, when step-wise screening methods are used, the identification rate increases to between 7 or 8% (8, 21) and 30% (14) in different populations. Selective screening is also more cost-effective in the 40-70

year age band, and in those who are obese or hypertensive(22). Validated risk scores can be used as pre-screening tools(19), with a high sensitivity and specificity, minimizing the number of people requiring sequential blood testing(23), thus, potentially saving resources and patient-discomfort.

Though screening programs may detect individuals at risk of disease, involving participants' doctors can increase a program's benefits(9) and is crucial. CHAD was designed to incorporate family physicians and inform them of the risk assessment results. This strategy has been previously tried in hypertension screening(24) but not diabetes. Other community-based diabetes screening programs have been entirely population–based(20) and participants were invited on the basis of their birth-date from census data.

The use of PHEs in CHAD is an interesting component of the program. Literature shows that programs can be improved and costs lessened by using community resources such as community-based pharmacies, volunteers and other resources(9). Using local, trained volunteers not only keeps costs to a minimum(9), but decreases the need for precious and expensive health professionals' time and has been shown to have a consistent positive effect on participants(25).

In 2003, the World Health Organization recommended that the most important population considerations of any community diabetes screening program should be the acceptability of the screening program to those invited to attend and the extent to which any lack of acceptability reduced uptake, as well as

the ability to modify the risk of those found to be at risk of developing future diabetes(26). The CHAD program fulfilled all of these criteria. Information regarding participants' satisfaction with previous community-based programs was sparse, and the response of CHAD participants was encouraging in that pre-fasting, capillary blood testing, and risk-scoring questions are all components that could be repeated in subsequent iterations of CHAD.

Those who attended CHAD had a number of risk factors that could be modified. It is interesting, though not surprising, to note that the 'at-risk' group had significantly more risk factors that were potentially modifiable, and also that they were less likely to adhere to their medication for hypertension. This identifies this population as being interested in their lifestyle and health, by virtue of having participated in CHAD, and perhaps at a stage when they may be able to address some of their poor lifestyle choices. Literature identifies this specific population (hypertensive and obese) as being the ones in whom diabetes screening is the most cost-effective(19).

Limitations

The main limitation of the CHAD program was that it heavily relied on community participation, both in the form of volunteers who could act as PHEs and also pharmacists who provided a venue for the screening tests. At times, the venue could be crowded and busy, and not an ideal place for filling out lifestyle questionnaires. The CHAD program required that patient participants fasted prior to their appointment, and though some did not, this was not a very large problem.

There is likely to be some selection bias in the attendees who participated in the program. The fact that the attendees were more educated reflects the self-selected nature of the sample, and could indicate that they were a group of people more likely to be concerned with their health, and therefore less likely to develop diabetes. This type of individual may also be more able and ready to modify their lifestyle in the event of screening recommendations.

Conclusion

The objectives of the CHAD program were to assess feasibility of a low-cost community-wide diabetes-awareness program that could provide local family physicians with additional information in order that they might initiate targeted, appropriate diabetes-testing. It was not designed to be a stand-alone, continuously running program, but developed to be used in conjunction with members of community primary health care teams (family doctors, nurse practitioners and pharmacists) to provide short 'bursts' of intensive targeting of high risk individuals to screening, which could be applied to the community at a suitable interval of time. Attendance rates were acceptable and participants were satisfied with the program in such a way as to make the program worth repeating in different communities. Innovative community strategies like CHAD provide possible solutions to the problem of implementation of Canadian population-based diabetes-screening programs, though they require further careful evaluation.

Table 1: Questions posed as part of risk assessment

Question	**From Finnrisk*** (12)	**From Cambridge Risk Score*** (13)
Sex Male Female		X
Age in years		X
Are you currently taking steroids (e.g. prednisone) regularly? *Yes No*		X
Age in categories *<45 (0) 45-54 (2) 55-64 (3) >64 (4)*	X	
What is your height? *(Convert inches to cm by multiplying by 2.54)*	X	
What is your weight? (as before) *(Convert lbs to kg multiply by 0.4536)*	X	
BMI value (weight in kg over height in cm squared) *< 25 kg/m2 (0) 25-30 kg/m2 (1) >30kg/m2 (2)*	X	X
What is your waist circumference? (measured at the navel) *Men: <94cm (0) 94-102cm (3) >102cm (4)* *Women: <80cm (0) 80-88cm (3) >88cm (4)*	X	
Do you have daily at least 30 minutes of physical activity at work and/or during leisure time (including normal activity)? *Yes (0) No (2)*	X	
How often do you eat fruit, vegetables or berries? *Every day (0) Not every day (1)*	X	

Have you taken anti hypertensive medication regularly? *No (0) Yes (2)* *Don't know (0) Not daily (0)*	X	X
Have you ever been found to have high blood glucose (e.g. In a health exam, during an illness, during pregnancy) *No (0) Yes (2)*	X	
Have any of the members of your immediate family or other relatives been diagnosed with either type 1 or type 2 diabetes? *No (0) Yes (grandparent, aunt, uncle, 1st cousin) (3) Yes (Parent, Brother, Sister, Own Child)(5)*	X	X
Do you smoke? *Yes No*		X

Score obtained is indicated in brackets for each answer; answer options in italics
** These questions have been validated in previous studies*
*** Total Finnrisk score; 0 – 7 =low risk, 7 – 10 =slightly elevated risk, 10 – 15= moderate risk, 15 – 20= high risk, >20 = very high risk of developing diabetes in future*

Table 2: Performance characteristics of the individual approaches used by the CHAD program compared to gold standard

Screening test	Sensitivity when used in community	Specificity when used in community	Requires sample to be sent laboratory	Requires fasting	Requires blood test
Oral glucose tolerance test, 2 hour PG >= 11.1 mmol/l	100% (Gold standard)	100% (Gold standard)	Yes	Yes	Yes
Fasting plasma glucose measurement (FPG)	75%, at > 6.3 mmol/l cut off (14)	92%, at > 6.3 mmol/l cut off (14)	Yes	Yes	Yes
HbA1c measurement	66 - 72% (15)	66 - 98% (15)	No	No	Yes
Capillary blood glucose measurement (CBG)	56–84% (15, 16)	86–96% (15,16)	No	No	Yes
Cambridge risk score (12)	78% (12)	51% (12)	No	No	No
Finnish Diabetes Risk score (11)	78% - 81% (11)	76 - 77% (11)	No	No	No

* The oral glucose tolerance test is the gold standard and only one measurement is diagnostic for diabetes; FPG and CPG may not be, so 2 measurements are required.

Table 3: Algorithm used in the preparation of report sent to family doctors for their patients who attended

Fasting Capillary Blood Glucose (mmol/l)		**HbA1c (%)**		**Blood results summary**		
Low risk <6.1	High risk >=6.1	Low risk <6.3	High risk >=6.3	*Low risk*	*Medium risk*	*High risk*
X		X		*X*		
	X		X			*X*
	X	X				*X*
X			X		*X*	

AND

Finnish Diabetes Risk Score			**Cambridge risk score**		**Risk score summary**		
Low risk <7	Medium risk 7-14	High risk >= 15	Low risk <0.199	High Risk >= 0.199	Low risk	Medium risk	High risk
X			X		X		
		X		X			X
X				X		X	
	X		X			X	
	X			X			X
		X	X			X	

The summaries from the 2 tables above were amalgamated to produce the CHAD composite risk score:

Blood tests summary			**Risk scores summary**			***CHAD COMPOSITE DIABETES RISK SCORE***		
Low risk	Medium risk	High risk	Low risk	Medium risk	High risk	Low risk	Medium risk	***High risk***
X			X			X		
	X		X				X	
		X	**X**					***X***
X				X			X	
	X			X			X	
		X		***X***				***X***
X					X		X	
	X				***X***			***X***
		X			***X***			***X***

Table 4: Satisfaction score of participants based on 12 questions

Question*	Number of respondents out of 204 total	Percentage at extreme level of agreement (5) with Likert scale (%)	Actual mean scores	SD
I need to be screened for diabetes	192	22.4	2.85	1.52
My Doctor needs to be informed of my risk for diabetes	188	43.1	3.39	1.66
Fasting before was easy	190	82.1	4.66	.83
Location of clinics was convenient	191	93.2	4.87	.54
The blood test was easy to administer on myself	172	79.1	4.57	.98
The blood test was not too painful for me to have undergone	185	**88.6	1.37	1.12
The volunteer was invaluable	187	75.4	4.46	1.15
The risk assessment process was very worthwhile	193	86.0	4.79	.60
I will change my lifestyle as a result of the risk assessment procedure	179	36.9	3.59	1.38
I will go to the family doctor to discuss my results	188	62.2	4.00	1.46
The risk assessment helped me to understand my risk of developing diabetes	182	61.5	4.29	1.07
Overall, I was satisfied with the risk assessment process	186	88.7	4.84	0.52
TOTAL SCORE from ALL 12 questions above (maximum of 60)	***137***		***50.95***	***6.69***

* Answers for questions on a 6 point Likert scale ranged from lowest (0) 'disagree' up to highest (5) 'agree'

** Likert scale reversed for this question, agreement with (0) or 'disagree' is quoted here

Table 5: Performance Characteristics of different individual and aggregate tests used by the CHAD program in participants

Screening test[$]	**At Risk CHAD attendee % (n=84)**	**Not at Risk CHAD attendee % (N=442)**	**Chi squared test p value**
HbA1c measurement > 0.63	15.5 (13)	0.5 (2)	**<0.00***
Capillary blood glucose measurement (CBG) > 6.1mmol/l	95.2 (80)	0.00 (0)	**<0.00***
High Cambridge risk score > 0.199	79.8 (67)	51.0 (221)	**<0.00***
High Finnish Diabetes Risk score >15	28.6 (24)	10.9 (47)	**<0.00***

[$]The CHAD composite diabetes risk of 'at risk' was determined with the following algorithm (see Table 3):

- Fasting CBG > 6.1mmol/l OR
- Finnish Diabetes Score >15 OR
- Finnish Diabetes Score >7 AND Cambridge Score >0.199

Other measures such as the HbA1c and values of the scores and tests were amalgamated in a similar way to determine low and medium risks.

Table 6: Comparison of modifiable risk factors in those identified as being "at risk" and remaining participants

Modifiable RF	**At risk % (n, N=84)**	**Not at Risk % (n, N= 442)**	**Chi Sq. P value**
Overweight (BMI >25kg/m^2)	77 (61)	62 (245)	**0.012***
Physically active for 30 minutes a day	14 (74)	83 (330)	**0.024***
Waist circumference high (>80cm for females, >94cm for males)	81 (68)	68 (296)	**0.021***
Low vegetable consumption	9.8 (8)	5.3 (21)	0.121
*#**Smoking***	*2.4 (2)*	*8.6 (36)*	*0.140*
*$**High or Moderate fat/ fast food consumption***	*45.8 (38)*	*30.3 (128)*	***0.006****
*$**High/Moderate salt intake***	*45.2 (38)*	*32.1 (135)*	***0.021****
*$**On BP medication***	*54.8 (46)*	*33.3 (144)*	***<0.000****
Does not take BP medication regularly	44.0 (37)	65.6 (284)	**<0.000***
*$**Mean systolic BP (taken at risk assessment session)*** *Mean (SD)*	*140.37 (21.639)*	*134.97 (21.516)*	***0.037**** *(F test, p value)*
*$**Mean diastolic BP (taken at risk assessment session)*** *Mean (SD)*	*81.31 (9.457)*	*79.63 (10.973)*	*0.191 (F test, p value)*
*$**High Systolic BP (taken at risk assessment session)***	*42.2 (35)*	*36.0 (155)*	*0.290*
*$**High Diastolic BP (taken at risk assessment session)***	*51.8 (43)*	*47.4 (204)*	*0.466*
*$**Both high systolic AND diastolic BP (taken at risk assessment session)***	*28.9 (24)*	*25.3 (109)*	*0.497*
*$**Cholesterol***	*51.2 (42)*	*40.0 (163)*	*0.061*

$ Variables described were NOT part of the risk assessment questionnaire

 # Smoking was a variable included in the Cambridge risk score, but not part of the Finnish Risk Score

Note: identification of being 'at risk' was based on the algorithm developed as part of the CHAD program and described in the methods section

Table 7: Comparison of non-modifiable factors in those identified as being "at risk" and remaining participants

Non-Modifiable Factors	At risk % (n, N=84)	Not at Risk % (n, N= 442)	Chi Sq. P value
Told that they have diabetes or sugar in past	7.1 (6)	3.2 (13)	0.083
Heart attack, Stroke or TIA in past	14.3 (12)	9.2 (39)	0.161
Ethnic origin (non-white)	1.2 (1)	1.4 (6)	0.154

Note: identification of being 'at risk' was based on the algorithm (see Table 3) developed as part of the CHAD program

Table 8: Demographics of those 'at risk' vs. 'not at risk' of diabetes

% (n)	At Risk CHAD attendee	Not at Risk CHAD attendee	Chi squared test p value
Age (n=517)[$]	**N= (84)**	**N=(433)**	**0.025***
45-54	8.3 (7)	13.4 (54)	
55-64	28.6 (24)	18.5 (80)	
Over 64	59.5 (50)	56.1 (243)	
Under 45	3.6 (3)	5.5 (24)	
Male (n=197)	38.8 (41)	36.0 (156)	**0.027***

[$]28 cases did not disclose their age
Note: identification of being 'at risk' was based on the algorithm developed as part of the CHAD program and described in the methods section

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Is a community-based diabetes awareness program effective at increasing detection of diabetes?

Abstract

Diabetes is a serious chronic condition for which screening in primary care is recommended in those over 40 years old; usually, family physicians are expected to perform this screening, though they have ample work. The CHAD (Community Health Awareness of Diabetes) Program was piloted to assist family physicians, by assessing patients in community pharmacies for diabetes risk. The paper determines the effectiveness of the program at detecting incident diabetes.

Patients of family physicians were invited to attend risk-assessment sessions in the form of a diabetes risk questionnaire and capillary blood glucose test. Results were sent to family physicians and given to attendees immediately. The effect of the program on incident diabetes detection rates was measured using a retrospective observational chart audit of patients in local family practices, before-and-after the program.

Overall 1030 charts were audited; 387 charts were of CHAD program attendees. The diabetes incidence rate-ratio in program attendees versus non-attendees, comparing one year before-and-after a community diabetes screening program, was 1.65(0.028/0.017), [95% CI = 0.04 - 61.6]. The difference between the rates of diabetes diagnosis for the 28 physicians before-and-after the program

was not significantly different for the whole sample when assessed using a paired t-test (p= 0.28, df = 27, [95% CI -0.09, 0.03].

A community diabetes risk-assessment program can increase the detection of diabetes by family physicians in their patients, though not statistically significant here, due to small numbers. This may be useful community program approach that could be modified for different communities by health services planners.

Introduction

Diabetes is a chronic condition, increasing in prevalence (1), that results in the consumption of a great deal of health care resources (2-4). Over the past ten years, the prevalence of Type 2 Diabetes (T2DM) in Ontario has increased at a much faster rate than anticipated. For example, the age and sex adjusted prevalence of diagnosed diabetes increased by 69%, from 5.2% in 1995 to 8.8% in 2005 (5), thereby exceeding the global prevalence of T2DM of 6.4% projected for 2030 (6). Furthermore, up to one third of the people with diabetes are estimated to be undiagnosed (7,8). People with diabetes or dysglycemia are at over a twofold risk of developing cardiovascular disease compared to diabetes-free individuals (9-11). To try to reduce mortality and morbidity associated with diabetes, the Canadian Diabetes Association clinical practice guidelines of 2008 recommended that all individuals over the age of 40 be routinely screened for diabetes (12). This is likely to become the family doctors' responsibility. However, family doctors are a scarce resource (13) and may not be able to initiate successful screening programs for all their patients. Indeed, evidence shows that they may be too busy (14), or resources too scarce to implement comprehensive screening either opportunistically or targeted, or to provide appropriate follow up to identified individuals.

Rather than a universal screening program of everybody over the age of 40 years, selective screening of subgroups at high risk of having the disease may reduce the workload and the cost to the healthcare system by reducing the number

of individuals who need a diagnostic test (15), while still identifying the vast majority of new cases. Involving patients themselves in the decision to attend screening may also lessen the burden on family physicians, since a consultation initiated for risk assessment alone, is likely to be more focused than one initiated for other reasons (16). Taking into account these issues, the Community Health Awareness of Diabetes program (CHAD; see Appendix 1 for a full description) was developed and piloted between February 22nd and April 26th 2005 in Grimsby, Beamsville, Smithville and Vineland, Ontario.

CHAD assessed risk of diabetes in the over 40 year old population using the Finnish Diabetes Risk Score (17) (for impaired glucose tolerance detection), the Cambridge Diabetes Risk Score (18) (for undiagnosed diabetes), fasting capillary blood glucose and a glycosylated hemoglobin level. Individuals were invited by their family doctors, for 'diabetes awareness and risk assessment' sessions delivered by specially trained community peers, in a network of local community pharmacies.

Evidence regarding the effectiveness of screening programs at actually detecting diabetes in primary care populations is sparse. Therefore, to determine the short term effectiveness and the usefulness of any further expansion of the CHAD program into other communities as part of a larger public health screening initiative, keeping costs low but effectiveness high, this study aimed to answer the following questions:

1. In family practice patients aged 40 years or more who were diabetes free, did the availability of diabetes risk assessment program in the community increase the detection of diabetes regardless of whether people attended or did not attend the program?

2. In the same population, did attendance at a diabetes risk assessment program increase the detectable annual incidence (rate) of diabetes compared to patients from the same practices that did not attend the program?

a) Accounting for the age/gender differences and physician differences between attendees and non attendees, did exposure to the CHAD diabetes risk-assessment program lead to an increase in the diagnosis of diabetes one year after compared to one year before the program, as noted in the charts of a sample of the population of eligible patients compared to usual practice?

b) Assuming there were different diabetes incidence rates in the two groups when comparing those who attended the CHAD program, and those who did not, were there differences in characteristics of physicians who patients were rostered to, which could account for different incidence rate ratios?

3. What type of risk information from the CHAD diabetes risk assessment program, when presented to family physicians, was associated with the subsequent diagnosis in a population of patients who had attended the CHAD program?

Methods

Design

The study was a retrospective observational chart audit comparing incidence rates of diabetes during one year before and one year after the introduction of the CHAD program in two populations – those who had attended the CHAD program (attendee group) and those who did not and thus were subject to usual care (non-attendee group).

Study Population and Recruitment

Community-dwelling individuals 40 years of age and older who resided in Grimsby, Beamsville, Vineland and Smithville Ontario during the program were included in the study. Those patients who attended the CHAD Program were asked if they consented to an audit of their family physician medical charts 1 year after the program – they formed the sample of CHAD 'attendees'. For the sample of 'non attendees', participating local family doctors, and patients under their care were the main subjects of interest, and patients were chosen randomly from a list of all patients over the age of 40 years for inclusion. This population was not consented for chart review, but no identifying data was extracted from the charts, therefore consent was not required. Consent was required from the attendees since their identifying characteristics were required to access their specific charts from their family doctors; however, the non-attendee group was a random sample, not consisting of specific individuals who needed to be followed.

Inclusion/Exclusion criteria

For the chart audit, patients were included if they were aged 40 years of age or older (on Feb 22nd 2004 for the before period, or on Feb 22nd 2005 for the after period); and received their regular medical care from a family doctor in that practice (defined as having seen their doctor once during the preceding 3 years). Patients were excluded if they had died, or moved away and ceased to see the physician (between 22nd Feb 2004 – Feb 21st 2005 for the before group, and Feb 22nd 2005 – 21st Feb 2006 for the after group).

Sample size

Based on Canadian figures (19) from 1999, a 'normative annual incidence' rate of 12* cases per 1000 people over 40 years of age was assumed. A twofold increase in the incidence rate was postulated (24 cases per 1000 people over 40) as a result of the CHAD program. Using the difference in annual rate of new diabetes diagnosis per physician as the primary outcome, and performing a paired t-test before and after the program, with a power of 80% at a significance level of 0.05#, the sample size was calculated to be 8 physicians (20). Further

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* in 1999 there the incidence of diabetes was 1.045 per 100 in >35 year old women, and 1.378 in over 35 year old men (ICES Diabetes in Ontario, A Practice Atlas p1.4)

using the formula for sample size (Machin and Campbell, p.79):

$$m = \frac{(z_{1-\alpha} + z_{1-\beta})^2 + \frac{1}{2} z^2_{1-\alpha}}{d^2}$$

where m = sample size; $z_{1-\alpha} = 1.96$; $z_{1-\beta} = 0.84$; d = effect size of Cohen's d
Cohen's d = $\mu 0 - \mu 1$/ std deviation
std deviation = 0.009 (based on range of incidence rates possible/4); range of incidence rates estimated as 0 to 0.036
and $\mu 0$ is rate of diabetes incidence at time 0; estimated as 0.012
and $\mu 1$ is rate of diabetes incidence at time 1; estimated as 0.024
therefore Cohen's d = 0.012 / 0.009 = 1.33333333

estimating recruitment of approximately 125 charts per physician, a total patient sample size of 1000 would be obtained.

Data Collection

Data was collected between October 2006 and December 2007 in family practices in the Grimsby and Smithville areas of Ontario. Randomly selected charts of patients who had been eligible to attend the risk assessment program were reviewed, as well as charts of all patients who did attend the risk assessment program. A standardized data collection form was used, which was then double-entered by 2 research assistants. Gender, age and employment status were the only demographic variables for which data was collected in both groups. This was because the CHAD risk assessment questionnaire had limited space, and the decision was made to collect the minimum number of variables possible.

Outcomes

Incidence rates of diabetes during a one year period before and one year period after the introduction of the CHAD program were compared. Diabetes diagnosis in the charts was determined as either having been noted by a health care practitioner or as medication for diabetes having been prescribed (e.g. glyburide, metformin).

Analysis

Two separate analytical techniques, either at the physician level (paired t-test) or at the individual patient level (multi-level regression modeling), were used, each making different assumptions about the data. The difference in rates

of diabetes diagnosis before and after the program was calculated per physician (pooling the sample and also comparing attendees to non-attendees).

From the chart audit data, incidence rates per 1000 patients, incidence rate ratios and likelihood ratios comparing change in incidence rate in risk assessment attendees versus non attendees were calculated. An estimate of the intra-cluster correlation coefficient for the outcome of diagnosis of diabetes was also calculated. Multi-level modeling (random effects logit model) was used to conduct a multivariate analysis, accounting for potential patient-level and physician-level confounders. The main dependent variable was the diagnosis of diabetes during one year following the CHAD program and the independent variables were patient's age, gender, employment status and actual attendance at the CHAD program. Effects of unknown factors were estimated in the random error component of the model. A second model looked at the likelihood of being diagnosed with diabetes in those who had attended the program only, and the impact of risk assessment status, fasting capillary glucose and blood pressure on this. The statistical programs SPSS version 17 (21), STATA intercooled version 8.1 (22) and SAS (23) were used to analyze the data. The demographics of attendees versus non attendees were compared.

Ethics

The McMaster University Research Ethics Board approved the study protocol. (Project number 04-404).

Results

Overall, 1030 charts of people eligible to attend the CHAD program were audited from 28 family doctor practices (patients audited per doctor ranged from 2 to 147); of these, 387 charts were of patients who had attended the CHAD program (from a potential pool of 585 CHAD attendees) and 643 charts were of people who did not attend (from a potential sample of 656) but who met the program eligibility criteria (Diagram 1).

Absolute diabetes detection rates (irrespective of attendance at the program)

The difference between the rates of diabetes diagnosis for the 28 physicians before-and-after the program was not significantly different for the whole sample when assessed using a paired t-test [p= 0.28, df = 28, (95% CI -0.09, 0.03)]. The impact of patient clustering by physician on the outcome of diabetes diagnosis was estimated by calculating the intra-cluster correlation (ICC) coefficient and found to be 0.0182 using the sum of mean squares method, and 0.0193 using the Chi Squared test calculation method.

Comparing Diabetes Incidence Rates

In the attendee group, 3 people (annual new diabetes diagnosis rate of 8 per 1000 patients) had diabetes diagnosed before the CHAD program and 11 (28 per 1000 patients) had diabetes diagnosed during one year following the program. In the non-attendee group, 12 (19 per 1000) had diabetes diagnosed before and 11 had it diagnosed after (17 per 1000). The difference in rate of diabetes diagnosis annually in the attendee group was 20 per 1000 and in the non-attendee group was

-2 per 1000. Comparing the incidence rate ratios before and after in the attendee group, the incidence rate ratio was 3.5 (0.028/0.008) [95% CI = 2.25 – 3.5] and for the non-attendee group 0.9 (0.017/0.019) [95% CI = 0.9 – 1.00]. The rate ratio in those who attended the program and those who did not was 1.65 (0.028/0.017) [95% CI = 0.04 - 61.6].

In the community, pooling the numbers for analysis from those who had attended the CHAD program and those who did not, the annual rate of new diabetes diagnosis was 27 per 1000 [95% CI = 17.90 – 39.00] in the year before the introduction of the CHAD program, and 45 per 1000 [95% CI = 33.00 – 59.80] in the year after; the rate ratio was 0.06 (0.027/0.045) [95% CI = 0.60 – 1.00].

Comparing the attendee and non-attendee group

The demographics of the non-attendee sample compared to those who had attended the CHAD program are shown in Table 1. The two groups were significantly different demographically in that the CHAD attendees were more likely to be female, retried and older than the random sample. The patients in each sample were clustered to their physicians differently. The attendee sample consisted of 29 physician-patient clusters ranging from 3 to 51 in size, while the non-attendee sample consisted of only 10 clusters ranging from 59 to 75 in size, primarily due to chart audit implementation factors.

Diabetes diagnosis accounting for confounding factors

Multi-level regression modeling showed that attending CHAD (see Table 2) did seem to have a positive effect on whether diabetes was diagnosed; however, this effect was lessened both in statistical significance and magnitude when taking in to account the effect of the physician, patient gender, patient employment status and patient age.

Predicting Diabetes Diagnosis

In the CHAD group, of those diagnosed with diabetes (n=14), 9 were identified as at high risk of diabetes from the CHAD risk score, and 3 had a moderate risk score and 1 was not identified as being at elevated risk. The yield of diabetes diagnosis from the CHAD risk score was 11.3% (9/80) for the high risk category and 1.3% (3/266) for the moderate risk category. In the group who attended the CHAD program, logistic regression showed that a high CHAD risk score was significantly predictive of later diabetes diagnosis (OR=22.11 CI = 4.58-100.78) and a fasting capillary glucose greater than 7mmol/l was also significantly predictive (OR=17.96, CI=3.71-86.84) (see Table 3). Accounting for physician level clustering using robust modeling and random effects modeling, the significance remained unchanged. Male gender and systolic blood pressure greater than 130 mmHg were associated with diabetes diagnosis though non significant at conventional levels. Diastolic BP was not significantly associated. A comparable analysis in the non-attendee group was not possible as this group did not have variables collected from the CHAD risk scoring

assessment in their charts since they had not attended the program. Nor was it possible to approximate a risk score from their charts due to lack of information or missing information needed to complete the CHAD risk scores.

Discussion

The CHAD program may have had an effect on the diagnosis of diabetes in the community practices involved, though the results are difficult to conclusively interpret since most are not statistically significant. This is most likely due to a number of limiting factors, which are discussed in more detail below. However, it is clear that there was an impact on diagnosis of diabetes in the community practices studied as a result of CHAD.

The objective of the CHAD program was not to formally diagnose patients but to increase community awareness of diabetes, encourage attendance for timely risk assessment, and to provide local family physicians with additional risk stratification information so that they might initiate further appropriate testing for diabetes. The ultimate program goals were multiple; to detect incident diabetes earlier; reduce complications and mortality from diabetes (since literature shows that lifestyle prevents diabetes, and diabetes prevention may prevent the complications of diabetes) (24,25); save healthcare money spent on diabetes-related complications and help family physicians meet the increased expectations of early screening for diabetes placed upon them. The key to the program was that family doctors received information about their patients who attended the

sessions, which assisted them in targeting certain high risk individuals for diabetes screening.

The CHAD Program provided a risk assessment to encourage subsequent, more targeted screening as per the Canadian Diabetes Guidelines. To reach the population sample of over 40 year olds, the program provided sessions at different times in the day and sessions were also offered during the weekend. Despite this, the people who attended CHAD were a distinct group different from a population of primary care patients potentially eligible for T2DM screening, comprised of more females, more elderly people and more retired or unemployed people. The demographic differences between the CHAD and random sample groups are not surprising since the CHAD sessions took place in the day, and older people are more likely to be free in the day to attend and females attend health care services more frequently. Diabetes is more prevalent with increasing age and if a greater number of younger people had attended the sessions the yield would have been potentially lower. This illustrates that in designing an ideal program specific groups need to be targeted in different ways. Perhaps in the case of community diabetes screening, the older population can be reached using methods demonstrated by the CHAD program, but a different strategy is required for those between the ages of 40 and 65 (e.g. workplace screening). This should be investigated in future projects.

Pharmacists may act as a link between the patient and the primary care physician in situations where "healthy" patients do not seek preventive care and

when they do, priority is given to the presenting problem (26). The use of community volunteers (members of the public who are trained to work as session health advisors on a regular basis) is in itself an effective intervention for health promotion (27).

The limitations of the study were as follows. Practices chosen from Grimsby, Beamsville, Vineland and Smithville were likely to be representative of family practices in South Western Ontario but not totally representative of rural populations (who would require a separate study). The study area did not contain many people from visible minorities (28) (such as South East Asians, Aboriginals and Hispanics who have a higher rate of diabetes incidence)(29,30,31) and so cannot be generalised to areas that have populations containing more people at higher risk of diabetes by virtue of their ethnic origin. Both attendees and non-attendees chart audit groups had missing patients due to a variety of similar factors (see Diagram 1). There were more missing records in the CHAD attendee group (19 vs. 2 in control group), since this audit involved locating the family doctors of many patients, and these doctors were located across Grimsby and the surrounding areas and had not been actively participating in the CHAD program, therefore some were reluctant to allow their patients records to be audited despite pre-arranged patient consent. Also, more were found to be deceased (14 vs. 4 in non-attendee group).

The CHAD program may have had an effect on the diagnosis of diabetes in the community practices involved, but the results are difficult to conclusively

interpret since they are not statistically significant. This is most likely to be due to the fact that the number of cases of people who were diagnosed with diabetes was small overall, thus the power of the study was not large enough to detect a statistically significant difference before and after the program occurred. A twofold effect size was assumed in calculating the sample size, and in the study, less than a twofold effect size was found (actual effect size was 1.67). Therefore, this could partially explain why statistical significance was not reached in this sample when comparing the diagnosis rates using a paired t-test. The clustered nature of the data also served to decrease the effect size of the CHAD program (32,33). In addition, the original sample size calculations required an estimation of the standard deviation, which was estimated following a commonly applied algorithm (SD = [largest possible value - smallest possible value]/4). Though the incidence estimations used for this calculation were based on the literature (19)[#], a post-hoc calculation has shown that, most likely due to inter-practice variability, the standard deviation was actually much larger (0.15 instead of 0.009), which resulted in a smaller sample size estimation.

Furthermore, results displayed in Tables 2 and 3, though valid, were not a result of the primary hypothesis from which the study was driven and therefore did not reach sufficient power. However, it is clear that there was an impact on diagnosis of diabetes in the community as a result of CHAD.

Explaining the statistical methods and findings in more detail, the intervention was targeted at patients, who had to attend the CHAD program, but

also at family doctors who had to behave in an appropriate way in response to the CHAD risk assessment results; therefore, the unit of inference was the patient cluster under each physician. Since individual patients belonged to clusters of patients under the care of a single physician, the standard assumption for statistical procedures that observations for each patient were independent could have been violated. Ignoring the non-independence of observations reduces the accuracy and significance of the results. The intracluster correlation coefficient (ICC) describes the extent of any similarity within versus between the patient clusters. Here the ICC was found to be small (0.0182, 0.0193), demonstrating that there was a small but measureable effect that physicians exert on the diagnosis of diabetes in their patients. However, the notion that diabetes diagnosis was affected by practice, physician and other environmental characteristics is highly plausible and likely. This is demonstrated by the clustering effects in the results and specifically the change in confidence intervals on random effects modeling techniques.

Looking at the individual level analysis where multilevel modeling technique was used (Table 2), when each confounder (physician, age, gender, employment status) was taken into account, the overall effect of the CHAD program was still positive (OR = 1.67), indicating a true effect of the program on diabetes diagnosis. With the addition of confounders in the data, statistical precision was reduced and the confidence intervals widened as expected.

Looking at predictors for diabetes diagnosis in attendees of the CHAD program, it is possible that combinations of tests and scores could have been used to have a similar outcome. Given that a fasting capillary glucose level of more than seven was a significant positive predictor for later diabetes diagnosis, the screening process may need modification to explore the use of such a single test as a prompt to target family physicians to screen people potentially at high risk. The numbers of cases of people with diabetes here are not large enough to warrant the use of a questionnaire only in the targeting of individuals for screening but this clearly needs to be studied further.

The method chosen to evaluate the program here is not optimal; however, pragmatic evaluation is needed and before and after methodology is reasonable. An alternative method may have involved randomization of the program to different communities and evaluation as a randomized controlled trial. However, it is difficult to be able to match communities fairly, and there may be many confounding factors this way as well, which makes this process more complex and much more costly.

Conclusion

In conclusion, the results suggest that the CHAD program did appear to have a positive effect on increasing the detection of diabetes; but, the magnitude and significance of this effect was not clearly demonstrated due to the inadequate sample size attained during the study. Despite the numerous statistical methods

employed, statistical significance could not be reached, though the incidence rate ratios suggest a positive program effect on diabetes diagnosis. Further studies reaching adequate power would be required to definitively support the notion that the CHAD program did have a statistically significant effect on diabetes diagnosis in the community.

Diagram 1: To show source of chart audit data

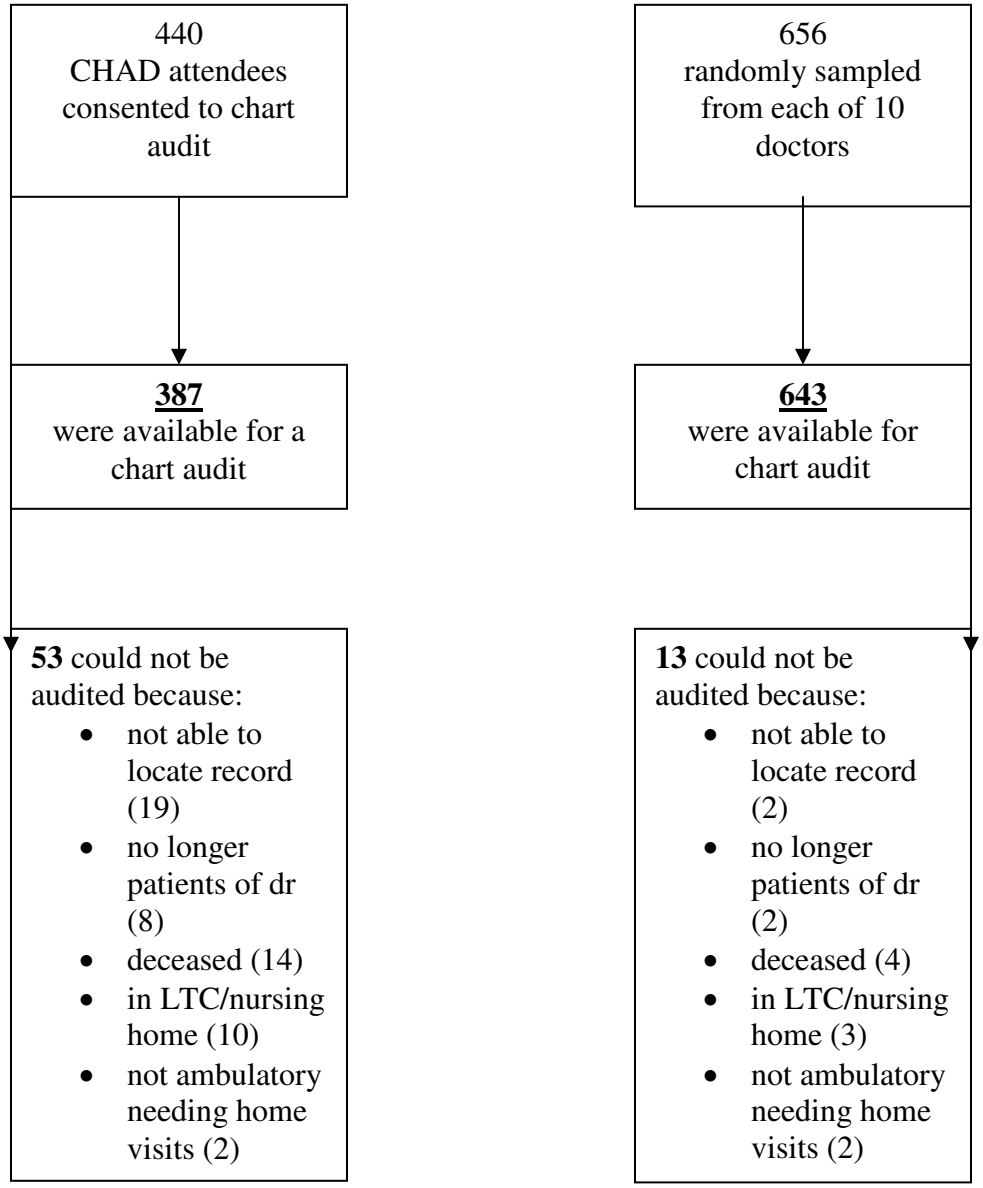

Table 1: Comparison of demographics of samples

	CHAD attendees (n=387)	**Random sample (n=643)**	**(Chi sq, df, p value)**
Female (%)	62	54	7.832, 1, **0.005***
Employed (details below)	23.0	48.6	
Unemployed	4.7	4.7	
Retired	36.4	13.3	
On disability	1.6	1.9	
Employed vs. other	23.0	48.6	66.36, 1, **0.000***
Retired vs. other	36.4	13.3	74.9,1,**0.000***
40-44	3.9	19.4	
45-49	4.5	22.3	
50-54	8.2	14.5	
55-59	10.0	14.1	
60-64	13.9	8.6	
65-69	16.8	4.6	
70-74	13.2	6.7	
75-79	14.8	4.3	
80-84	10.0	2.6	
85-89	3.0	.9	
>90	0.9	19.4	
Mean age	66.6	53.9	6.3 (t-test), **0.000*,** [8.8, 16.6] 95% CI of difference

* denotes statistical significance

Table 2: Odds Ratios of being diagnosed with DM after the risk assessment Program for CHAD attendees vs. Non attendees, taking account of confounding factors using multi-level regression modeling

After controlling for:	Analysis with random effects modeling (physician as random variable effect)* - reported as OR	CI	P value
Physician	***2.96***	***1.03 – 8.54***	***0.04****
Physician, Gender	***3.12***	***1.06 – 9.53***	***0.04****
Physician, Gender, Employment status	2.37	0.81 - 6.99	0.12
Physician, Gender, Employment status, Age	1.67	0.55 – 5.11	0.37

*assumptions made are;
1) attributes of individuals (τ_I) within clusters are the results of random variation and do not correlate with the individual regressors
2) the random effects (τ_I) are normally distributed with a mean of '0' and constant variance (i.e., NID(0,σ_τ)

Table 3: Odds ratios derived from multi-level regression models on the CHAD sample (n=387) to show the predictive effect of variables on diagnosis of diabetes

Odds ratio of variable described within the model specified (P value, 95% CI);	**Individual variable in model only:**	**Age, Gender, CHAD Risk Score, Systolic BP, Diastolic BP:**	**Age, Gender, Glucose, Systolic BP, Diastolic BP:**
Age (continuous)	1.02 (0.40, 0.97 – 1.08)	1.05 (0.25, 0.96 – 1.15)	0.98 (0.71, 0.86 – 1.10)
Male Gender	2.22 (0.22, 0.63 – 7.91)	1.77 (0.47, 0.37 – 8.44)	2.79 (0.43, 0.21 – 36.32)
CHAD Risk Status Score, low/moderate or high	***21. 76 (0.00, 4.38 – 108.03)**	***18.28 (0.00, 3.41 – 97.96)**	
Glucose, <7, >=7	***39.51 (0.00, 3.89 – 401.13)**		***86.07 (0.01, 2.52 – 2879.77)**
Systolic BP, <130 or >130	2.08 (0.31, 0.51 – 8.56)	1.12. (0.81, 0.43 – 2.97)	2.03 (0.37, 0.44 – 9.47)
Diastolic BP, <90 or >90	0.70 (0.74, 0.08 – 6.05)	0.63 (0.47, 0.37 – 8.44)	1.33 (0.87, 0.09 – 19.53)

Appendix 1: Description of the CHAD program

The Community Health Awareness of Diabetes (CHAD) program was a community based diabetes risk assessment program, whereby community members 40 years and older were invited to attend special sessions using a combination of questionnaire based risk-scoring (the Finnish Diabetes Risk Score) and near-patient testing (fasting capillary blood glucose and HbA1c) at specific local pharmacies in Grimsby, Beamsville, Smithville and Vineland, between February 22nd and April 26th 2005. Extensive community-wide advertising (household flyers with local newspapers detailing the prior need for fasting and the location and timings of the sessions) and program promotion occurred concurrently throughout the program. Some family physicians personally invited, by mail, all of their rostered patients over the age of 40, to specific sessions. All local family physicians received the results of the risk assessment sessions for their patients. The risk assessment sessions were either by invitation or drop-in in nature, lasted for 3 hours and took place twice weekly in 4 different pharmacy locations. Community peers (trained for 10 hours by a public health nurse) performed the diabetes risk assessments on the session participants and completed a health data form on each attendee. Data from these forms were entered into the CHAD electronic database and a 'CHAD combined risk score for diabetes' (which was an aggregate of the blood tests and scoring tool score) was generated. The CHAD combined risk score was faxed to the participants' appropriate family doctor, together with an explanation of what it comprised and the recommendations following on from this (as per the 2003 Canadian Diabetes Association guidelines). These recommendations encouraged family doctors to initiate formal screening for diabetes in those who had a high CHAD combined risk score. Both patients and pharmacists also received a copy of the health data forms. Results requiring urgent attention* were faxed immediately. In addition, participants identified as having high risk for being diagnosed with diabetes, received educational information and individual counseling around diabetes and modifiable risk factors, and were referred to the local diabetes education centre.

* Capillary Blood Glucose >15 mmol/l

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Care for patients with type 2 diabetes in a random sample of community family practices in Grimsby, Ontario

Abstract

Diabetes care is an important part of family practice. Previous work indicates diabetes management is variable. This study was conducted to get a view of diabetes care according to the guidelines in one part of Ontario. A retrospective chart audit of 96 charts from 18 physicians was carried out to examine diabetes care between February 2004 and February 2005. The mean HbA1c was within target (less than or equal to 7.00) in 76% of patients (ICC = -0.02), and at least 4 readings per annum were taken in 75% of patients (ICC = 0.006). Nearly 2/3 of patients had been counselled about diet in some form, more than 1/2 on exercise and nearly all (90%) were on medication. Nearly all patients had a documented blood pressure reading and lipid profile. Over half (60%) had a record of their weight and/or BMI. Although there was room for improvement, for the most part diabetes targets were being met according to the 2003 CDA guidelines.

Introduction

Routine diabetes care remains largely a family practice activity lead by family doctors. In Canada, standards for the care of people with type 2 diabetes have been set by the regularly updated Canadian Diabetes Association (CDA) guidelines since 1999 (1). These guidelines form part of the principles of diabetes care that all family doctors are aware of and are considered to be markers of primary care quality. Indeed, in other countries, such as the UK, specific diabetes clinical indicators, such as the HbA1c level of patients with diabetes on the practice diabetes registry, are considered a standard for which family doctors may be eligible for performance incentives (2). Twenty percent of the performance incentives that are available in the UK are for diabetes indicators. Previous work (3) has examined family physicians' management of patients with diabetes in seven provinces of Canada between 1998 and 1999. Management was found to fall short of the guidelines generally, but particularly in the areas of micro-vascular disease screening, hypertension management, hyperlipidemia and appropriate prescribing of anti-platelet medication.

Following on from this work, it is not currently known how well family physicians in Ontario are performing at following the CDA guidelines with their patients. This knowledge could help family physicians target certain areas of diabetes care in planning for the future. The goal of this study was to examine a small group (N=18) of community-based family physicians' management practices (according to the CDA guidelines) and how well they achieved clinical

care targets in the following areas: glycemic screening, control and management strategies, documentation and counselling for lifestyle habits, prevalence of co-morbidities, screening for hypertension, hyperlipidemia and use of appropriate recommended preventive medications (see Appendix 1). The specific objectives measured were:

Primary Outcome:

1. Percentage of patients in which glycosylated haemoglobin (A1c) targets were reached (≤ 7.00 mmol/l) (Appendix 1, CDA Guideline #1).

Secondary outcomes:

1. Percentage of patients who reached the following glycemic targets: at least 4 A1c readings in a 1 year period and a mean fasting plasma glucose (FPG) within target of 4.0–7.0mmol/l (Appendix 1, CDA Guideline #1).

2. Percentage of patients who were managed by lifestyle modification as documented in their chart (Appendix 1, CDA Guideline #5) and other descriptive information about glycemic management.

3. Percentage of patients exercising regularly as documented in their chart (Appendix 1, CDA Guideline #4) and other descriptive information about diet and exercise.

4. Prevalence of co-morbidities (hypertension, dyslipidemia, retinopathy/neuropathy/nephropathy, cerebrovascular disease, coronary artery disease) and specialist consultations.

5. Percentage of patients reaching blood pressure targets (Appendix 1, CDA Guideline #3).

6. Percentage of patients who had lipids monitored (Appendix 1, CDA Guideline #2).

7. Percentage of patients who were prescribed aspirin and ACE inhibitor medication (Appendix 1, CDA Guideline #8 and 9).

8. Percentage of patients in whom there was documentation of smoking and alcohol consumption status (Appendix 1, CDA Guideline #6 and 7).

9. Percentage of patients in whom there was documentation of body mass index.

Methods

Design and Study Population

As part of a study evaluating the effectiveness of a community-based diabetes risk assessment program (4), a retrospective chart audit in a total of 29 family doctors offices in Grimsby and its surrounding area was undertaken (see Diagram 1). All of these family doctors had been involved in the community diabetes risk assessment program to varying degrees and their charts were being audited to assess program effectiveness by collecting information about patients who attended and who had not attended the screening program. The charts were located in multiple different family practices and were audited by 4 trained audit staff. The practices were predominantly fee-for-service with some primary care group practices with a mixture of fee-for-service and capitation.

Data Collection

Three of the practices, in which 18 of these family doctors practiced, had specifically agreed to a chart audit of a random sample of patients who were eligible to be screened for diabetes, but did not attend the sessions. These practices provided lists of names of all patients who were rostered to each family physician and who were over the age of 40. Charts were randomly selected, using a statistical program [SPSS (5)] from the lists by a research assistant with the intent of purposely sampling 75 eligible patient charts per physician. The actual number sampled ranged from 59 to 75 per physician.

As part of this sampling strategy, a number of charts of people with diagnosed diabetes were included (n=96). These patients had not been purposely sampled due to their diabetes diagnosis status, but, had been included in the overall random lists. The practices were unable to remove people with known diabetes from the lists they provided; therefore, the random sample contained both those with and without diabetes. These individuals had not been screened by the risk assessment program for diabetes. Patients who had a previous diagnosis of diabetes prior to February 2004 were audited (ranging from 1-11 charts per doctor). Information was extracted from these charts concerning the routine family practice diabetes care that they received between February 1st 2004 and February 1st 2005. This care would have been received before the diabetes risk assessment program started, and thus, would not have been affected by it.

The chart auditors consisted of 2 health research assistants, a retired nurse and a retired medical secretary, both with extensive experience in medical chart auditing. All underwent 2 days of training, involving duplicate auditing of 5 charts.

The data extracted by the chart auditors was based upon the CDA 2003 guidelines (1). These guidelines recommended that the following factors needed to be checked on an annual or more regular basis: glycosylated haemoglobin (A1c), lipid values, blood pressure values, lifestyle, diet and exercise factors, smoking and alcohol consumption, and use of medications. Where there were several readings, these were averaged for the whole year and the average reading was considered in the analysis. In addition, data concerning the demographics of the physicians and their practices was collected by a direct questionnaire to each physician. Physician variables included practice, gender, years in practice and certificant status with the College of Family Physicians of Canada. Data was extracted onto a structured chart audit form that had been prepared for follow up of patients from the community diabetes risk assessment study. It was then double-entered into a separate database.

The charts analysed here formed a secondary analysis of the data collected for the primary study, which examined the effectiveness of a diabetes risk-assessment program on the detection of incident diabetes. However, it was estimated that for this sample size of approximately 100, under the most

conservative assumptions, the 95% confidence intervals could be calculated to the nearest +/- 10% (5).

Analysis

Analysis of the data was conducted using SPSS version 17 (6). Physician and patient demographic data were summarised using descriptive statistics. Data was analysed at the patient level. Univariate analysis was performed to look at the proportions of patients who had specific clinical characteristics. To take into account clustering due to the potential similarities of patients attending a particular physician, intra cluster correlations (ICCs) and their 95% confidence intervals were calculated. The ICC is a measure of the degree of similarity among patients' variables within each physician's practice (7). A small ICC indicates that the physician will have a minimal influence on each patient-specific variable. An ICC of 1 indicates the patient-specific variable is completely dependent on the physician.

Results

Physician Participants

From the 3 eligible practices, a total of 18 physicians had charts audited. The family physician characteristics are shown in Table 1. Most were male (74%), had graduated more than 5 years previously, were certificants of the College of Family Physicians (88%), were Canadian graduates (82%) and more specifically, were local medical graduates to their area of practice (41%). Half the

sample responded to the practice characteristic questions in which physicians were asked to estimate the number of patients on their roster (including all ages), the numbers of patients in their roster over the age of 40 years and the numbers of patients over 40 years of age with diagnosed diabetes. Calculating a mean for each of these estimations; the mean estimated patient roster size per physician was 1472, mean estimated number of patients per physician over 40 was 785, and the mean estimated proportion of physicians' patients with diabetes, out of the total roster size, was 11.4%. Most used electronic medical records (78%) in their practices. Thirty three percent were involved in undergraduate education, and 44% took residents in their practice; and a total of 50% were involved in medical education of some sort within their practices.

Patient Demographics

A total of 96 charts were audited of people who had a diagnosis of diabetes recorded in their charts. The sample was made up of 51% males, a third were employed, 5% were unemployed, the majority (38%) were retired, and 3% were on disability (see Table 2). The bulk of the sample was from the 60-64 year old age group, and the mean age was 68 years old (SD =12.02). The mean number of years since diagnosis of diabetes was 8.8 and all 96 patients had visited their family doctor at least once during the 1 year audit period. Patients were unevenly clustered between the family physicians, and number of patients with diabetes per physician ranged from one to eleven.

Glycemic Control, Monitoring and Management

The average HbA1c reading was 7.07 and 96% of patients had had their HbA1c tested at least once in the audited period of time (1 Year) (Table 3). The mean HbA1c was within target (less than or equal to 7.00) in 76% of patients (ICC = -0.02), at least 4 readings per annum were taken in 75% of patients (ICC = 0.006). The FPG was tested in 85% of patients and was within the targets in 46% of patients, with a mean value of 7.84mmol/l. A minority of patients were treated with lifestyle only (12.5%). Most (89%) were on medication, 42% were on oral medication, about half just one oral agent (50%), a small proportion on insulin only (10%), and very small proportion on both types of agent (1%). In more than half of the charts, exercise (57.3%) and diet (57.7%) were mentioned as having been discussed, and a small number (15.5%) had been referred to a dietician.

According to the CDA 2003 guidelines (Appendix 1), secondary data analysis shows that 17.8% of patients (n=16, ICC = 0) had optimal control (HbA1c less than or equal to 0.06%), 32.2% (n=29, ICC = 0) had achieved target control (less than or equal to 0.07%) and 50.0% (n=45, ICC =0) had suboptimal control (greater than 0.07%).

Prevalence of Diabetes related co-morbidities and complications

More than half of the patients had hypertension (59%), a quarter had dyslipidemia (24%) and 15% had diabetes-related complications (Table 4).

Screening for and Management of Risk Factors

With respect to macrovascular complications, nearly all patients had documentation of blood pressure (BP) readings (98%) and lipid profiles (97%) (Table 5). The mean BP reading was 134/74 mmHg and 31% (ICC = 0) met the target for systolic BP and 85% (ICC = 0) for diastolic BP. The average number of BP readings was 15 (ICC = 0.054). The mean total cholesterol was 4.58% (ICC = -0.067).

Lipid-lowering agents were prescribed for 39% (ICC = 0.382) of patients and ASA was prescribed for 23% (ICC = 0.0456). With respect to prevention of microvascular complications, 40% were prescribed an ACE I inhibitor (ICC= -0.023).

Lifestyle Habits

Absolute weight was recorded in all but 2 individuals and height was not recorded in 37 individuals at all. Therefore, BMI could not be calculated for 40% (ICC = 0.094). Where BMI was recorded, 27% of patients were obese and 20% were overweight (ICC = 0.132). One in 10 were current smokers (10.2%, ICC = 0.433) and only 1% consumed alcohol heavily (ICC = -0.150).

Discussion

This study has been able to present data from medical charts covering 18 different practitioners in a small region of Ontario. Existing data concerned with management and control of diabetes in family practice concentrates on small numbers of practices (8, 9) or has looked at recruiting charts of those who have

attended the physician for check ups, and have not been randomly selected (10); therefore, may not be an accurate representation of the state of diabetes management. Others use different time periods for audit of charts, different criteria for physician and patient recruitment, and focus on different locations (11). In this study in the Grimsby region, family physicians were successfully monitoring A1c levels, and reaching targets in 3/4 of patients. Nearly 2/3 of patients had been counselled about diet in some form, more than 1/2 on exercise, and nearly all (90%) were on medication. Nearly all patients had a documented blood pressure reading and lipid profile. Over half (60%) had a record of their weight and/or BMI.

In a previous, and much larger study, Harris et al (3) collected data from 16 practices, 55 physicians, 549 charts and 10 charts per physician, located all over Canada for one year from February 1st 1998. Less patients had reached CDA targets for A1c (40% less, with A1c target reached in 35%), fewer had their A1c readings recorded (25% less), 25% more patients were on oral medication only, nearly 20% less of the charts documented dietician counselling, nearly 30% less documented exercise, 30% less charts had lipid profiles measured and the mean total cholesterol was higher, and there was a greater proportion of patients with hypertension and hyperlipidemia. These results suggest that the Grimsby group of family physicians have been more successful in the care of their patients than those in the Harris study. However, this could be due to the fact that this group of physicians was a more select group, with fewer patients who were different

demographically, and that the studies were sampled differently (one specifically for the purpose of chart audit for diabetes care, the other as an incidental chart audit). It could also be indicative of a wider change amongst family physicians and their behaviour in practice.

Another more recent study in Newfoundland among 160 patients from 8 practices (9), showed that 48% had reached the 2008 CDA guideline target for A1c. This study sampled patients having identified them from billing records. More patients were at target for systolic and diastolic BP readings, and the same percentage were documented as having hypertension, but more as having cerebrovascular and coronary artery disease. It was not possible to compare medication, lifestyle and physician demographics since these were not reported. When physicians were asked to estimate what proportion of patients were at targets forA1c, this group of practitioners over-estimated their results by 20%. Forty percent were at target for systolic BP compared to 31% in Grimsby and 42% for diastolic BP compared to 85%.

In this data, most of the ICCs reported are consistent with what is frequently reported in literature (12,13), with higher values for process issues and thus, more likely to reflect a particular practising-style of a particular family doctor. Though the ICC values are small, they are positive, indicating that for certain variables such as mean FPG value (ICC = 0.16), being on medication / insulin for glycemic control (ICC = 0.05), on lipid lowering medication (ICC = 0.02), number of readings for blood pressure (ICC = 0.06), and dietician

consultation having been sought (ICC = 0.08), the specific physician to which the patient belonged would somewhat influence the patients' values for these variables. The 95% confidence intervals for most of the ICCs are small, indicating that the ICC values reported are likely to accurately represent the true values. Some variables more related to physician management, such as medication for lipids (ICC = 0.38), would have been expected to have higher clustering effect by physician, since each physician had a different practice, which would determine which patients in the practice were treated or not. Within a physician's practice, disease management strategies would be expected to be more homogeneous than patients' outcomes resulting from disease management (14). Some ICC values were zero or near zero, indicating that the physician a patient belonged to did not exert any influence on that variable (14). Compared to Harris et al, more negative ICCs were reported in this study, as in the Harris study they chose to report negative ICCs as zero and assumed that in the context of this type of data, a negative ICC indicated that there was no physician effect.

This data from Canada can be compared to some extent with published data from the UK Quality and Outcomes Framework, which was introduced in 2004, and reported on 1.8 million patients with diabetes (15). After the introduction of incentives for diabetes (targets which needed to be met on a proportion of patients with diabetes to qualify for financial bonuses), the percentage of patients with an HbA1c of less than or equal to 0.074% increased from 2000 (22%) to 2005 (38%) by 16% (16). Reporting on standards of care in

primary care in the UK in 2006 (17), roughly the same targets were reached for documentation of HbA1c in the charts (94% compared to 96% in Ontario), 58% reached the target of HbA1c level less than or equal to 0.074% compared to 76% reaching a target of less than 0.07% in Ontario, BP readings were documented in 97% compared to 98% in Ontario and targets of less than or equal to145/85 were reached in 70% compared to 31% reaching systolic targets of <130 and 84% reaching diastolic targets of less than or equal to in Ontario. Ontario data was better than that from the UK for cholesterol documentation (93% compared to 97% in Ontario); and UK data was better than Ontario data for recording of BMIs (only 9% of charts did not have a BMI in the chart, as opposed to 40% in Ontario).

Limitations of this study

Though the sampling scheme was adequate to investigate the objectives outlined in the introduction at a patient level, results may not be generaliseable to a larger sample of practices from different areas. The audit was conducted in practices located in a particular geographical area, which may not be comparable or representative of other Canadian locations. In 2001, compared to Ontario as a whole, the Grimsby area population had less ethnic minorities, was more educated and had a higher income (18). In addition, although chart audit is an accepted form of data collection (19), charts and charting styles may differ between practices and may lead to under-reporting of the contents of clinical encounters with patients (20). Also, the physicians were mostly all certificants and Grimsby

is not a rural but an urban area, both of which can be correlated with higher quality care (21). Although diabetes care seems to be improving, it is possible that this improvement is just regional (not Ontario-wide or Canada-wide) and specific to the Grimsby area. This is possibly due to the fact that most of the family doctors were using EMRs, had more allied health professionals helping them, or had greater access to guidelines due to the fact that they were teaching residents. Another limitation is a relatively small sample size, which means that most of the estimates have relatively wide error margins.

The diabetes sample used here is not a true representation of all people with diabetes in general in a primary care population since they were not sampled to be able to gain a complete list of all patients with diabetes for each of the 18 physicians, but were sampled incidentally as part of another larger study. However, the 96 patients with diabetes were selected from each physician's list randomly. Since none of the practices had working diabetes registers, patients were not selected in a biased fashion and are representative of people with diabetes from the 18 physicians audited. A total of 1192 charts of people over the age of 40 years were randomly selected for audit, out of which 96 had diabetes. This indicates a diabetes prevalence of 8.1% in this population. This is a reasonable considering in 2009 the prevalence of T2DM was estimated to be 6.4% (22) and this population is 40 years of age and over, and the prevalence would be expected to be higher in this group.

Remuneration methods of each practice could have affected the diabetes care offered in that practice. In capitated models of remuneration there are incentives for reaching certain targets for patient care, but these do not exist in a fee-for-service model of care. It was not possible to explore this effect in this data due to the small number of practices. Typical clinical practices of each physician, with respect to diabetes care, were not collected due to the small number of physicians (n=18) in the sample. Nor was it possible to state in what proportion of patient's optimal care was provided with respect to appropriately prescribed medication, since accurate information regarding prescribing had not been collected in relation to the illnesses, only proportions of patients on certain medications.

Implications

According to the CDA 2008 guidelines (23), more stringent targets of <0.065 HbA1c are recommended for those at risk of nephropathy, and targets of < 7.0 for others with T2DM. Using these categories with this data, optimal control for those at risk of nephropathy (<0.065%) was achieved in 27.5%, optimal control in general was achieved in 23.1%, and suboptimal control was found in 49%. It was not possible to estimate which subjects in the groups were at risk of nephropathy in order to assess if the appropriate group had achieved control in this sample. Future management chart audits would have to incorporate this variable in data collection.

The attainment of targets in this sample of family doctors from Grimsby was not drastically altered by the application of the later 2008 CDA guideline's target to the same data. Target attainment was comparable to other information available from Ontario and the UK. However, it may not be realistic to suppose that further improvements can be made and this realistically may be as good as clinical care can get in primary care for diabetes. The literature suggests that one of the challenges to further improving care has been 'clinical inertia' (24) or failure to intensify therapy appropriately for a variety of reasons (rationalisation to avoid treatment intensification, lack of knowledge of targets, fears of non compliance of patients with both lifestyle and medication) and this was confirmed by Harris et al (10). Another challenge would be the saturation of the environment with clinical practice guidelines that are difficult to keep abreast of (25). However, despite these challenges, these results show that although there was room for improvement, diabetes targets were mainly being met according to the 2003 CDA guidelines in this sample of family doctors and this population.

Diagram 1: To show the source of charts for the chart audit

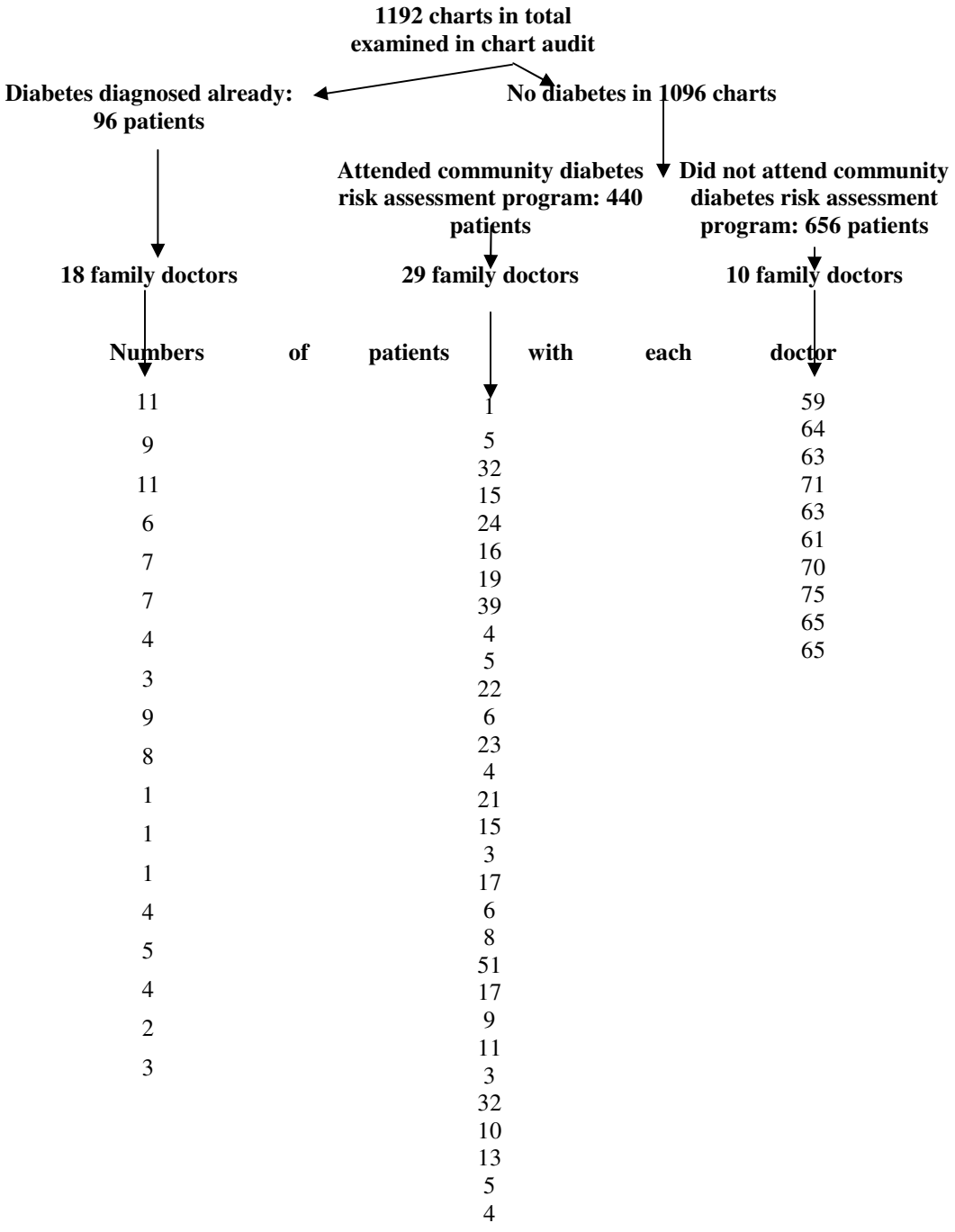

Table 1: Physician Characteristics Reported in Summary:

Characteristic (N=17)	**Value (median; SD)**	**Range**
Female Gender (n=16)	26%	
Years since graduation	17.4 (17.0, 8.6)	4 – 30
Recent Graduate (<5 years) (n=16)	12%	
Certificant of CFPC (n=16)	88%	
Canadian Medical Graduate (n=16)	82%	
Local Medical Graduate (McMaster) (n=16)	41%	
Foreign Medical Graduate	18% (n=16)	
How many years in practice (self-reported)? (n=9)	10.9 (10; 8.21)	0.5 – 24.0
Approx. how many pts do you have in your practice (self-reported)? (n=9)	1472 (1500, 601)	700 – 2500
About how many of your pts are 40 yrs or older (self-reported)? (n=9)	785 (600; 417)	420 – 1500
Estimate what % of your pts 40+ have been diagnosed with diabetes (self-reported) (n=9)	11.4 (8.5; 10.5)	2 – 30

Table 2: Patient Characteristics

Characteristic (N)	**Value (median; SD)**	**Range**
Mean age at diagnosis in years		
Mean duration of diabetes in years (81)	6.8 (7.0)	0.6 – 42.2
Mean age at audit in years	68.0 (69.5; 12.0)	42.6 – 89.4
Female (96) in %	49	
Employment status:	**Percent (n=96)**	
Employed	29.5	
Unemployed	5.3	
Retired	37.9	
On disability	3.2	
Not reported	24.2	
Age category	**Percent (n=96)**	
<39	4.2	
40-44	3.1	
45-49	8.3	
50-54	13.5	
55-59	10.4	
60-64	15.6	
65-69	14.6	
70-74	8.3	
75-79	15.6	
80-84	6.3	
85-89	4.2	
>90	3.1	
Years since diagnosis of diabetes (n=81)	8.8 (7.0)	2.2 – 44.2

Table 3: Glycemic Control, Monitoring and Management

Measure	Value	Median, SD, Range (where applicable)	ICC (95% Confidence interval)
Glycemic screening and control			
A1c tested once, % of patients	96.00		0.00 (-0.003311, 0.003311)
Mean A1c, %	7.07	7.00, 1.1, 5.0-11.0	0.00 (-0.003311, 0.003311)
Mean A1c within target of ≤7.0, %	76.0		-0.018989 (-0.021702, -0.016276)
Within target of at least 4 HbA1c readings in 1 year period, % patients	75.3		0.057496 (0.037328, 0.077664)
FPG tested, % patients	85.00		0.00 (-0.003311, 0.003311)
Mean FPG, mmol/l	7.84	7.58, 1.94, 3.90-13.10	0.163798 (0.117942, 0.209654)
Mean FPG within target of 4.0–7.0, %	46.4		0.00 (-0.003311, 0.003311)
RPG tested, % patients	43.80		
Mean RPG, mmol/l	8.40	7.83, 2.86, 2.30-17.40	0.0787675 (0.0734361, 0.0840989)
Glycemic management strategies			
Lifestyle only, % patients	0		
Lifestyle at all, % patients	12.5		-0.02244 (-0.026272, -0.018608)
Medication	89.00		0.019339 (0.010126, 0.028552)
Oral agents only, % patients	42.0		
Of patients on oral agents:			
1 oral agent, % patients	50.0		0.013274 (0.005886, 0.020662)
2 oral agents, % patients	43.0		-0.02424 (-0.028659, -0.019821)
3 oral agents, % patients	7.4		-0.10593 (-0.139121, -0.072739)
Insulin only, % patients	10.4		0.048603 (0.030906, 0.066300)
Insulin + oral agents. % patients	1.0		-0.09307 (-0.121453, -0.064687)

Measure	Value	Median, SD, Range (where applicable)	ICC (95% Confidence interval)
Counselling			
Dietician, % patients	15.5		0.07923 (0.053232, 0.105228)
Chart mentions diet counselling, % patients	57.7		0.00 (-0.003311, 0.003311)
Dietician and/or chart mentions diet counselling, % patients	62.0		0.098409 (0.067513, 0.129305)
Exercise, % patients	57.3 (mentioned)		0.066321 (0.043750, 0.088892)

Table 4: Prevalence of Diabetes Related co morbidities and complications

Diagnosis	**% of Patients**	**ICC**
Hypertension	59.8	0.158733 (0.113940, 0.203526)
Dyslipidemia	24	-0.0171 (-0.019203, -0.014997)
Retinopathy, nephropathy or neuropathy	15.4	0.0572 (0.037114, 0.077286
Cerebrovascular disease	2.1	0.005977 (0.000816, 0.011138)
Coronary Artery Disease	7.2	-0.081 (-0.104965, -0.057035)
Cardiovascular Consultation	23.7	-0.03058 (-0.037081, -0.024079)
Endocrinology consultation	5.2	-0.07619 (-0.098420, -0.053960)

Table 5: Screening for and management of risk factors

Clinical activity	**Value**	**Median, SD, Range (where applicable)**	**ICC**
BP result documented, %	98		
# BP readings	15	15, 9, 0-24	0.06424 (0.042231, 0.086249)
Mean BP;			
Systolic mmHg	134	135, 12, 102-165	-0.14068 (-0.187383, -0.093977)
Within Systolic BP targets of <=130	31.0		0.00 (-0.003311, 0.003311)
Diastolic, mmHg	74	74, 7, 54-94	0.03471 (0.020974, 0.048446)
Within Diastolic BP targets of <=80	84.5		0.00 (-0.003311, 0.003311)
Lipid profile obtained once, %	97		0.040813 (0.025322, 0.056304)
Mean Total Cholesterol	4.58	4.49, 0.99, 2.43-7.98	-0.06611 (-0.084751, -0.047469)
Medications to prevent complications	**% Patients**		
On ACE I	40.0		-0.02382 (-0.028101, -0.019539)
On Lipid lowering medications	39.2		0.38283 (0.306461, 0.459199)
On ASA	22.7		0.045959 (0.029007, 0.062911)

Table 6: Lifestyle habits

	% Patients	**ICC**
Current smokers	10.2	0.433308 (0.354187, 0.512429)
Alcoholic	1.0	-0.15016 (-0.200681, -0.099639)
Occasional/Social alcohol	25.5	
BMI obese >30	26.5	0.132369 (0.093368, 0.171370)
BMI overweight 25-30	20.4	
BMI not possible to calculate from chart	39.8	0.093952 (0.064173, 0.123731)

Appendix 1: Extract from the CDA 2003 Guidelines

1. HbA1c

Monitored every 3 months as per CDA guidelines. Targets should be:

	A1C (%)	**FPG/preprandial PG (mmol/L)**	**2-hour postprandial PG (mmol/L)**
Target for most patients	≤7.0	4.0–7.0	5.0–10.0
Normal range (consider for patients in whom it can be achieved safely)	≤6.0	4.0–6.0	5.0–8.0

2. Lipids

To be monitored. Targets for lipids should be:

RISK LEVEL	**LDL-C (MMOL/L)**	**TC:HDL-C**
High (most patients with diabetes)	<2.5 **and**	<4.0

3. BP

To be monitored. Target s should be:

Indications for treatment: BP >130 mm Hg or >80 mm Hg despite lifestyle modification
Target: BP ≤ 130/80 mm Hg

4. Everyone should do exercise
5. Everyone needs lifestyle modification
6. Be a non-smoker
7. Stay within healthy drinking guidelines: Limit intake to 1–2 drinks/day (<14 standard drinks/ week for men and <9/week for women)

Also;

For vascular protection should be on:

8. ACE inhibitor
9. ASA

PRIORITY OF CLINICAL ISSUE	**TARGET POPULATION**	**INTERVENTIONS***
Vascular protection	All people with diabetes	ACE inhibitor (as indicated) Antiplatelet therapy (80 – 325 mg/d ASA) Blood pressure control Glycemic control Lifestyle modification: nutrition therapy, regular physical activity, weight management Lipids control Smoking cessation

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GPs approach to insulin prescribing in elderly patients: A qualitative study

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Abstract

Background: Evidence suggests that insulin is under prescribed in the elderly. Some reasons for this include physician's concerns about potential side effects or patients' resistance to insulin. In general, however, little is known about how GPs make decisions related to insulin prescribing in the elderly.

Aim: To explore the process and rationale for prescribing decisions of GPs when treating elderly patients with type 2 diabetes.

Design of study: Qualitative individual interviews using a grounded theory approach.

Setting: Primary care.

Methods: A thematic analysis was conducted to identify themes that reflected factors that influence prescribing of insulin.

Results: Twenty-one GPs in active practice in Ontario completed interviews. Seven factors influencing prescribing of insulin for elderly patients were identified: 1) GPs' beliefs about the elderly; 2) GPs' beliefs about diabetes; 3) intensity of therapy required; 4) need for preparation for insulin therapy; 5) presence of support from informal or formal health care provider; 6) frustration with management complexity; and 7) experience with insulin. Though GPs indicated that they would prescribe insulin allowing for the above factors, there was a mismatch in intended approach to prescribing and self-reported prescribing.

Conclusion: GPs' rationale for prescribing (or not prescribing) insulin is mediated by both practitioner-related and patient-related factors. GPs intended and actual

prescribing varied depending on their assessment of the patients' situation. In order to improve prescribing for increasing numbers of elderly people with type 2 diabetes, more education for GPs, specialist-support, and use of allied health professionals is needed.

Keywords: Type 2 diabetes mellitus, insulin, primary health care, qualitative research

How this fits in:

Insulin therapy is under prescribed in the elderly and some known factors that influence prescribing are GPs' concern about patient resistance to insulin and potential side effects. This study has helped to identify that both patient and physician factors impact insulin prescribing, with GPs intended and actual prescribing varying depending on their assessment of the patients' situation. Under prescribing of insulin in the elderly could be improved by more GP education, better specialist-GP communication, and the use of more allied health professionals to provide support networks for patients and GPs.

Introduction

Current prevalence figures estimate that 16% of people aged 65 and over have diabetes.[1;2] In 1995, the number of people aged 65 and over with type 2 diabetes in the developed world was 28 million - this will double by 2025.[3] In the UK, it is estimated that between 10 and 25% of the elderly have diabetes.[4] As healthcare provision shifts from secondary to primary care type 2 diabetes management continues to be a growing and expected part of the GP's role. In an increasingly ageing population of people with type 2 diabetes, tighter control, including greater use of insulin and combination therapies, may possibly be important in ensuring better outcomes and less complications, but also helpful in the day-to-day management of diabetes.[5-9]

There is some literature to suggest that in the elderly, insulin may be under prescribed.[10] In 1999, only 11% of elderly people with diabetes were prescribed insulin (compared to approximately 40% engaged in either diet change or taking oral hypoglycaemics).[10] Some specialists believe that GPs fuel patient resistance to insulin[11] and postpone its use despite high patient plasma-glucose levels[12], yet little information is known about the GP perspective. This study fills an important gap by exploring the process and rationale for prescribing decisions of GPs regarding insulin when treating older adults with type 2 diabetes.

Methods

We used qualitative research methods. Sampling was purposive and we attempted to find physicians that varied in age, type of practice (academic vs. non-academic), and gender. In order to focus the search for general practitioners, potential participants were randomly selected from a list of actively practicing GPs within a 1 hour driving radius of a large suburban city in Ontario, Canada (Canadian Medical Directory of Doctors).[13] We randomly sampled from this list given the large number of physicians in the geographic area of interest. Letters of invitation that outlined study requirements were mailed to eligible doctors and those that expressed an interest in participating were contacted and consented by a research assistant.

An experienced, trained interviewer conducted the in-person interviews using a semi-structured interview guide that focussed on eliciting information related to the process used and factors considered when prescribing insulin. The interview guide was modified as interviews proceeded to reflect emerging themes that required further exploration.[14;15] Participant demographic information was also collected. Interviewing continued until no new ideas emerged and theoretical explanations of emerging phenomena were evident.[16] Interviews were recorded and transcribed verbatim.

Data were analysed using a grounded theory approach as we were interested in understanding the process of decision making related to insulin use

in the elderly and the factors that influence this process.[15] Two investigators (GA and KN) independently read all transcripts and discussed the findings with the research team, ensuring that emerging themes received adequate opportunity for discussion to allow the developing theory to become saturated. This involved repeated reading of all transcripts during the coding process to ensure that there was both depth and breadth within each theme, and that disconfirming evidence had also been accounted for in the analysis. Investigators validated themes by referring back to the original transcripts. Data collection stopped when saturation was reached as denoted by a repetition in information being heard in the interviews.[18] We used qualitative software (NVivo)[19] to assist with data organisation.

Results

Twenty-one GPs were interviewed for approximately 50 minutes each. Sixteen doctors were male. The median age of participants was 54 (range 37 to 74). Median age since graduation was 27 (range 8 to 46). Nine described themselves as being academic practitioners.

Seven main factors influenced insulin prescribing and each is described in more detail below.

1. GPs' beliefs about the elderly

GPs believed their elderly patients had many physical concerns, such as eyesight problems and compromise with manual dexterity that could cause

difficulties in insulin-administration and self-monitoring. They were also concerned that possible cognitive impairment could affect patients' ability to recall taking medication. They believed the elderly might react differently to medications in general and felt this group had a higher risk of developing a hypoglycemic episode after insulin therapy:

> *"Not a whole lot different than treating younger patients except that the special issues that come into play are I guess their physical ability to manipulate bottles and needles, their cognitive ability to monitor blood sugars and administer their medications as they should. I guess the other issue is you always kind of have the fear of the frail old diabetic person who is very sensitive to small changes in insulin, and the risk of causing a hypoglycaemic problem in that person if you treat them the same as maybe a younger robust person." [Int4]*

GPs felt elderly patients would be less receptive to medication regimen changes, though subsequently more compliant with new regimens than younger patients. Many GPs described how the challenges of initiating insulin therapy became easier as patients were encouraged by symptom improvement and as medication-related issues were discussed to improve knowledge.

2. GPs' beliefs regarding diabetes and its management

General beliefs related to diabetes were discussed that reflected experience with managing chronic illnesses. Many felt providing diabetes care caused a high clinical burden and increased the need for greater vigilance. For example, more tests and adherence to strict standards of monitoring added to already time-pressed consultations:

> *"The huge thing, which is raising its head already and will in the future, is the enormous burden of people with diabetes. The ever-increasing demand to reach tighter and tighter guidelines and the limited resources available to help us do that. So in an ideal world we could do more and do it better if we were more available. So in an ideal world you'd be on the phone with someone very regularly, as often as once every two or three days to do adjustments and get it right. It's not, it's barely realistic now and it will become less and less realistic next year and the year after and the year after." [Int8]*

GPs described diabetes as a disease that required self-management and input or ownership from patients. Empowering patients could be challenging, though very necessary in order to foster testing of blood sugars and improving understanding of why testing is needed. Patient self-management, though key, was difficult to foster:

"And the bottom line is the disease is difficult to control. It changes with the time of day. It changes with what you eat and what you haven't eaten and whether you exercise or whether you haven't exercised. It changes with the temperature of the day. I mean there are lots of factors that go into monitoring your sugars. It's not, you know, it's not friendly to be wandering around with your diabetic kit, you know in your purse or in your pant pocket. You don't necessarily, you're in church on a Sunday morning you're a bit sweaty and you're light headed and you're dizzy. You're not likely to slip out into the washroom, you're reluctant to go anywhere on your own, you want somebody with you. So even monitoring yourself in situations during the day is problematic." [Int18]

3. Gauging the intensiveness of therapy

Views varied among participants regarding how aggressive to treat elderly patients with diabetes. Most doctors felt less tight control in this age group was acceptable. Many expressed frustration that there seemed to be no definitive evidence upon which to base their actions; therefore, GPs used their own experience and beliefs to inform their actions:

"I would have a higher threshold for poor sugar control [more frail elderly]. So with younger people I guess I try to get a more tighter sugar control, and with older people I'm less concerned I guess."[Int10]

"I just haven't seen any evidence that shows that being really aggressive in elderly makes a difference in how long or how well they live. As soon as I see that, I will get aggressive, but I've never seen anything like UKPDS. If there is something out there, then somebody's got to convince me of it."[Int2]

Some GPs expressed the view that age alone should not necessarily be a sufficient indicator of physiological characteristics. They felt that there was a distinction between 'young-old' and 'old-old', almost drawing a line between the 65 year to late 70 year old age group, who appear fitter and healthier, and the over 80 year old age group who seem to be more frail. However, GPs also recognized that some elderly people did not fit into these stereotypes about age and preferred to personalize the care that they offered:

"I would individualize because each person is so different; different people age differently. There are some who are late into their 80's and early 90's who are quite lively and active and function well. And then there are others who are much younger and that are showing lots of ageing [right] physiologically." [Int15]

GPs were capable of analysing the contexts within which their patients lived, and trying to assess whether their patients would indeed benefit from insulin considering everything else.

"I think if somebody is older and there are a lot of other medical things going on, and you can't sit there and judge for sure how long somebody is going to live. But if they've got a lot of other medical problems, I'm thinking, well, what's the advantage of introducing insulin, how much more benefit are they going to get in terms of tighter control, is it really going to change their life expectancy that much?" [Int12]

"…At 54, 20 years later you know, I'm going to be on dialysis and you're gong to be running around the bay. But in seniors, I cut them a lot of slack, their lives are complicated enough, they may be on multiple pills, their vision may not be good. They kind of …look at me like you know, you're just such a kid dearie. Their…concept of risk is a little different than mine, there are worse ways than just dyng or having a heart attack… You just don't want more paraphernalia and more stuff to do in a day, testing and taking pills. So I kind of understand that for them…"[Int 21]

In their 'personalization of therapy', GPs were aware they were making an assessment of a patients' quality of life and that this would influence their prescribing behaviour. They sought affirmation of their assessments by having ongoing discussions with their patients and checking whether the patients' assessment of their quality of life was similar:

"Do I tend to be as aggressive when it comes to somebody nearing the end of their life? No. I tend not to be aggressive but more the thought that this is a better quality of life. Even though the sugars may not be as good, but that's pretty good because we might extend a life by a month, if that's a big deal, it depends on the person. If they say, "yes, doctor it's a big deal to me" then I'll do whatever they say. But I think at that age, most of the people are looking for quality not the quantity of life and I think we can work on that."[Int19]

4. Need for preparation for insulin therapy

Participants noted a patient's reaction towards needles as a significant barrier to prescribing insulin. The very words 'needle' or 'injection' carried complex connotations and sometimes the suggestion of starting insulin could signify a message of failure in other therapies to the patient, and that 'drastic' measures were now needed. GPs were cognisant of the psychological hurdles patients would need to go through in order to feel more comfortable with commencing insulin treatment; and the need for multiple discussions to lesson the fears their patients had. In this way, GPs sought to 'lay the groundwork' for the experience of going onto insulin to ensure future success:

"…I think it's helpful if it's introduced as just a one time thing at night to start, and then it's a gradual stepwise approach, and you don't just throw

out what you've done before, and just more see it as adding one more bit…"[Int10]

"*So starting patients for example, in office, giving them or giving themselves the first injection and having a demonstrator insulin pen sometimes is one of the, the best ice breakers to get them to understand. 'Well gee that was an injection. I hardly felt that. I didn't think that would be such an easy thing to do, to hold that pen you know against my skin. I hardly felt anything go in.' Just spending the time to familiarize themselves with what is insulin"[Int 18].*

Preparation seems to be a central factor (that leads a patient of a practitioner to switch from the decision to prescribe, to the decision not to prescribe or vice versa) once the decision to start insulin has been made. This preparation for therapy could be done by a variety of people (practice nurse, diabetes educator or GP), over several visits and in different settings (GP surgery, hospital, or local diabetes education centres).

5. Support with insulin administration for patients

All participants indicated that support (whether from family or health-professionals) was important for them and their patients in the decision to commence insulin therapy. The support and presence of family members was

essential for an elderly person to take insulin, whether in a role of overseeing everything totally, or a supportive adjunct to monitor progress independently and to check process:

". Because when they're(with somebody), the few patients that I have, there is somebody with them who are watching it so if they are not able to do it, somebody's living with them who does and who handles it quite well so I haven't run into that, that they're making mistakes…" [Int 10]

"One would be interested in what their supports were. Do they live alone? Is there someone coming in and visiting on a regular basis? What role the children played, was there a husband, was there a best friend, etc, someone who they could rely on, that would be important.," [Int19]

In some cases not wanting to put a burden on the family was a deterrent for starting insulin. In situations where the elderly patient received constant assistance from a caregiver/nurse, it was easier to recommend insulin, as the GP felt someone reliable would be administering the medications:

" Again, if their cognitive function is low then you need definitely some caregiver to do that. And I think it's more of a burden on the caregiver as she is doing so many things. Now on top of that if she has to give the insulin as well, then we make sure she does more sugar levels, which

means it's more of a burden on her and the caregiver has to have one more job to do this day...."[Int13]

However in some cases in which the care received by an elderly resident at a nursing home was not adequate, a GP would simplify the treatment:

I've been burned once by an elderly lady who lives in a very third rate retirement home. She's in her 90's and she's probably smarter than most of the care attendants that take care of her. And she's had some episodes where her sugars went way, way up, over 30 and that makes me worry about this kind of let it be philosophy I have about sugars in seniors because she was pretty sick. I can't remember, I think it was the UTI that kind of put her over the edge. So I may not be doing them any favours in terms of some degree of reasonable control to keep them from going from 5 to 30 with intercurrent infections but it's a real struggle. And the retirement home does not feed her the proper food for diabetic diet. The staff really don't know how to do things around her glucometor. So I guess it comes back to living circumstances. I also think I feel a little insecure about prescribing. [Int 21]

GPs also relied on specialists or clinics to reinforce the need for insulin and on nurses to assist with teaching and monitoring. The assistance provided helped

the GP overcome the initial barriers to starting insulin, and provided valuable time and input where he or she was burdened due to other practice pressures:

> *" Oh I'm lucky, I'm very lucky because I have a diabetic nurse who comes in on Saturdays and brings in all the pens and things and sits them down, and explains it to them [patients], gives them a sample and says, 'this is what you do'."[Int19]*

6. Frustration with management complexity

Some participants expressed a frustration towards the multiplicity of factors related to the prescribing, monitoring and use of insulin, the complexity of the treatment regimens, and the work implications of needing to start a patient on insulin. They felt many patients did not adequately understand the long-term ramifications of diabetes and how important insulin therapy could potentially be. For some GPs, these feelings were 'countered' by access to a good support system: *"Well frustration is one of them. You know you're trying to impress upon them [patients] this is important to their health, and for one reason or another you know, they're not getting it."[Int11]*

The addition of another layer of treatment such as insulin, which would make treatment even more complex, was challenging, and added further difficulties around administration, monitoring, dosing and possibilities of mistakes and side effects that were hard to face knowingly. This sentiment seems

to be able to influence the decision to actually prescribe insulin or not, despite the assessment of a patients' need for insulin.

7. GPs' experience with insulin administration

Within this group, most GPs had little experience treating elderly patients with insulin. This lack of experience made some apprehensive about initiating insulin. Many used a referral to a local diabetes clinic to support their decision to commence insulin:

> *"Personally, obviously as a GP I don't have the experience starting insulin as much as the specialists so I'm at much greater comfort with the pills. So sometimes you know what's right and then there's the little personal feeling that you have to make that step even though there's a little bit of a reluctance because of familiarity. I'm getting better at it."[Int4]*

> *"Well I think it's scary for them [patients], it's scary for me..... now the doctor is suggesting bringing out the big guns, the insulin as opposed to tablets. They don't see tablets as being a big threat. Certainly bringing out needles almost means, 'well, gee, we're at the end of a rope here.' It creates more fear with me because now I have to be very careful in making sure that they know how to do it".[Int7]*

Conversely, GPs also described situations where their own experience or knowledge of particular nursing homes or less than ideal care situations, hindered them from considering insulin treatment as a viable option. Thus, the presence of support is a factor that can facilitate GPs in starting insulin, helping them to action this decision.

Variability in doctors' approach

An overall observation was also made that there was a mismatch between what GPs considered ideal practice and what they themselves were able to offer in their individual settings. Some reasons for this mismatch between intent and behaviour included the GPs assessment that the quality of life of the individual patient needed to be considered; a sense that a more cautious approach was needed in real life; and a belief that less tight control is acceptable when treating real-life elderly patients. This highlights the likely unconscious beliefs that influence how treatment prescribing occurs in practice:

> *"I mean I treat them [the elderly with diabetes] pretty much as vigorously as I treat somebody who is younger … And I don't think that I see that any different. I don't think age is a problem ……. [later on]… If somebody who is 92 and diabetic, how keen am I going to be on putting them on insulin therapy? Obviously it's not going to be as much as somebody who is 35 and diabetic…or a teenager and a diabetic".[Int9]*

Discussion

Summary of main findings

This study demonstrates a wide range of factors that influence GPs prescribing of insulin for the elderly. Personal beliefs and appraisals of the elderly population, diabetes, and the intensiveness of insulin therapy influence GPs decision making. Once the decision has been made to commence insulin, GPs will be further influenced in their decision to proceed by the level of available supports from the patient's family or from professionals. GPs identified the importance of thoroughly preparing their patients for the decision to start insulin before initiating insulin therapy in this age group.

Comparison with existing literature

Previous research has also found that doctors' belief systems affect how they prescribe.[20] However, what specialists may have previously felt to be a dangerous 'postponement',[20] could in fact be part of a necessary and lengthy preparation process with the patient. GPs were careful to discuss issues, which may affect quality of life (e.g. patient fear) and also re-visited these issues in subsequent consultations.

The finding that GPs may not have a standard approach for all older patients with diabetes may also be part of their ability to gauge a situation based on intimate knowledge of their patients' background and personality. This reflects the process of individualizing therapy, rather than a consistent 'disconnect' between stated and actual behaviour. For example, GPs develop a threshold for

the maximum number of medications that they are willing to prescribe to a patient, but this number will vary amongst their patients.[17]

Strengths and limitations of this study

The study utilized many steps to ensure rigour in its design. The cleaning of transcripts for accuracy, multiple investigators involved in the coding and analysis, and refinement of the interview guide to capture emerging themes helped to facilitate saturation of themes. Despite these strengths, it is acknowledged that this sample of 21 GPs did not allow for in-depth comparison of different types of GPs (e.g. rural versus urban; solo versus group practice). As well, although GPs were screened prior to the interview to make certain that they did have seniors with diabetes in their practice, very few had actually initiated the use of insulin, and we recognise that this may not be reflective of practice at large. However it was reflective of the sample that we interviewed, since we sampled purposively to include GPs with elderly patients and this indicates the state of experience in our area. Future research that purposefully seeks out GPs with experience prescribing and monitoring insulin, as well as those that have deferred this route would contribute to the literature.

Implications for future research or clinical practice

This study offers useful insights regarding factors that influence insulin prescribing in the elderly in the primary care setting. In a scenario of ever-increasing numbers of elderly people with type 2 diabetes, GP prescribing of insulin would benefit from further support and intervention. Next steps could

include general practitioner targeted education modules to clarify the evidence for use of insulin in the elderly and focussed on better communication between specialists and GPs. A trial testing different modes of education could help to inform how best to improve GP confidence in insulin prescribing. If left unaddressed, the under prescribing of insulin due to the subconscious beliefs of GPs could increase the existing cohort of poorly controlled elderly people with type 2 diabetes.

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Conclusions from the thesis papers

This section discusses the key findings and their significance in the context of current Canadian healthcare and makes some recommendations for future work and policy changes with respect to improved detection and management of diabetes in Canada.

Paper 1: Screening for diabetes

The objective of this systematic review of the literature was to determine the yield, sensitivity, specificity and PPV of T2DM screening methods, where possible, when identified using a community or family practice based systematic screening approach, or an opportunistic family practice based approach and, if possible, to compare these approaches. From 1101 studies initially identified as meeting the inclusion criteria, 25 studies were found to be relevant to the question posed. Screening efforts examined in these studies varied, ranging from oral glucose tolerance tests to questionnaire-based risk assessments. Methodological quality was variable; the main methodological weakness was that compliance with the screening method was frequently not reported and in many studies, attrition and uptake rate for screening was either not described or difficult to interpret. The yield rates of diabetes diagnosis from community or family practice based screening strategies ranged from 0.017 – 0.066. There was no clear pattern linking the methods of screening used and the reported yield rates. The yield

rates of diabetes diagnosis from screening efforts in general practice using opportunistic methods were calculated, and ranged from 0.010- 0.026. The 3 studies that relied on electronic medical records had higher yield rates and those using diabetes registries generally reported lower yield rates. Neither sensitivity nor PPV could be estimated for either group of studies from the data reported.

The main limitation of this review was heterogeneity of the studies included and thus, meaningful comparisons between the two strategies were not possible. In the opportunistic screening in the family practice group of studies, although a diagnosis of diabetes may have been recorded, it was not clear that a gold standard diagnostic method was systematically used. In family practice studies, diagnoses may have been made without fully following guidelines; therefore, FBG and/or OGTT may not have been utilized. It was not possible to verify this for the studies included in the review. It was also not possible to calculate performance characteristics such as specificity since the data were not available from the papers for the numbers of patients who had true negative testing for diabetes, suggesting potential verification bias.

Thus, the first paper that attempted to systematically review the literature comparing the benefit of community or family practice-based screening for diabetes in primary care was inconclusive. Methodologically, comparing a community/family practice based intervention to routine care is challenging. Rigorous designs for future trials would be a cluster randomized trial design, with the random allocation of a screening intervention to different whole practices or

even to whole communities and a comparison with routine care in control practices or communities. Outcomes of such studies should include numbers diagnosed with diabetes using screening methods (interventions) compared to the gold standard (OGTT), as well as numbers of those who are missed when not using gold standard screening. These trial designs, though likely to provide an epidemiologically robust answer, would be prohibitively expensive, unpopular with patients and practitioners because of the involvement of complex laboratory testing and would require intensive organization and infrastructure that is currently lacking. Apparently, a trial using similar design (RCT) is currently underway in the UK, but will not report for several years to come (1).

Thus, the current literature is limited to designs that have used secondary data from studies with a different focus, or less robust designs. Unfortunately, this literature is very heterogeneous and not comparable, as already demonstrated in the systematic review prepared for Paper 1. Increasingly, there is debate concerning the use of other laboratory tests since although the OGTT is the gold standard it may not be used frequently (Ontario data shows that less than 1% of people underwent an OGTT between 1995 and 2005) (2). An increasing number of individuals without documented diabetes in Ontario have been tested using the A1c (1). Additionally, many Ontarians receive serum blood glucose testing, which is either random or fasting (80% of women and 66% of men) (3).

The debate for or against screening and even the method of screening in the community therefore has not been resolved. Currently in Canada the Canadian

Diabetes Association recommends screening all individuals over the age of 40 (4), while the Canadian Task Force on Preventive Health Care (CTFPHC) recommends screening only for adults with hypertension or hyperlipidemia (5). Both guidelines are currently under review and revised recommendations are anticipated shortly. For now, health policy makers will need to assess their own communities' needs, which may vary based on the population mix, and assess whether or not local programs for screening (whether targeted or universal) could be initiated; an example of this is the Aboriginal Diabetes Initiative (6). Through this program, targeting the Aboriginal population increased regular screening for early diagnosis using population-based and opportunistic screening methods is supported, with the use of mobile detection programs. It is possible that diabetes screening could be increased in communities predicted by population-based algorithms to have high rates of undiagnosed diabetes (7). Researchers have used population based data (national registries and other such data) and developed and validated an algorithm to estimate the number of individuals who will develop diabetes over a 9-year period (7). This algorithm could be applied to existing provincial data to decide where to focus diabetes screening strategies for greatest effect.

Papers 2 and 3: Potential of the CHAD Program

Papers 2 and 3 describe the CHAD (Community Health Awareness of Diabetes) program and its feasibility, acceptability and effectiveness. There were

588 participants in CHAD; of these, the majority that had received invitation letters were seniors and were females; 526 did not have pre-existing diabetes; and 16% of participants were identified as being at high risk for diabetes. Those at high risk of diabetes had significantly more modifiable risk factors, including higher fat, fast food and salt intake, and higher systolic blood pressure. Satisfaction with the program was high. Paper 2 shows that the CHAD program was feasible and it could be scaled up into a larger, perhaps province-wide program.

Paper 3 reports on an audit of 1030 medical charts of individuals eligible to attend the CHAD program, from 28 family doctors' practices in Grimsby, Ontario. Of these, 387 charts were of patients who had attended the CHAD program and 643 charts were of individuals who did not attend the program but who met the program eligibility criteria. Overall, the difference between the rates of diabetes diagnosis before-and-after the program was not statistically different. The difference in rate of diabetes diagnosis annually in the attendee group was 20 per 1000 and in the non-attendee group was -2 (to be interpreted as 0) per 1000. In the community, the annual rate of new diabetes diagnosis was 27 per 1000 (95% CI = 17.90 – 39.00) in the year before the introduction of the CHAD program, and 45 per 1000 (95% CI = 33.00 – 59.80) in the year after. The attendee and non-attendee groups were significantly different demographically in that the CHAD attendees were more likely to be female, retried and older than the random sample of eligible patients drawn from the same practices. Multi-level

regression modeling showed that attending CHAD did seem to have a positive effect on whether diabetes was diagnosed; however, this effect was lessened both in statistical significance and magnitude when taking in to account the physician effect (clustering), patient gender, patient employment status and patient age.

The main limitation of the CHAD program was that it heavily relied on community participation, both in the form of volunteers who could act as PHEs and also pharmacists who provided a venue for the screening tests. At times, the venue could be crowded and busy, and not an ideal place for completing lifestyle questionnaires. There is likely to have been some selection bias in the attendees who participated in the program. Attendees were more educated, reflecting the self-selected nature of the sample, indicating that they were a group of people more likely to be concerned with their health, and thus potentially at lower risk to develop diabetes.

A main limitation of the study was that practices were chosen from the Grimsby, Beamsville, Vineland and Smithville and were thus not likely to be representative of family practices in Ontario as a whole. The study area did not contain many people from visible minorities and so cannot be generalised to areas that have populations containing more people at higher risk of diabetes by virtue of their ethnic origin. Both the attendee group and non-attendee group had patients whose records were missing from the original sample and there were more missing records in the CHAD attendee group (19 vs. 2 in control group). Since this audit involved locating the family doctors of many patients, and these

doctors were located across Grimsby and the surrounding areas and had not been actively participant in the CHAD program, some were reluctant to allow their patients records to be audited despite pre-arranged patient consent. Also, more patients were found to be deceased (14 vs. 4 in non-attendee group).

The CHAD program may have had a positive effect on the increased diagnosis rate of diabetes in the community; but, the results are difficult to conclusively interpret since they are not statistically significant at the conventional levels. This is most likely to be due to the fact that the number of cases of people who were diagnosed with diabetes was small overall, thus, the power of the study was not sufficient to detect a difference before and after the program occurred. A twofold effect size was assumed in calculating the sample size, and in the study, less than a twofold effect size was found (actual effect size was 1.67). Therefore, this could partially explain why statistical significance was not reached in this sample when comparing the diagnosis rates using a paired t-test. The clustered nature of the data (patients nested within family practices) served to further decrease the statistical power.

Paper 3 demonstrates, however, that even with these limitations, the CHAD Program did appear effective in identifying people with diabetes in the community, though this was not significant. However, more work is required to establish whether this type of program could be successful when taking the long term effects and the economics of diabetes screening into account. Ideally, a future study should take place, as recommended in the section above. Though

CHAD uses self-reported risk assessment data, and this could be criticized as being potentially inaccurate, such data has been used before in the development of population based risk assessment for diabetes successfully (7). However, weight has been shown to be underestimated and height overestimated by individuals self reporting (8,9).

If found to be effective in both case detection and cost, a community diabetes screening program should be recommended to Canadian Health Policy makers. Current literature shows that screening is more cost effective in hypertensive and obese groups and the costs of screening are offset in many groups by lower treatment costs (10).

At present, building on the work from this thesis and other literature, the Public Health Agency of Canada (PHAC) has developed a Canadian diabetes risk questionnaire, the 'CANRISK' (11), and has been validating and piloting its effectiveness in Canadian communities. Here, the PHAC built on the notion that screening for diabetes using the OGTT can be targeted to high risk individuals only using the CANRISK. However, new evidence shows that methods utilized for laboratory testing for diabetes in Canada are changing and OGTT is used less frequently; but, the A1c is used more in individuals without diabetes, possibly as a screening measure (2). This implies that in developing a screening strategy changes in current practice should be accommodated and incorporated.

Paper 4: Current state of diabetes care

Paper 4 describes some of the current facets of family practice diabetes care in the community. In the retrospective chart audit of 96 charts of patients diagnosed with diabetes who receive care from 18 physicians the mean HbA1c was within target (less than or equal to 7.00) in 76% of patients and at least 4 readings per annum were taken in 75% of patients. Nearly 2/3 of patients had been counseled about diet in some form, more than 1/2 on exercise and nearly all (90%) were on medication. Nearly all patients had a documented blood pressure reading and lipid profile. Over half (60%) had a record of their weight and/or BMI. Although there was room for improvement, diabetes targets were mainly being met according to the 2003 CDA guidelines.

Limitations of this work are multiple. Firstly, though the sampling scheme was adequate to investigate the objectives outlined in the introduction at a patient level, results may not be generaliseable to other practices in Ontario or Canada. The audit was conducted in practices located in a particular geographical area, which may not be comparable to or representative of other Canadian locations. The Grimsby area population is less ethnically diversified, more educated and has a higher income than most areas in the province. Although medical chart audit is an accepted form of data collection, charts and charting styles may differ between practices and may lead to under-reporting of the contents of clinical encounters with patients. Finally, the physicians were mostly all CFPC certificants and Grimsby is not a rural but an urban area, both of which can be correlated with

higher quality care. Although diabetes care seems to be improving it is possible that this improvement is just regional (not Ontario-wide or Canada-wide) and specific to the Grimsby area, possibly due to the fact that most of the family doctors were using EMRs, had more allied health professionals helping them, or had greater awareness of the current guidelines due to the fact that they were teaching residents. Another limitation is a relatively small sample size which means that most of the estimates have relatively wide error margins.

The diabetes sample used here cannot be a true representation of all people with diabetes in general in a primary care population since they were not sampled to be able to gain a complete list of all patients with diabetes for each of the 18 physicians, but were sampled as part of another larger study. Remuneration methods of each practice could have affected the diabetes care offered in that practice. In capitated models of remuneration there are incentives for reaching certain targets for patient care, but these do not exist in a fee-for-service model of care. It was not possible to explore this effect in this data due to the small number of practices. Typical clinical practices of each physician with respect to diabetes care were not collected due to the small number of physicians (n=18) in the sample. Nor was it possible to state in what proportion of patient's optimal care was provided with respect to appropriately prescribed medication since accurate information regarding prescribing had not been collected in relation to the illnesses, only proportions of patients on certain medications.

Family practitioners in this group were performing well, adequately following guidelines. In Canada, studies have shown that there is a substantial gap between CDA guidelines and Canadian family practice standards (12,13). Family physician performance, regarding care of patients with diabetes, is important since most patients with diabetes are cared for by their family doctor (12).

Though literature abounds on the studies of family doctors not optimally following the guidelines (14) in Canada, only 51% of patients with diabetes achieve target A1c levels (13), this is not reflected in this cross-sectional audit of diabetes care presented in Paper 4. It is possible that this group of practitioners is more diligent than others, and thus not representative of most. Also, it is possible that practice has improved and practitioners are better at following guidelines for diabetes.

Diabetes is a condition that many practices have registries for, and in Ontario, physicians can receive financial incentives for annual and quarterly review (15), which could have influenced care. Another possibility is that patients in this area are more diligent than most or that patients are taking increasing responsibility for their health. It is possible that diabetes care cannot be improved much more from this point, given all the non-physician related patient and environment factors that should be accounted and allowed for.

Paper 5: Management of the elderly with diabetes

After interviewing 21 physicians regarding their views on the care of elderly patients with diabetes, identifiable themes that indicated factors influencing the under-prescribing of insulin emerged. A model describing their prescribing habits in this circumstance was generated. The model identified 7 factors influencing prescribing of insulin for elderly patients: 1) doctors' beliefs about the elderly; 2) doctors' beliefs about diabetes; 3) intensity of therapy required; 4) need for preparation for insulin therapy; 5) the presence of a support system from informal or formal health care provider; 6) frustration with management complexity; and 7) doctors' experience of insulin. Though doctors indicated that they would prescribe insulin allowing for the above factors, there was a mismatch in intended approach to prescribing and self-reported prescribing. Family physicians' rationale for prescribing (or not prescribing) insulin seemed to be mediated by both doctor-related and patient-related factors. In order to improve prescribing for increasing numbers of elderly people with T2DM more education for family physicians, specialist-support and use of allied health professionals is needed.

The main limitations of the study are that the sample chosen may have had a limited experience of using insulin despite the attempts made to recruit more experienced physicians. The model is only a preliminary model at present and needs further validation in larger samples of physicians. Following on from Paper 4 and clinical practice guidelines, Paper 5 shows that a general area in which

physicians do have problems adhering to diabetes care guidelines is in the care of elderly patients. The difficulties that practitioners have when caring for people with diabetes in this age group is described in this paper. Family physicians clearly articulate the multitude of other factors that they must consider when managing their elderly patients with diabetes. This illustrates the fact that in the real world, following guidelines may not be entirely appropriate or possible. More work is required to describe what might help family doctors and their elderly patients with diabetes in this situation.

It may be that with adequate support, whether from family or health care professionals, that insulin could be initiated more easily in primary care. This is something that will become more and more important given that there are more elderly patients than previously (16), and the prevalence rates of diabetes have been increasing steadily (17).

Health care costs generated by seniors are increasing. Reports suggest that per capita spending for people over 65 years of age is greater than 5.4 times that spent on those younger than 65 (18) and that by 2020 seniors will use 55% of all health expenditure. Focusing on prevention, rather than cure will help to keep health costs down (19). Therefore, greater use of insulin in seniors may have a place in ultimately reducing health care costs in this group, if used appropriately and with adequate support.

Overall recommendations

T2DM and prediabetes are on the rise, as shown by numerous studies. Changes to primary care may need to be made based on this fact since current models of prevention, detection and on-going management are unlikely to be able to cope with projected increases in the prevalence of T2DM. Literature-based evidence to suggest that community or family practice-based screening is beneficial is scant. Therefore, it is not plausible to suggest that diabetes screening for everybody should be programmed for completion within this environment, in a strategic way to capture all individuals needing screening. Based on the evidence from the analysis of outcomes from the CHAD Program, restructuring of family practice offices to accommodate universal screening for diabetes cannot be recommended. However, given that the evidence was promising, targeted screening efforts that are concentrated in practices surrounded by populations with a high risk of developing diabetes seem more appropriate.

Community Programs like CHAD may indeed have a place within the primary health care system if properly designed and properly supported by family physicians, in such a way that screening activity can be acted upon by them. Policies that support this type of community initiative that partners with primary healthcare should be promoted in an effort to share the burden of screening for diabetes, and also to target appropriate screening to populations that need it the most, delivered in the most effective way. CHAD was successful since it built upon existing community infrastructure; therefore, programs that can be adapted

from existing public health or community initiatives are to be encouraged. Another strategy that was unique in CHAD was the utilization of peer health educators who had been appropriately trained. This can help keep the costs of any health screening program low, and also facilitate in engaging the community in the prevention and screening efforts. Though evidence is not overwhelmingly positive, initiatives of this nature could represent a feasible and low cost way of assisting Canadian primary care physicians in detecting individuals with T2DM.

Management of T2DM in Canada is largely conducted by family physicians. Guidelines exist for appropriate care of people with T2DM, and family physicians are expected to adhere to them. These guidelines have changed regularly and have become more stringent, requiring people with T2DM to strive for lower fasting glucose levels and better control. According to recent guidelines, optimal control is not being met in some areas of diabetes care (nephrological monitoring). In primary care, there has been a lot of attention focused on patients reaching targets and on practitioners monitoring patients appropriately and checking that targets are met. Data does seem to indicate that though physicians do play a role in achieving targets, much of the variability that patients exhibit with target attainment is not related to the physician. More focus on other aspects of improving targets in patients, such as external factors, behaviour, environment and lifestyle changes, are recommended in further improving standards of care for T2DM in the community.

With an ageing population and an increasing number of elderly people with diabetes, management of diabetes in the elderly is part of everyday practice for family physicians. Clinicians clearly struggle with many factors regarding the use of insulin in the elderly. Policies that promote the use of allied health care professionals in support of the family physician, specifically trained in the challenges that the elderly face when initiating insulin, may be beneficial (for example, a diabetes nurse specialist with a focus on insulin starts in the elderly, that is available to community family physicians could be an asset to any primary care organization or health network). More postgraduate educational activities describing the process of insulin starts in the elderly would also be beneficial in increasing confidence of family physicians in this area. These could be initiated as part of the College of Family Physicians of Canada Mainpro-C continuing Medical Education Program and offered in any location, or as an educational module for small group learning such as the Problem Based Small Group Learning Program that currently exists. In addition, an educational campaign that targeted the elderly and their caregivers specifically and educated them on the benefits of insulin and process of starting it would be helpful in assisting the family doctor trying to initiate this therapy in their patient.

All these recommendations, either individually or together, could make a difference in the timely identification and care of individuals with diabetes within the primary care system in Canada.

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Ethical issues for consideration in the thesis

Both studies, around which this thesis is based, obtained full ethics approval from the McMaster University Research Ethics Board (#04-404) or the Hamilton Health Sciences Research Ethics Board (# 04-166). Appendix 1 contains the participant and family physician consent forms and study information for the CHAD study and Appendix 2 contains the consent form and study information for the Insulin Beliefs study.

Ethical issues encountered in the CHAD Study (Papers 2 and 3)

Informed consent:

The investigator first obtained informed consent from the family physicians involved and was then provided with the names of all the over 40 year old patients rostered to that physician. Patients were then invited by their family doctor, in the form of a letter that included details of the risk screening sessions as well as the risk scoring sheets that needed to be filled out.

All participants were adults aged 40 and over (and of suitable age and status to give consent), who voluntarily attended the risk screening sessions and had been invited by letter, which had detailed the tests to be undergone. At each stage of the project the participants were asked if they still wished to participate. On attendance at the risk screening clinic in the pharmacies, patients were asked again and consent obtained in written format. Participants were free to withdraw from the study at any time. Participants who did not wish to participate were not penalized in any way or form by the pharmacy or their family doctor.

Participants' decisions to not allow their results to be sent to their family physicians were respected.

Relationships between investigators, study staff and participants:

The patients had no relationship to the study staff. They attended risk screening sessions at a local pharmacy, voluntarily, where they were seen by a peer health educator (a local volunteer from the community was trained in how to obtain the necessary finger prick testing required for risk assessment of diabetes). It was possible that the patient may have known the peer health educator, and if either of these participants felt uneasy about this, then it was possible for another peer health educator to be sought (there were 3 at each clinic session) or for the participant to decline.

Confidentiality:

Peer Health Educators were trained by a public health nurse and inducted into the principles of confidentiality for this project. Data was stored at McMaster University in the Department of Family Medicine, in a password protected computer, and also in Clinforma offices on a similarly password protected computer there.

Benefits and Risks to Participants:

There were many proposed benefits to the CHAD Program that justified asking individuals to participate. Participants received an individualized risk assessment for diabetes as well as educational information about how to reduce the risks of these conditions, and if they were at risk, they were directed to their

family doctor (who also received their risk results). The benefits to society were that the CHAD Program presented information that family physicians were expected to act upon, which should have resulted in the increased and sooner diagnosis of diabetes. This should have had an impact on patients' health, as they would have have less complications (because of the earlier diagnosis) and this should have lead to decreased health costs for the area.

The success of the program had great implications for family physicians, as some of the responsibility for risk assessment was placed on the population, enabling family doctors to focus on those who really has high diabetes risk and to actively try to diagnose them, rather than trying to screen everyone (which was not feasible nor cost effective).

There were some risks to all the participants involved in this study. Firstly to the patients, the pain of the lancet finger-prick and hunger from fasting overnight for a fasting blood result and the embarrassment potentially encountered from some of the risk profile answers (weight, waist circumference) were the main risks. Participants were prepared for the finger prick pain and reassured (that they would be able to withdraw at any time). They were asked to come having filled out their risk profiles at home, and having weighed themselves and measured themselves already. It was explained in the letter that participants need to fast for 8 hours beforehand, for the morning clinic. Secondly, though the Peer Health Educators (PHEs) were assisting participants in taking their own near patient blood testing, the risk of transmission of blood borne diseases was very

minimal. PHEs were provided with a clean pair of gloves for each participant they saw, and also trained by a public health nurse on handling blood safely with lancets. They were not expected to actually perform the finger prick test – they merely stood by and instructed the participant in what they needed to do, so there was no contact with blood whatsoever. Thirdly, participants may have become anxious about their risk of diabetes unnecessarily if they were found to have a moderately high or high risk of diabetes on the risk assessment tool. However, the PHE reassured them that this was not diagnostic of diabetes and they were directed to see their family doctor and also the public health nurse who was actually on hand for all the assessment sessions. Participants were never falsely told that they had diabetes as they were never told that they had diabetes at all. In addition they were offered group education sessions to help allay any fears.

Ethical issues encountered in 'screening' asymptomatic participants:

The CHAD study did not seek to diagnose participants with diabetes but to assess their risk status with respect to diabetes. This was clearly explained to participants in the consent form (See Appendix 1). In addition, participants had access to a public health nurse at each risk-assessment session who was able to discuss the difference between diagnosis and risk assessment with them, if needed. However, in consideration of ethical issues, some of the same principles that are applied to screening programs could be applied to this risk-assessment program also. The screening of asymptomatic individuals raises a number of important ethical issues around informed consent, privacy and confidentiality,

risks and potential benefits, availability of an effective treatment, acceptability of the screening test and the allocation of finite public resources for screening these are worth further consideration (1,2). Some of these have been discussed above already, and the remainder I will address below.

There is available treatment which is readily available for diabetes ranging from lifestyle modification to medication. Since this is the case, it is indeed ethical to offer screening for diabetes. The risk-assessment offered was by means of a questionnaire and a finger prick blood test. The assessment was not invasive and caused minimal discomfort if any, and was voluntary. The last point concerning resource allocation has not been thoroughly assessed enough in this study to be able to comment upon in detail. However, the CHAD Program built upon community resources and was not developed with the idea that large amounts of money would be required to sustain it. It was designed with the premise that communities who were interested in such a program could modify some of the particulars to suit their own community. Indeed, it is likely that a risk assessment program that targets people to attend for sooner screening and potential diagnosis of diabetes may in fact lead to utilisation of less health care resources in the long run, though this would have be to formally evaluated in a follow up study.

Ethical issues encountered in Paper 5

Benefits and risks to Participants:

The aims of this study was to be able to identify barriers from the physicians' perspective related to the use of insulin in seniors and to then develop strategies to overcome these barriers.

There were no risks to participants involved in this study.
A $250 honorarium was given to physicians who participated in the in-person interview and a $175 honorarium was given to each physician who participated in the nominal telephone interviews.

Informed consent:

Recruitment letters were faxed to randomly selected family physicians that described the objectives of the study, the methods as well as the honorarium being offered to participants in accordance to the amount of their time required for the interview requested. Physicians were be selected from the Canadian Medical Directory Master file of Physicians (MD Select). This database was a comprehensive Canadian database, maintained and updated from over 20 accredited sources that represented 99% of practicing physicians in Canada.

Relationships between investigators, study staff and participants:

Investigators did not conduct the interviews and only had access to the data once all personal identifiers had been removed from the transcripts. The research assistant conducting the interviews obtained consent. For the in-person interviews consent was obtained at the beginning of the interview. Participants were all competent to give informed consent. Physicians were given the opportunity to leave the study at every intervention or contact and this was clearly

stated on the consent form. At any time if any participant wished to withdraw from the study he or she could do so and his or her data was removed from all study results.

Confidentiality:

All participants were identified by a unique study identification code and only the research assistant was able to link the ID code to the participant. All personal identifiers were removed from the transcripts and all data prior to giving the data to any investigator. No personal identifiers were used in any publication of the data. Data were stored in a locked filing cabinet at the Centre for Evaluation of Medicines. The research assistant was the only person with access to the data.

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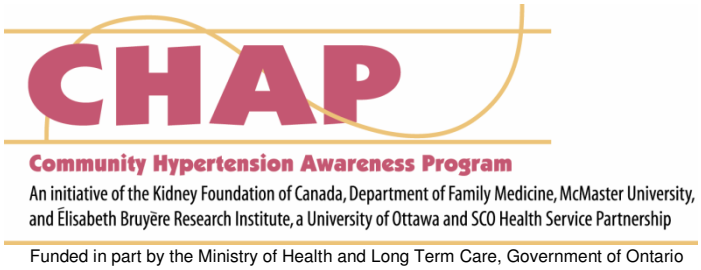
Appendix 1



SESSION INFORMATION

Location:

PARTICIPANT INFORMATION AND CONSENT

I understand that my family physician is participating in a community program for **detecting risk of diabetes and high blood pressure.** I have been invited to participate and my family physician would like the program staff to send a copy of my results if I attend a session. This program is taking place in pharmacies in my community. I understand that my decision to participate or not will *not* affect the care that I receive from my family physician or pharmacist.

At the sessions, a trained volunteer will help me to measure my blood glucose and blood pressure with a portable device. He/she will help me to record other cardiovascular risk factors. I can discuss questions or concerns about my health with my family physician or pharmacist.

I will be given a copy of my results. By consenting to participate, I agree that my family physician will be sent a copy of this information. The volunteer will ask me if I want my results sent to my regular pharmacist.

The information collected will be kept secure and confidential. It will *only* be used to provide feedback to my family physician, and to my pharmacist if I choose. It will not be given to any other person or organization. Identifying patient information will not be retained after feedback is sent. Reporting about the program will be for groups of patients. Individual patients will not be identified in published results.

I understand that my participation is voluntary. I understand that I am not required to provide any information or answer any questions that I do not wish to answer. I can discontinue my participation at any time by calling the Kidney Foundation CHAP Program Coordinator (1-800-414-3484).

I acknowledge that all the information I needed to make an informed decision was given to me and all of my questions were answered. My family physician, pharmacist, or the program public health nurse will answer any future questions I may have.

I understand the information on this consent form and I will receive a signed copy. I am willing to take part in this program.

_____

NAME OF PARTICIPANT (PLEASE PRINT)

_____ _____

SIGNATURE OF PARTICIPANT **DATE**

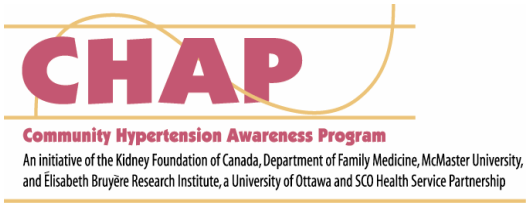
_____ _____

SIGNATURE OF WITNESS **DATE**

For more information about the program, please contact The Kidney Foundation CHAP Program Coordinator at 1-800-414-3484.
If you have any questions regarding your rights as a research subject, you may contact the Hamilton Health Sciences Patient Relations Specialist at 905-521-2100 ext. 75240.

PROGRAM COPY – WHITE **PATIENT COPY – YELLOW**

The Kidney Foundation of Canada - Greater Ontario Branch
35 Goderich Road, Unit 9, Hamilton, ON L8E 4P2, 905-318-8627, 1-800-414-3484, Fax: 905-318-8491, E-mail: bloodpressure_clinic@bellnet.ca, www.kidney.ca



Family Physician Letter of Understanding

I agree to participate in the **Community Health Awareness of Diabetes Study (CHAD).** The purpose of this study is to determine whether diabetes risk assessment clinics held in community pharmacies, with transfer of results to family physicians, can improve the diagnosis of diabetes among over 40 year old patients.

All of my regular patients who are 40 years of age or older, community dwelling, and able to leave their home to visit the community pharmacy, will be invited to attend a diabetes risk assessment clinic in pharmacies near my office. I understand that a research nurse will assist my staff to generate a list of eligible patients to be invited to the clinics. Peer health educators will obtain written, informed consent from patients who attend a clinic. At each clinic visit, patients will be assisted to accurately measure their capillary blood glucose, glycosylated hemoglobin and record their blood pressure, and to record their diabetes risk questionnaire and cardiovascular risk factor information.

A randomly selected sample of 150 health records of eligible patients will be reviewed by a research nurse at the end of the study period to assess the effect of the intervention on patients' diagnosis and subsequent management of diabetes.

I understand that only aggregate data will be reported. Data collected for this project will be kept secure and confidential and will not be given to any other person(s) or organization(s).

_____

Name of Physician (Please Print)

_____ _____

Signature of Physician ***Date***

_____ _____

Signature of Witness ***Date***

For more information, please contact one of the Principal Investigators:

Gina Agarwal	905-523-6611	agarg@mcmaster.ca
Janusz Kaczorowski	905-521-2100 ext 76198	kaczorow@mcmaster.ca

Appendix 2

Individual Interviews: PHYSICIAN CONSENT FORM

Exploring the Attitudes, Beliefs and Knowledge of Canadian Family Physicians Towards Management Decisions in Seniors with Type 2 Diabetes

The Study

The goal of this project is to explore the process and rationale related to prescribing decisions of family physicians when treating people with type 2 diabetes over the age of 65 years. Your participation consists of 1 in-person interview that will be audio-recorded. The duration of the interview is expected to last 45 minutes and will take place at a time and location most convenient to you. The honorarium for your participation is $150 and will be paid to you within 30 days of your completion of the project. The study is being funded by the Canadian Institute of Health Research and the Team for Individualizing Pharmacotherapy in Primary Care for Seniors and has been approved by the Hamilton Health Sciences Research Ethics Board.

Confidentiality

All information received during this study is confidential. All names and other identifying information will be removed from the study results and all subsequent publications. Only a coded identification number will identify your participation. All information received, including audiotapes will be kept in a locked cabinet. Audiotapes will not be used for any other purposes and will be destroyed once the study has been published. Only members of the research team will have access to study information.

Voluntary Participation

The choice to participate in this study is completely your own. You may withdraw yourself from this study at anytime with no penalty to yourself. If you have any questions please contact Dr. Gina Agarwal, Family Physician, North Hamilton Community Health Centre at 905-523-6611.
If you have any questions regarding your rights as a research participant you may contact the Hamilton Health Sciences Patient Relations Specialist at 905-521-2100, Ext. 75240.

I have reviewed the consent form, understand the nature of this study, understand I will receive a copy of this form, and agree to participate in this study.

_____	_____	_____
NAME	SIGNATURE	DATE

I have explained the nature of this study to the participant and believe that he or she has understood it.

_____	_____	_____
RESEARCH ASSISTANT	SIGNATURE	