Family Physicians’ Perspectives on Computer-based Health Risk Assessment Tools for Chronic Diseases

by

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A thesis submitted in conformity with the requirements for the degree of Master of Science
Institute of Health Policy, Management and Evaluation
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Abstract

Health risk assessment tools compute an individual’s risk of developing a disease. They are potentially useful in chronic disease prevention mediated by family physicians. We sought to learn family physicians’ awareness, and perspectives on the usefulness, usability and feasibility of implementation of risk assessment tools. Focus groups, discussion with key informants, and usability testing with an EMR-embedded risk assessment tool were conducted with family physicians (n=30) from academic and community-based practices. Analysis following grounded theory methodology was used to generate categories and themes. Our findings indicate that participants are aware of the implications of risk assessment calculations though very few tools are used regularly. Tool integration with EMR systems was felt to be essential in assisting tool usability, uptake and efficiency of use. Results provide insight into current risk assessment tool use and the facilitation of wider implementation of risk assessment tools in family practice settings.
Acknowledgments

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Chapter 1
BACKGROUND AND RATIONALE

1.1 Study overview

Health risk assessment tools calculate an individual’s risk of developing a chronic disease based on risk factor information. They are a potentially effective aid in motivating individuals to adopt a healthier lifestyle. This study investigated family physicians’ awareness, and opinions on the usefulness, usability and feasibility of implementing health risk assessment tools in clinical practice. Focus groups, discussion with key informants and usability testing were conducted with family physicians (FPs) from academic and community-based family practices in Toronto, Ontario and Edmonton, Alberta. Grounded theory methodology was used to synthesize qualitative data into a framework to better understand FPs’ awareness, and opinions on the usefulness, usability and feasibility of implementing chronic disease health risk assessment tools in family practice.

1.2 Chronic disease prevention and modifiable risk factors

Chronic disease prevention and management have emerged as the most important priorities in modern health care because of a shift in focus from treating diseases and their complications to primary prevention and risk reduction. The World Health Organization (WHO) published the first Global Status Report on Non-communicable Diseases (NCDs) in 2010 which highlighted four modifiable behavioural risk factors that are strongly associated with the incidence of most chronic diseases\(^1\). These are tobacco use, physical inactivity, unhealthy diet and excessive alcohol consumption. Of the 57 million deaths globally in 2008, 63% of deaths in 2008 were due to NCDs. According to the report, over 4 million deaths worldwide per year were attributed to tobacco use, 4 million deaths were attributed to inadequate physical activity and unhealthy diet,
and 3.2 million deaths were attributed to harmful levels of alcohol consumption. Furthermore, another report by the WHO states that 80% of premature cardiovascular disease (CVD), stroke and diabetes, and 40% of cancers in Canada could be prevented through healthy diet, regular physical activity and smoking cessation\(^2\). Clearly, a very significant reduction in chronic disease mortality and morbidity could be accomplished through reduction of these key modifiable risks.

Identifying risk factors and minimizing their impact underlies the desire of healthcare providers to guide their patients in making better lifestyle choices. Though already challenging, gathering accurate risk information, communicating it, and optimizing how well it is perceived by the recipient becomes even more complex for chronic diseases\(^3\). In Western medicine, the FP provides “continuing, comprehensive health care for the individual…based on knowledge of the patient in the context of the family and the community, emphasizing disease prevention and health promotion”\(^4\). Since FPs play a crucial role in helping their patients manage modifiable risk factors, risk reduction is dependent on the communication between the patient and FP. By engaging with patients in dialogue about the benefits of physical activity or smoking cessation, FPs are intrinsically involved in helping patients make decisions about lifestyle choices.

### 1.3 Risk communication

Making informed decisions is based on an understanding of the evidence of risks and benefits of choices. Risk, in the health care setting, has been conceptualized as the probability of physical, psychological or social loss\(^5-8\). As new studies reveal information about the factors that increase an individual’s risk for developing a chronic condition, comprehension of this information can potentially promote patient involvement in decision-making and motivate patients to make better lifestyle choices.
Numerous studies have evaluated the impact of risk perception on making lifestyle choices\textsuperscript{9-12}. A systematic review by Edwards et al., analyzed 22 randomized controlled trials (RCTs) examining the effect of individualizing risk information on behavioural and health outcomes for screening tests. It was found that personalized risk communication increased uptake of screening tests (odds ratio=1.31), although little evidence was identified indicating that personalized risk communication allows individuals to make more informed decisions\textsuperscript{11}. Cross-sectional studies by Choi et al., and Asimakopoulou et al., found that patients who misunderstood their risk of developing CVD, or diabetes, respectively, were less likely to self-manage their health\textsuperscript{9,10,12}. Furthermore, two RCTs found that an improved perception of risk results in an intention to modify lifestyle, although whether greater intent to change actually resulted in lifestyle modification was not examined\textsuperscript{13,14}. Clinicians typically report risk information in the form of a relative risk or odds ratio. However, this form of risk presentation can be misunderstood by the general population\textsuperscript{15,16}. It therefore becomes important to healthcare teams to translate these results into meaningful information, whether it is through the use of visual or verbal communication of numerical findings\textsuperscript{17-19}.

Numerical risk communication has been the predominant mode of communicating risk because it is derived directly from quantitative study data\textsuperscript{17}. Numerical risk can be communicated in percentages, odds, or frequencies or through statistical means such as absolute risk, relative risk, odds ratios or number needed to treat\textsuperscript{20}. However, because numeracy in patient populations is highly variable, this form of presentation is not always effective\textsuperscript{21,22}. Alternatively, verbal and visual presentation formats are also used. Verbal risk communication involves the use of phrases or measures of attitude (eg. not likely to very likely). Visual presentation formats include risk gradients, ladders, bar graphs, and survival curves (Table 1.1 pg. 5), and interview and questionnaire-based studies have shown that they tend to be the most effective in conveying risk
information\textsuperscript{23-25}. This is facilitated by the versatility of graphics to present different kinds of information on a single diagram, the wider interpretability of visual information among patients with different levels of literacy and numeracy, and the increased accessibility of graphics design methods\textsuperscript{26,27}.

Despite research that promotes the use of visual information, and recommendations by medical associations encouraging visual and numerical formats for risk communication, physicians’ communication strategies vary significantly. One study audio-recorded 70 cardiovascular risk consultations and found that, 75\% of the time, general practitioners communicated only with verbal qualifiers; male physicians used mostly verbal, and occasionally numerical techniques to communicate risk, while female physicians exclusively used verbal means to communicate risk \textsuperscript{28}. Other studies have supported these findings. Gramling et al., surveyed 300 FPs and found that although 76\% of FPs agreed with the statement that communicating risk numerically was important, 65\% felt more confident communicating qualitatively rather than numerically\textsuperscript{29}. With regards to communication strategies used during consultations, Kalet et al., audio-recorded 106 consultations with community-based FPs and found that 40\% of patient-physician discussions of risk were entirely qualitative \textsuperscript{30}.

These findings reveal a gap in current practices of communicating risk by physicians and the implementation of study results on risk presentation formats. Survey and focus group studies identified confidence and time to be significant barriers that prevent physicians from identifying and explaining numerical risk to patients, especially because this requires experience interpreting research findings and medical statistics\textsuperscript{31,32}. However, communicating quantitative risk data numerically or visually has the benefit of personalizing risk information through use of statistical
models. A systematic review concluded that individualized risk information has been associated with increased participation in screening programs\textsuperscript{26}.

### Table 1.1 Visual presentation formats

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<td>Icon Diagram</td>
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<td>Visual Rx- computer modeled frequency format diagram</td>
<td><img src="image" alt="Visual Rx" /></td>
<td>Edwards et al., 2002</td>
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### 1.4 Health risk assessment tools

The Framingham Heart Study is a longitudinal cohort study that established the association between lifestyle choices, such as exercise and diet, to cardiovascular disease\textsuperscript{33,34}. Since then, numerous studies have evaluated the association between risk factors and the development of
chronic conditions. With evidence-based medicine at the forefront of clinical practice standards, the science of risk communication in medical decision-making has evolved to become more empirically driven\textsuperscript{35,36}. Longitudinal studies of cancer, diabetes, cardiovascular disease, and respiratory conditions have continued to yield additional evidence about risk factors for chronic disease risks. The disease incidence and risk factor data gathered from longitudinal studies is fitted with a model which can be used to project the risk of disease development for an individual based on their risk factors. Health risk assessment tools are instruments that compute risk using a risk model algorithm, and the resulting risk value is conveyed in numerical, verbal or visual formats\textsuperscript{37}. Numerous statistical models have been developed to calculate risk of disease development or progression with input of modifiable (eg. diet, obesity) and/or non-modifiable (eg. gender, age, familial history) risk factors. Compared to conventional clinical estimations of risk, this individualized information can be understood in a personal context, thereby placing more value on relevant risk factors and their management\textsuperscript{26}.

The rate of development of health risk assessment tools has been increasing because of the flexibility afforded by computers in calculating and conveying risk information, and also because the number of studies to support associations between exposure and disease incidence is also growing\textsuperscript{27}. A risk model, thus, forms the foundation for health risk assessment tools. Health risk assessment tools come in both paper-based and computer-based formats; the latter of which is the primary interest in this study. Physicians, patients or allied health professionals enter risk information onto a computer or web-based interface, which computes an individualized risk score and displays it in the form of a numerical risk profile. Developing computer-based tools has smoothed the uptake of health risk assessment tools because complex hand calculations for paper-based tools are now automated. However, developing an interface on the computer to facilitate the use of this information is likely beyond the scope of those creating the models.
Furthermore, there are few instruments that have been specifically developed for use by FPs, and their feasibility, utility and effectiveness have not been extensively studied or validated.\textsuperscript{38} Computerization of clinical care has evolved in other directions as well including with electronic medical records (EMRs) and computerized clinical decision support systems (CCDSSs) which overlap to some extent with computer-based health risk assessment tools. EMRs are limited to gathering and storing patient-related information, computer-based risk assessment tools focus on computing individual risk for specific diseases and CCDSSs provide recommendations based on this specific risk and are designed to improve decision-making.\textsuperscript{39}

Integration of risk assessment tools with CCDSSs and EMRs is the ultimate goal of a computerized clinical risk tool however several impediments to the process of EMR adoption have been identified. One qualitative study conducted focus groups with physicians to identify barriers to EMR use.\textsuperscript{40} Barriers were classified into financial, data exchange, interpersonal, and technical. Financial barriers highlighted start-up, maintenance and training costs. Lack of uniform industry standards and interoperability (ability of different systems to exchange information) comprised data exchange barriers. Interpersonal barriers included impact of computer use on the doctor-patient relationship, and privacy or security concerns. Technical barriers included lack of computer skills, lack of technical support and availability of computers. Many of these barriers to EMR uptake may be shared with the uptake of computer-based risk assessment tools.

Health risk assessment tools present a unique opportunity to translate longitudinal research study findings into personalized health information. As a decision support tool, risk assessment tools have the potential to enable patients to make healthier lifestyle choices. However, until tools can
communicate risk information meaningfully, and are integrated seamlessly with computer-based infrastructure, the input can only be as effective as the output.

### 1.5 Risk assessment in family practice

In Canada, family practices provide point-of-entry into the healthcare system and facilitate the continued care for each individual. The practice of performing annual health assessments helps the FP identify an individual’s risk for specific diseases and counsel them accordingly. As such, FPs coordinate decision-making in disease prevention. Furthermore, research is showing that the established relationship between FP and patient means that FPs can be effective facilitators of chronic disease prevention and care.

However, sometimes physicians may be unaware of the value of communicating risk to patients in an understandable manner or may misjudge patients’ desires to be involved in decision-making. Some of the issues contributing to these attitudes may include the fact that though FPs are aware that risk reduction is crucial to chronic disease prevention, keeping abreast of current information is a challenge. Typically, FPs seek information online. However, if not affiliated with an academic center, access to online library resources can be difficult. This could be a possible contributing factor to the variation in how physicians communicate risk; the more accurate and current the information they know, the more accurate the information they can convey. Several health risk assessment tools used in various contexts serve to improve the accuracy of information provided to patients because they convey an evidence-based and precise risk value or range. It is important to note that physicians’ skills and attitudes toward the use of computer-based tools are widely varied, however.
Health risk assessment tools have the potential to facilitate risk communication between physicians and patients. Personalized risk values may have a greater impact on motivation to make healthier lifestyle choices. In one study examining this interaction, Ahmad et al., developed a computer-based health risk assessment tool for counselling patients at risk of intimate partner violence for use with FPs, and employed an RCT design comparing patient attitudes of those who used the tool to those who received usual care. Patients’ attitudes towards the tool were overwhelmingly positive. A follow-up study of FPs’ opinions of this tool revealed that they felt that the tool improved patient disclosure, increased the efficiency of the appointment, and guided discussion on the influence of partner violence on patient health.

Health risk assessment tools have been in existence for nearly 40 years, though it is unclear what barriers exist to tool adoption by FPs, as research in the area has been sparse. Studies on physicians’ non-adherence to other best practices offer additional insights on this subject. In a systematic review of literature, Cabana et al., reviewed 76 original studies published between 1966 and 1998, and identified 293 barriers to physician adherence to clinical practice guidelines. These included lack of awareness, lack of familiarity, lack of agreement over recommendations, lack of apparent credibility of guidelines and inconsistency with previous practices. Other importance factors identified include convenience and clarity of the guidelines.

Many medical associations have begun to include computer-based health risk assessments as tools for practice in published clinical practice guidelines. For example, Cancer Care Ontario has mandated as Strategic Priority 1 and Strategic Priority 6 in the Ontario Cancer Plan 2011-2015 that primary care providers be given tools to work with individuals to reduce their cancer risks. Another example is the FRAX tool, which is a bone fracture risk calculator used frequently by rheumatologists and orthopaedic specialists. It has been recommended by the American College
of Preventive Medicine. Risk assessment for breast cancer using the Gail model is recommended by the National Society of Genetic Counsellors (see Appendix 1.3 Table 1 pg. 103)\textsuperscript{53}.

In summary, utilization of computer-based health risk assessment tools in primary care has been sporadic. Lack of awareness, inadequate training, time constraints and lack of financial incentives have been identified as potential barriers to uniform implementation of health risk assessment tools in preventive counselling in primary care settings. This study hopes to illuminate some of the opinions of FPs to increase adoption of health risk assessment tools in clinical practice.

1.6 Summary

This review of the literature indicates that chronic diseases form an important healthcare concern and that there is ample scope for risk assessment tools to be used in this regard. The focus of chronic disease management now encompasses the treatment of disease, as well as risk reduction and primary prevention\textsuperscript{1}. Health risk assessment tools help in assessing risk of developing disease and could potentially aid in the communication of risk in a meaningful way to the patient, so that preventive strategies can be implemented for risk reduction. FPs could benefit from such tools that help them convey precise risk information.

The concept and use of computer-based health risk assessment tools is relatively new and very little literature is available about the use of these tools by FPs. Further research is needed to identify pragmatic ways of using these tools and the barriers encountered in incorporating these tools in computerized clinical practices. The present study focused on investigating the opinions of FPs with regards to awareness, usefulness, usability and feasibility of implementation of computer-based health risk assessment tools.
CHAPTER 2
STUDY QUESTION AND OBJECTIVES

2.1 Study question

In appraising and communicating a patient’s risk of developing a chronic disease, such as cancer, cardiovascular disease or diabetes, what are FPs’ attitudes toward computer-based health risk assessment tools, how do they make use of them to help patients better understand risk, and in what ways could risk assessment tools be improved to aid this process?

2.2 Research objectives

Our overarching goal is to develop a composite health risk assessment tool for multiple chronic diseases (cancer, diabetes, cardiovascular disease) integrating the cumulative action of modifiable risk factors and comorbidities for use by FPs with patients. To our knowledge, no such tool has been developed. In order to develop such a tool, our immediate aim in this study was to explore FPs’ awareness and perspectives on the usefulness, usability and the feasibility of implementation of health risk assessment tools for chronic diseases (see Section 1.5 and 1.6 for review of literature). This will lay the ground work for further investigation of patients’ perspectives and future usability testing using a prototype tool with FPs and patients. According to health behaviour change theory (see Section 3.3 pg. 17), an understanding of risk may enhance one’s willingness to modify behaviours to reduce risk\textsuperscript{13,54,55}. Therefore, health risk assessment tools support interventions aimed at behaviour change, many of which are mediated by FPs in Canada\textsuperscript{56,57}. To this end, the views of FPs on using health risk assessment tools were explored.
**Primary Objectives**

1. To identify and critically review evidence-based, pre-screening risk assessment tools available for chronic diseases (cancer, diabetes, and cardiovascular disease) which are usable by FPs;

2. To determine FPs’ awareness, and perspectives on the usefulness and feasibility of implementation of computer-based health risk assessment tools for the prevention of chronic diseases;

   a. **Awareness** - knowledge of, or regarding the purposes, availability and variety of computer-based health risk assessment tools (Oxford English Dictionary definition in context). Awareness was assessed in focus group discussions with questions prompting participants to discuss their awareness of and familiarity with health risk assessment tools.

   b. **Usefulness** - opinions regarding the helpfulness and utility of computer-based health risk assessment tools to frame chronic disease risk information and guide health-related lifestyle decision-making. Participant discussions regarding experience and utility of health risk assessment tools constitute evidence of usefulness.

   c. **Feasibility of Implementation** - opinions regarding the practicality of implementing a computer-based health risk assessment tool in primary care practice, specifically regarding its role in expediting or impeding appointment flow and time, and about readiness of clinical practices to adopt computer-based risk assessment tools.

3. To determine the opinions of FPs regarding the usability of a currently-available health risk assessment tool for chronic disease prevention;
a. **Usability**- opinions regarding the textual and graphical interface, accessibility, ease-of-use, organization of subject matter, and functionality for the target population. Usability data was collected using the ‘think aloud’ technique in which participants describe out loud their thoughts and reasons for their actions while using the instrument. Data was analyzed qualitatively, with quotes as evidence for opinions.

4. To synthesize these constructs into a framework of FPs’ awareness, and perspectives on the usefulness, usability and feasibility of implementation of health risk assessment tools for chronic diseases.
CHAPTER 3
METHODS

3.1 Overview of methods

This study investigated the opinions of FPs on health risk assessment tools. The first objective of this study was to review of health risk assessment tools for cancer, cardiovascular disease, and diabetes (see Section 3.2 pg. 15 for search methods and Section 4.1 pg. 30 for results). The second, third and fourth objectives involved the ascertainment of FPs opinions’ on risk assessment tools. Grounded theory methodology, as described by Strauss and Corbin\textsuperscript{60,61}, was used to study these objectives. To investigate their awareness and views on the usefulness and feasibility of implementation of a health risk assessment tool for chronic diseases, five focus groups (semi-structured group interviews) were conducted with FPs. Digital recordings and transcripts of the discussions were made and analyzed using the constant comparative method of analysis from grounded theory methodology (see Section 3.9 pg. 25)\textsuperscript{60}. Tool usability was studied using usability testing techniques (i.e. accessibility, ease-of-use and user experience) of a health risk assessment tool currently in use, conducted with individual FPs\textsuperscript{59}. Participants were prompted to think aloud while a series of tasks was completed (see Section 3.7 pg. 24 for description of the ‘think aloud’ technique)\textsuperscript{58}. Usability testing transcripts of digital recordings and field notes from observers were analyzed in a separate, but similar fashion to that of focus group data. All participants were asked to complete a demographic and opinion survey (see Section 3.8 pg. 25) at the conclusion of the focus group or usability testing session. Data was analyzed inductively and coded independently by two coders (the main study investigator and a research associate). As categories emerged from the data, findings were used to develop a framework of themes contributing to FPs’ awareness and opinions on the usefulness, usability and feasibility of implementation of health risk assessment tools.
Table 3.1 Data collection methods for each objective

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<td>Usability Testing</td>
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3.2 Methods for the review of health risk assessment tools

As per the first objective, a review was conducted of health risk assessment tools for cancer, cardiovascular disease and diabetes, for average-risk individuals, which could be used by FPs at point-of-care. As disease prevention strategies are mediated by FPs\(^6\), and tools support these disease prevention strategies, the search was focused on tools which could be used by FPs (though not designed exclusively for FPs to use). Tools broadly identify the interface which both computes and subsequently displays an individual’s specific risk profile. More narrowly, models refer to the specific part of the tool which is algorithmically used to compute the risk.

The search strategy was devised in consultation with an academic librarian. MEDLINE, EMBASE, CINAHL, Cochrane Central Register of Controlled Trials, Web of Science and article cross-references were searched without date restrictions up to March 15, 2012. Key words used included: Risk Assessment AND (Tool OR Algorithm OR Model) AND (Neoplasms OR Diabetes OR Cardiovascular Disease) (See Appendix 1.2 pg. 102 for sample search strategy). Since many health risk assessment tools have been developed using the same underlying model, with each tool conveying the same risk values in different ways, risk calculators were identified by statistical model and classified by disease. Models were included only if they met the following criteria: 1) used in a health risk assessment tool; 2) supported by a peer-reviewed
publication; 3) were in English; and 4) had a usable interface (paper-based or computer-based) which could be used without statistical training. Models were excluded if they determined 1) prognosis of those already diagnosed with disease; 2) probability of disease-related events, including metastasis or recurrence; 3) probability of stage of disease; 4) prediction of life expectancy or mortality; and 5) probability of disease heredity. Information was collected about the risk factors included in the model, the method of conveying the risk value, the data source the model was developed from, the medium of presentation (computer-based/paper-based) and whether the model has been independently validated on a different study population. The results from the review of health risk assessment tools are presented in Section 4.1 pg. 30.

3.3 Study design methodologies and qualitative traditions

A qualitative research study design using grounded theory methodology was employed to explore FPs perceptions on using health risk assessment tools. The nature of this investigation benefits from a qualitative study design because, in ascertaining the views of FPs, opinions and themes constitute evidence to explain a social process or phenomenon. The data in this study was used to generate a framework for understanding the awareness and perceptions of FPs on the usefulness, usability and feasibility of implementation of health risk assessment tools.

In grounded theory, the rigor of data collection and analysis methods (namely, selective sampling and the constant comparative method) ensure that emerging findings and frameworks are “grounded”, or justified, in empirical, factual data. Since little research has been done specifically on physicians’ opinions of risk assessment tools (see Sections 1.4 and 1.5 for review of pertinent literature), this methodology allowed us to commence initial data collection without a priori knowledge of the phenomenon of interest to support the study methods.
The research objectives in this study were developed from the theoretical perspective of symbolic interactionism. This worldview posits that social interaction is driven by the meaning that we attribute to phenomena and that our interaction changes as a consequence of our actions. Risk communication between patients and physicians, when examined from this perspective, involves the interaction of words that physicians use to describe risk (such as “you are at a low risk of developing cardiovascular disease”) as symbols of meaning that are interpreted by the patient and form the basis for making health-related choices. The perspective from which this study is conducted makes the assumptions that through this dialogue, understanding and meaning is conveyed and that the meaning relayed is perceived by the patient to have consequences on his/her health. Health risk assessment tools support lifestyle changes that reduce risks to health. Disclosure of these assumptions strengthens the credibility of the study.

The communication of risk mediated through physicians and risk assessment tools are founded on the paradigm that when a health risk, such as an increased risk of colorectal cancer, is effectively communicated with and understood by a patient, he or she might engage in protective behaviour, such as undergoing regular screening. This paradigm is known as health behaviour change theory and has been implemented in numerous theory-based interventions with positive results. The underlying social process of health risk assessment tools, that risk communication can influence lifestyle modification, is reflected in this theory. Studies of risk perception on behaviour change have shown that perceived susceptibility is associated with intent to change, although it remains unclear whether an increased perceived risk is associated with behaviour change. Therefore, it is important that the risk presentation strategies that physicians use while conveying risk to patients are evaluated and applied to the development of a chronic disease health risk assessment tool.
3.4 Setting and participants

FPs were recruited for this study from the Departments of Family Medicine at the Universities of Toronto and Alberta. The University of Toronto Department of Family and Community Medicine (DFCM) is the largest faculty of family medicine in North America with approximately 250 FPs appointed as full-time faculty and an additional 900 FPs with part-time faculty affiliation. Faculty are located in academic centers, affiliated hospitals and community clinics from across the Greater Toronto Area (GTA), serving a diverse population of 5.6 million people. The University of Alberta, Department of Family Medicine, located in Edmonton, has both academic and community family practice units that serve urban and rural populations. Participants were chosen to include a blend of academic and community FPs serving urban and rural populations.

3.5 Sampling and recruitment

The sampling methods that were used in this study were in accordance with grounded theory data collection methods. In grounded theory, initial participant recruitment follows selective sampling strategies, including snowball chain sampling, in which recruitment follows from referrals of information-rich participants from other participants and community leaders.\textsuperscript{60,75} Through the recommendations of researchers and family medicine practice unit chiefs, we contacted potential participants across different sites in both Toronto and Edmonton.

Selective sampling drove initial sampling. However, as concepts and their interrelatedness emerged from the data of initial focus groups and usability tests, sampling practices shifted to theoretical sampling methods, directing recruitment to that of participants who could yield richer, more concept-relevant data.\textsuperscript{60,64,75}
FPs were sampled from four subgroups: Toronto-based academic centers, Edmonton-based academic centers, Toronto-based community clinics, and Edmonton-based community clinics (see Table 3.2 below). Potential contacts at each practice site were sent a letter, via e-mail, inviting them to participate (see Appendix 3.1 pg. 123 for letter of invitation) and participants were recruited from each respective site through e-mail notifications. Practice locations may be an influential factor of FP awareness and experience with health risk assessment tools. This may be due to the distinction in access to technology in community-based clinics versus academic centers. FPs from academic and community-based centers were actively recruited to take part in separate focus groups and individual usability studies because it is believed that these differing perspectives added to the breadth of the data. Additionally, FPs with expertise in eHealth were recruited once the computerized aspects of risk assessment tools emerged as a theme requiring further insight. The opinions of key informants were solicited because of their unique insights into the themes under study, particularly the feasibility of risk assessment tool implementation in family practices.

Derived from previous studies using similar methodology, a proposed target sample of size of five to eight physicians for each focus group and between five to eight individuals for usability testing were recruited to participate in the study. One focus group for each subgroup was conducted (for a total of four) and one focus group with key informants was conducted. The number of focus groups was determined as per the practices of theoretical sampling methods whereby the number of focus groups conducted is based on sampling populations which could contribute to the breadth of hypothesized themes; initially, four focus groups had been planned, but the gaps in themes about the computer-based aspects of risk assessment tools led to holding a focus groups with key informants whose expertise was in eHealth. Once it was felt that no new
themes were emerging from discussions, themes were said to be “saturated” (see Section 3.6 pg. 22) and no new focus groups were conducted79.

Table 3.2 Sampling subgroups

<table>
<thead>
<tr>
<th>Location</th>
<th>Practice Type</th>
<th>Community-based</th>
<th>Location</th>
<th>Practice Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toronto, ON</td>
<td>Focus Group (5 to 8 participants)</td>
<td>Focus Group (5 to 8 participants)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Usability Testing (1 to 2 participants)</td>
<td>Usability Testing (1 to 2 participants)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edmonton, AB</td>
<td>Focus Group (5 to 8 participants)</td>
<td>Focus Group (5 to 8 participants)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Usability Testing (1 to 2 participants)</td>
<td>Usability Testing (1 to 2 participants)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.6 Focus group methods

The second study objective outlined in Chapter 2 was to determine FPs’ awareness and perspectives on the usefulness of, and feasibility of implementing computer-based health risk assessment tools into clinical practice to support chronic disease prevention. To address this objective, focus groups were conducted with FPs. Participants who participated in focus groups did not participate in usability testing.

3.6.1 Study manoeuvre

Focus groups were conducted to collect information regarding FPs’ awareness, perceived usefulness and feasibility of implementation of health risk assessment tools. Qualitative manoeuvres, such as focus groups, are an effective method to collect information about participant beliefs and attitudes toward an issue or service, and needs of a population. They gather opinions and explanations that cannot be obtained from surveys or questionnaires80. The information gathered from focus groups can be helpful in developing a hypothesis for further inquiry. Focus groups are best when the discussion content is based on open-ended questions because “people’s knowledge and attitudes are not entirely encapsulated in reasoned responses to
direct questions”\textsuperscript{78}. Furthermore, group discussions may stimulate conversations from shared experiences with other members.

Four separate focus groups were conducted, each composed of a group of physicians from one of four subgroups (see Section 3.5 Table 3.2 pg. 20). In addition, a fifth focus group composed of three experts in the area of eHealth and health technology implementation (key informants) was conducted. It was necessary to hold focus groups with participants from each subgroup, separately, to maintain group homogeneity with regards to location and practice type (academic/community-based). Studies on the dynamics of focus groups have identified that a homogenous sample of individuals allows for more equal participation from each participant\textsuperscript{80}. Focus groups took place at a location convenient for the participants.

Participants took part in a discussion mediated by the study investigator (this author). A semi-structured group interview guide was used to prompt and direct the group discussion around the topic of interest (see Appendix 3.4 pg. 128 for focus group interview guide). Informed consent was obtained from participants prior to the discussion (see Appendix 3.9 pg. 138). At the conclusion of the focus group, participants were asked to complete a demographic and opinion survey (see Appendix 3.3 pg. 125).

3.6.2 Data collection

Since no previously published literature has looked at the opinions of FPs regarding the awareness, usefulness, feasibility, and usability of health risk assessment tools, the interview guide was developed with open-ended probing questions reflecting the study-specific objectives.

Specifically, interview subject matter discussed whether physicians engage in health risk assessment and how the dialogue typically proceeds, whether FPs were aware of health risk
assessment tools and if so, how physicians employed health risk assessment tools when engaging in risk communication with patients. This included probing for previous experiences, current knowledge of tools, likeliness to use tools, and the value they see in using a health risk assessment tool that integrates multiple chronic disease risks. Questions also asked participants for their opinions on the feasibility of implementing such a tool into regular clinical practice. Another area of inquiry was whether risk assessment tools help save time or whether it would hinder the “flow” of a typical appointment with a patient.

A pilot focus group was conducted among the study investigators to assess the process and content issues and to confirm consistency with study objectives. Based on this, the interview guide was revised. Pilot testing also allowed for face validity of the study questions to be confirmed.

The study investigator mediated focus group discussions according to the semi-structured group interview guide. Focus group discussions were digitally recorded and transcribed verbatim. Field notes were taken during and after each interview to aid accurate documentation of discussion. Another researcher (research associate) from the investigating team took field notes during the focus group. The study investigator and research associate conferred with each other on an ongoing basis, to maintain uniformity in approach. The focus groups lasted approximately one hour. Data was collected until categorical saturation was achieved, as indicated by data replication or redundancy within categories. This was determined by, and agreed upon by the study investigator and research associate when redundancy was observed as data was compared with the coding guide.
3.7 Usability testing methods

The third objective, outlined in Chapter 2, was to determine FPs’ opinions on the usability of a health risk assessment tool. This was done by conducting usability tests with a well-known health risk assessment tool and asking participants to ‘think aloud’ while they were prompted to complete tasks. Participants who participated in usability testing were excluded from participating in focus groups.

3.7.1 Study manoeuvre

Usability testing was conducted with individual FPs to gather information about the usability (i.e. accessibility, organization and functionality) of a commonly-used chronic disease health risk assessment tool. An EMR program, called OSCAR, was installed on a laptop computer, which the study investigator used to administer the usability test. The OSCAR EMR system was selected because it is open-source software available freely for download. It is modifiable and available for offline use, allowing for the simulation of clinical scenarios without purchase a commercially-available EMR system. OSCAR contained a mock patient record for a fictitious patient. The participant was asked to retrieve the patient’s information from the EMR record and calculate the patient’s risk of coronary heart disease using an embedded risk assessment tool. The tool that was used in this study is the Framingham Coronary Heart Disease and Stroke Risk Assessment Tool (see Appendix 3.7 pg. 135 for screen shot). This risk calculator is a tool designed to calculate an individual’s risk of developing coronary heart disease over ten years for individuals over the age of 30 based on an algorithm from the Framingham Heart Study (FHS) model of cardiovascular disease risk. The FHS model has been validated and is regularly updated to reflect epidemiologic data from different study populations. This tool requests information about age, gender, total cholesterol, HDL cholesterol, smoking status, systolic blood
pressure and status of medication for high blood pressure. This risk assessment tool was selected because it is well-known and has been validated in many different populations. It is also recommended in clinical practice guidelines\(^{83}\).

Usability tests were performed with each participant in a closed office at a computer. First, the study investigator prompted the participant to complete a set of tasks simulating a patient encounter (see Appendix 3.6 pg. 132 for usability testing interview guide). Following the usability test, participants were asked to complete the demographic and opinion survey (see Section 3.8 pg. 25 and Appendix 3.3 pg. 125).

3.7.2 Data collection

Usability testing is frequently used in commercial industries to assess consumer opinions of a product. We conducted usability tests with a currently-used tool (Framingham Ten-Year Coronary Heart Disease and Stroke Risk Calculator) in order to gather information about usability from the perspective of end-users, (i.e. FPs).

The study investigator directed the participant to complete a series of tasks according to the structured interview guide. A hypothetical case scenario was presented, prompting the participant to use the EMR and risk calculator to calculate and communicate the patient’s risk as displayed on the screen. The participant was asked to ‘think aloud’ as each task was performed, describing their experience using the EMR and risk assessment tool while completing the tasks. The think aloud technique is used to collect qualitative verbal data about reasoning as users verbalized their thoughts during completion of a pre-specified task and is well-suited for identifying usability barriers\(^{84}\). A pilot usability test was done with the study investigator and research associates to assess process and content issues and to confirm consistency with study objectives. The interview guide was revised as needed\(^{81}\).
Informed consent was obtained, including consent to use anonymized participant quotations, prior to commencement of the usability test. Usability testing sessions were audio recorded and transcribed verbatim. Each usability test lasted half an hour.

### 3.8 Demographic and opinion survey

At the conclusion of the focus groups and usability tests, participants were asked to complete a three-page demographic and opinion survey (see Appendix 3.3 pg. 125). The survey collected information about participant age, sex, year since graduation from medical school, practice type (academic or community-based) and location, and included questions about awareness of risk assessment tools and perceived usefulness of tools, as rated on a 5-point Likert scale with 1 being least agreeable and 5 being most agreeable. The questions were devised by the study investigator and checked for face validity by a survey methods expert who was not associated with study. Survey data was not coded and analyzed for themes as was done with data from focus groups and usability testing. This data was reported to establish and verify the opinions of individual participants based on consistent, closed-ended questions, as opposed to the open-ended questions of focus groups and usability testing.

### 3.9 Data analysis

Focus group and usability testing data were analyzed separately to maintain the distinction of the respective objectives associated with each data collection procedure. Additionally, the focus group with key informants was analyzed separately from other focus group data to minimize the influence of the themes that have arisen during analysis of the other focus groups. Analysis proceeded inductively, beginning with the first focus group, using grounded theory methodology and acknowledging the objectivist assumptions that the data collected in this study is the
perspective of the participant and not an interpretation of the researcher. The constant comparative approach, of capturing and analyzing data simultaneously, was employed to compare newly collected data to developing themes and categories.

Following the methods outlined by Corbin and Strauss (1990) on grounded theory, transcripts were coded and analyzed in three stages: open coding, axial coding and selective coding. The initial, open coding stage, entails breaking down data analytically and comparing similarities and differences. Grouping of tags into categories, and the collapsing of meaningful categories into concepts is done in this stage. The conceptualization of text evolves from the “fracturing” of data into themes. Following the open coding phase, axial coding involves the abstraction of significant categories, processes or phenomena. Links between related concepts are observed as causal, consequential or contextual. As a final step, selective coding leads to the development of a framework summarizing the connectedness of themes through the unification of a core theme (See Figure 3.1 pg. 27). Open coding was conducted independently, but in parallel, by the study investigator and a research associate and compared. Transcripts were studied and passages were labelled with descriptive tags. A coding guide evolved as knowledge in the area developed (See Appendix 3.8 pg. 136 for the coding guide). During axial coding, a 20% sample of the data was coded independently by the research associate and compared with the coding done by the study investigator. Selective coding was conducted with both coders discussing themes and developing the framework.

The objectives of this study guided the coding and analysis. Specifically, the awareness, usefulness, usability and feasibility of implementation of health risk assessment tools were examined. Data collection was conducted in an open-ended manner because, as prescribed by grounded theory methodology, concepts are grounded in the reality of the data. This gives the
methodology theory-observation compatibility\textsuperscript{60}. Throughout the analysis process, the study investigators regularly wrote memos to document personal views (and biases), analysis and insight from the transcripts. Qualitative data analysis software, NVivo 9 (QSR International), was used to store, organize and facilitate the coding of data.

**Figure 3.1 Data analysis methods**

![Diagram of data analysis methods]

**3.10 Minimization of bias**

To maintain the rigor of methods used and fidelity of results, numerous measures to reduce bias were employed. The qualitative methodology of grounded theory that is outlined by Corbin and Strauss is a well-utilized method of capturing and analyzing qualitative data\textsuperscript{86}. The methodology outlined was closely adhered to, thereby ensuring consistency of approach.

Methodological triangulation is the process of cross-verifying data from different sources and data collection methods. Triangulation of focus groups, key informant discussions and usability testing data was done to corroborate concepts and themes with data from other sources as they emerged. Triangulation minimizes bias associated with using a single data collection technique.
The study setting and participants were recruited from multiple study sites (Toronto and Edmonton) to minimize biases based on practice-type or location.

The study investigators regularly conferred to ensure consistency in note-taking procedures. As described in Section 3.9 pg. 25, the sampling and analysis methods of grounded theory require that data is regularly checked for consistency and compared between multiple analyzers (here, consisting of the study investigator and research associate). Disagreement was resolved by discussion and justification thereby minimizing coding bias.

### 3.11 Ethics

This study adhered to the ethical standards set out by participating institutions at the University of Toronto and the University of Alberta. Written informed consent was obtained from participants prior to focus groups and usability testing (see Appendix 3.9 pg. 138). This included consent to use anonymized verbatim quotes in publications or reports that come from this study.

Physician identities and their practice locations, focus group recordings, usability testing recordings, transcripts and field notes were assigned alphanumeric codes to de-personalize collected information. Prior to focus group discussions, participants were asked to sign an informed consent form. During discussions, participants were asked to refer to themselves by their first names so as to anonymize their identities on digital audio recordings. All forms and paper transcripts were stored in a locked cabinet when not in use in the Department of Family and Community Medicine at the University of Toronto. Digital recordings were uploaded and stored on a password-protected computer which was accessible only to the study investigator. Transcription services were used to transcribe digital recording data into typed transcripts. Once transcripts were verified for their accuracy, digital recordings were destroyed. Data will be stored
for five years and destroyed thereafter. To compensate for participation in focus groups, participating practice units were given a $200 honorarium. Usability testing participants were compensated with a $100 honorarium. Ethical approval to conduct the study was obtained from the research ethics boards of the University of Toronto and University of Alberta and is presented in Appendix 3.9 pg. 138.

3.12 Summary

In summary, the grounded theory methodology described by Corbin and Strauss was used to guide this qualitative study. FPs from Toronto, Ontario and Edmonton, Alberta, academic and community-based family practice units were recruited to participate in this study. Five focus groups were conducted exploring the perspectives of FPs’ awareness, perceived usefulness and feasibility of chronic disease health risk assessment tools. Usability studies were conducted with individual FPs to explore the accessibility, organization and functionality of a currently-used computer-based health risk assessment tool (the Framingham Coronary Heart Disease and Stroke Tool). Data analysis followed the prescribed procedures for grounded theory. Results are presented in Chapter 4.
CHAPTER 4
RESULTS

Results include a description of characteristics of study participants, followed by themes identified from focus groups, opinions of key informants, and physicians’ feedback based on use of a risk assessment tool during usability testing sessions. The quotes presented here were drawn from a range of participants at all study locations.

4.1 Results of health risk assessment tool review

A systematic review of health risk assessment tools for cancer, cardiovascular disease and diabetes was conducted. Details of the search methods are presented in Section 3.2 pg. 15. A summary of the identified tools is presented in Table 4.1.

Table 4.1 Number of tools identified, classified by disease

<table>
<thead>
<tr>
<th>Disease</th>
<th>Number of tools identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td>4</td>
</tr>
<tr>
<td>Cervix</td>
<td>1</td>
</tr>
<tr>
<td>Colorectal</td>
<td>7</td>
</tr>
<tr>
<td>Gastro-esophageal</td>
<td>1</td>
</tr>
<tr>
<td>Lung</td>
<td>3</td>
</tr>
<tr>
<td>Melanoma</td>
<td>3</td>
</tr>
<tr>
<td>Ovarian</td>
<td>2</td>
</tr>
<tr>
<td>Prostate</td>
<td>10</td>
</tr>
<tr>
<td>Pancreatic</td>
<td>2</td>
</tr>
<tr>
<td>Diabetes</td>
<td>16</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>9</td>
</tr>
<tr>
<td>Multiple diseases</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>60</strong></td>
</tr>
</tbody>
</table>
The search of all five databases returned 9343 hits (see Appendix 1.1 pg. 101 for QUOROM diagram). A total of 60 models were identified of which health risk assessment tools for diabetes are the most common (see Appendix 1.3 pg. 103 for tables summarizing the identified tools). Tools for cardiovascular disease, and breast, colorectal and prostate cancers are also well-represented. The type and extent of risk factors included and the target population of each model varies greatly as a result of the varying data available from the research studies from which the model was designed. A number of tools are available on computers, accessible to the public, though a number of them are specifically designed for use by physicians. Of the 60 identified tools, 20 health risk assessment tools are paper-based, 32 are web-based and 8 are stand-alone software programs (computer-based). The health risk assessment tools that were identified most often presented risk in the form of percent risk. Organization or government-sponsored tools were more likely to present risk in different forms including both numerical values and as graphical diagrams. The Framingham risk assessment model for cardiovascular disease prediction is among the oldest and most often cited risk prediction model amongst health risk assessment tools. It has been verified in a number of populations and been endorsed in clinical practice guidelines\textsuperscript{34,87}.

A number of models that were excluded from this search were those that were based on genetic screening tests or results from tests for high-risk individuals because such tools are typically tailored for use by specialists making decisions on treatment options for high-risk or confirmed cases.

4.2 Characteristics of participants

Five focus groups, including one with key informants, were conducted with 25 practicing FPs and usability tests were conducted with 5 FPs who did not participate in focus groups (see Table
Two focus groups were conducted in Toronto, Ontario and three focus groups were conducted in Edmonton, Alberta. In each location, one focus group with physicians from an academic practice and one focus group with physicians from a community-based practice was conducted (See Section 3.5 pg. 18 for definitions of academic and community-based practices). A third focus group in Edmonton consisted of FPs that were considered key informants or experts on EMR development and implementation. Usability testing was conducted with an additional five practicing FPs. Two participants were from Edmonton and three participants were from Toronto. Results from usability testing are presented in Section 4.5 pg. 58.

The demographic and professional background of the participants is summarized in Table 4.1. All clinical practices utilized an EMR system. Forty-four percent of participants were under the age of 35 and 26% percent were over the age of 55. Twenty percent of participants had graduated from medical school within the past five years. Thirty-three percent of participants had been practicing for more than 25 years. Nearly all participants had support from allied health professionals (97%) including nurse practitioners, physician assistants, and dieticians.
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>7 (23)</td>
</tr>
<tr>
<td>Women</td>
<td>23 (77)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>25-35</td>
<td>13 (44)</td>
</tr>
<tr>
<td>36-45</td>
<td>6 (20)</td>
</tr>
<tr>
<td>46-55</td>
<td>3 (10)</td>
</tr>
<tr>
<td>56-65</td>
<td>7 (23)</td>
</tr>
<tr>
<td>&gt;65</td>
<td>1 (3)</td>
</tr>
<tr>
<td><strong>Years since medical school graduation</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;5</td>
<td>6 (20)</td>
</tr>
<tr>
<td>5-15</td>
<td>12 (40)</td>
</tr>
<tr>
<td>16-25</td>
<td>2 (7)</td>
</tr>
<tr>
<td>&gt;25</td>
<td>10 (33)</td>
</tr>
<tr>
<td><strong>Practice location</strong></td>
<td></td>
</tr>
<tr>
<td>Edmonton, Alberta</td>
<td>13 (43)</td>
</tr>
<tr>
<td>Toronto, Ontario</td>
<td>17 (57)</td>
</tr>
<tr>
<td><strong>Patient roster size</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;500</td>
<td>5 (17)</td>
</tr>
<tr>
<td>500-1500</td>
<td>23 (76)</td>
</tr>
<tr>
<td>1501-2500</td>
<td>2 (7)</td>
</tr>
<tr>
<td><strong>Support from Allied Health Professionals</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>29 (97)</td>
</tr>
<tr>
<td>No</td>
<td>1 (3)</td>
</tr>
</tbody>
</table>
4.3 Physicians’ opinions on computer-based risk assessment tools: an overview

All participants were asked to complete a demographic and opinion survey at the completion of the focus group or usability test. Responses are presented in Table 4.2.1 and Table 4.2.2.

Table 4.3.1 Physicians’ opinions of computer-based risk assessment tools* (N=30)

<table>
<thead>
<tr>
<th>Questions</th>
<th>Median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How comfortable are you using computers?</td>
<td>5.0 (4,5)</td>
</tr>
<tr>
<td>In your opinion, how useful are computer-based health risk assessment tools for patients?</td>
<td>4.0 (3,4)</td>
</tr>
<tr>
<td>In your opinion, how useful are computer-based health risk assessment tools for family physicians?</td>
<td>4.0 (4,5)</td>
</tr>
<tr>
<td>How often do you use instruments like health risk assessment tools in your practice to provide information to patients?</td>
<td>4.0 (3,5)</td>
</tr>
<tr>
<td>How likely are you to use health risk assessment tools with patients during appointments?</td>
<td>4.0 (3,4)</td>
</tr>
<tr>
<td>How likely are you to discuss risk assessment results with a patient during an appointment?</td>
<td>4.0 (4,4.75)</td>
</tr>
<tr>
<td>In your opinion, will computer-based health risk assessment tools improve patient flow?</td>
<td>3.0 (2,3.75)</td>
</tr>
<tr>
<td>Would you be more likely to use a risk assessment tool if it was embedded in your Electronic Medical Record (EMR) system than if it was available as a stand-alone program?</td>
<td>5.0 (5,5)</td>
</tr>
</tbody>
</table>

* Responses rated on a 5-point Likert scale with 5 being most agreeable
IQR = Interquartile Range
Table 4.3.2 Physicians’ awareness of computer-based risk assessment tools* (N=30)

<table>
<thead>
<tr>
<th>Question: Are you aware of any of the following computer-based health risk assessment tools?</th>
<th>Yes (N)</th>
<th>No (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gail Model/Breast Cancer Risk Assessment Tool</td>
<td>9</td>
<td>21</td>
</tr>
<tr>
<td>Framingham Heart Calculator/Cardiovascular Disease Risk Assessment Tool</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>FRAX/Fracture Risk Assessment Tool</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>Prostate Cancer Prevention Trial Risk Calculator</td>
<td>3</td>
<td>27</td>
</tr>
<tr>
<td>Liverpool Lung Project Risk Assessment Tool</td>
<td>0</td>
<td>30</td>
</tr>
<tr>
<td>Other: IBIS, CHADS2, BowelCa, CCS Hereditary Breast Cancer screening tool, WELLS criteria, CAROC, Reynolds’ Risk Score, Colorectal Cancer Risk Assessment Tool, BiliTool, EthRisk</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Respondents asked to indicate choice with a dichotomous choice (Yes/No)

4.4 Focus group themes

Focus group themes were grouped into two categories: 1) Physicians’ awareness and appraisal of risk assessment tools, and 2) Physicians outlook about the future of risk assessment in family practice settings. For each category, illustrative quotes are presented according to location and practice-type: 1) Toronto, Academic; 2) Toronto, Community; 3) Edmonton, Academic; and 4) Edmonton, Community. Table 4.4 on pg. 36 summarizes the categories, themes and subthemes.
### Table 4.4 Summary of categories, themes and subthemes from focus groups excluding those from the key informants focus group

<table>
<thead>
<tr>
<th>4.3.1 Physicians’ Awareness and Appraisal of Risk Assessment Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Physicians’ current risk assessment practices</td>
</tr>
<tr>
<td>a) Who initiates risk assessment?</td>
</tr>
<tr>
<td>b) How often is the risk assessment performed?</td>
</tr>
<tr>
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4.4.1 Physicians’ awareness and appraisal of risk assessment tools

This section is organized into the following themes: 1) Physicians current risk assessment practices; 2) Physicians current use of risk assessment tools; 3) Physicians’ perceived benefits and shortcomings of risk assessment tools; and 4) Physicians’ feedback on the attributes of an ideal risk assessment tool.

1) Physicians’ current risk assessment practices

The initial discussion focused on: A) Who initiates risk assessment, B) How often it is performed and C) How risk information is communicated to patients.

A) Who initiates risk assessment?

Generally, chronic disease risk assessment was viewed by the participants as a fundamental part of the annual physical exam. This was articulated as following:

“I would say with almost every patient there is some facet of risk management, risk assessment that we do, depending on whether it’s a teenage girl and we’re doing risk assessment as far as sexually transmitted infection; an older person, risk of falls. I don’t know, it’s every day” [Edmonton, Academic]

Sometimes discussion about risk is patient-driven,

“People will say something like, ‘My great-grandmother had breast cancer, what is my risk factor? What’s my risk of actually having breast cancer?’ and I’ll often just start with... the circumstances around them developing, how old they were, that sort of thing, and then discuss the nature of the relationship with the patient, and then review some of the patient’s risk factors...I talk generally about what would increase her risk of having breast cancer versus things that are protective for having breast cancer.” [Toronto, Academic]

B) How often is risk assessment performed?

When asked about the frequency with which risk assessments are conducted, the general consensus by participants was that risk assessment is an integral part of practice and is done, 

“daily. I mean, whenever we see patients, I would say.” [Edmonton, Academic]
C) How is risk information communicated to patients?

It was felt that conveying risk information derived from a clinical assessment is a significant component of the risk counselling process. Patients’ widely varying abilities to understand statistical information often necessitates use of different strategies for communicating risk by physicians. The complexity of risk communication was best summarized in the following comment,

“The thing I still struggle with after 35 years of practice is conveying risk to people in language that actually has some meaning. Saying to someone they’ve got a 20% chance in the next five years of such and such, most people I know and many of the physicians I know, like, Whoop-de-do.’ Like, how do you actually convey to people what is really meant by risk? The closest I think we’ve ever come - I’ve ever come - to a reasonable explanation is when we look at the use of PSA testing, if you have, like, a hundred little people, little bodies, you can talk about them when there’s false positives and then there’s the false negatives. Visually most people seem to get that. But the vast majority of risk calculations I still struggle with, particularly when people say, ‘Well, so what does that mean?’” [Edmonton, Academic]

However, a few participants felt that describing risk qualitatively was sufficient in most cases,

“I often like to use a qualitative approach, like, ‘You’re at higher risk for this and,’ you know, ‘therefore...’ but for decisions where we actually know there’s a quantifiable risk reduction that can be obtained then I might use an... then I start to use the numbers of the quantitative stuff, but mostly I’m using qualitative.” [Toronto, Academic]

Many participants had described that they use risk assessment tools, like the Framingham risk calculator to assist in communicating risk quantitatively,

“I’m pretty good at being, like... with our Framingham tool you get sort of, like, a yellow bar. It’s actually visible in graphics, so I can be like, ‘The average person’s ten-year risk is, like, two little yellow bars, and your average risk is maybe like five little yellow bars, but it’s still maybe only 9%.’” [Toronto, Academic]

Participants indicated that risk assessment is an implicit part of patient assessment in family practices. Often, patients are curious to know their risk of developing a chronic disease because of family history or known risk factors. However, there are persisting challenges in performing formal risk assessments on a routine basis and conveying the risk information to patients. FPs also seem to be grappling with the task of translating risk information into a lay person’s
language. Research on the presentation of risk information has shown that both quantitative and qualitative information is necessary for the optimal conveyance of risk, however, results here indicate that individual physicians still differ greatly in their preferred method of communicating risk.

2) Physicians’ current use of risk assessment tools

Themes focussing on currently-used risk assessment tools were grouped as the following: A) Physician awareness of risk assessment tools; B) Frequency of use of tools; and C) Mode of administration. Risk assessment tools mentioned in focus group discussions are listed in Table 4.5 on pg. 42.

A) Physician awareness of risk assessment tools

Physicians at all participating clinics were aware of several tools for assessing disease risk. All participants had heard of the Framingham Risk Calculator, and a majority (80%) of participants had heard of the FRAX tool for assessing fracture risk. The Framingham tool is available in a paper-based format, a web-based calculator, and is integrated into several brands of EMR systems. For those who do not have EMRs, the paper-based tool is still used,

“I don’t have the EMR, but I go through the Framingham list with them.” [Toronto, Community]

In the area of cancer prevention and screening, the Gail model for breast cancer risk assessment is the most cited tool in research publications. However, only nine participants had heard of the Gail model for breast cancer risk assessment,

“So I mean he’s even bringing up these Gail things, and I’m thinking, ‘Well, I’ve never even heard of this Gail. Where the hell am I in terms of...?’” [Edmonton, Academic]
The type of patient population that the FP serves contributes to their knowledge and awareness of the types of tools. One participant’s works as a general practitioner in oncology. As a result he was aware of several breast cancer risk assessment tools,

“I use the IBIS risk tool, not the Gail. Gail’s not accepted currently for that,” [Toronto, Academic]

Another participant stated that he is familiar with many tools, including some that are no longer used.

“on our Internet Explorer we’ve got all our favourites, so the CHAD score, breast cancer screening score from the uscancer.org, BiliTool is another simple tool, the ethnic risk - which is the Framingham data with a little ethnicity risk component to it - I think there’s five or six marked as favourites, so in real-time we can pick which ones we need to engage the patient with and do them at the time.” [Toronto, Community]

However, despite being aware, many practitioners do not seem to use the tools. As one participant stated,

“Yes, so anyways I’m aware of them, I use some of them.” [Edmonton, Academic]

To summarize, the Framingham tool is the archetypal risk assessment tool which all the participants were aware of. Some participants were aware of tools for cancer, but no tools used to calculate diabetes risk were mentioned. Awareness is largely based on the patient population the physician treats, and physician’s personal interest and motivation. There is also a divergence between what tools participants were aware of and tools they actually use in practice.

### B) Frequency of use of tools

Participants stated that they used risk assessment tools, such as the Framingham tool, regularly.

“I use the Framingham risk tool a lot in practice, during my routine physicals.” [Toronto, Academic]

“Sometimes I think we use so many of them so often that we don’t even realize we’re using them, so I mean you can’t get a bone density report without an attached risk assessment tool,” [Toronto, Community]
Often times, risk assessment tools were integrated into daily clinical practice for calculating risk of disease recurrence, disease prognosis and other health outcomes.
**Table 4.5 Risk assessment tools mentioned by participants in focus group discussions, organized by format/platform**

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<tr>
<th>Platform</th>
<th>Tool</th>
<th>Tool purpose</th>
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<tr>
<td>EMR-Integrated</td>
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<td>10-year risk of cardiovascular disease</td>
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<tr>
<td>Paper-based tools</td>
<td>Framingham</td>
<td>10-year risk of cardiovascular disease</td>
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<td></td>
<td>PHQ9</td>
<td>Depression scale of the Patient Health Questionnaire</td>
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<td>Smartphone-based tools</td>
<td>Strep-score on Palm-pilot</td>
<td>Probability of streptococcal pharyngitis</td>
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<td></td>
<td>FRAX tool as an app</td>
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<td>Stand-alone computer tools</td>
<td>BOADICEA</td>
<td>Probability of carrying a BRCA1/BRCA2 mutation</td>
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<td></td>
<td>BRCAPRO</td>
<td>Probability of carrying a BRCA1/BRCA2 mutation</td>
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<tr>
<td>Web-based tools</td>
<td>BiliTool</td>
<td>Risk of developing jaundice in newborns</td>
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<tr>
<td></td>
<td>Breast Cancer Risk Assessment Tool</td>
<td>10-year probability of breast cancer</td>
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<td></td>
<td>CAROC</td>
<td>10-year fracture risk</td>
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<td></td>
<td>CHADS2 score</td>
<td>Risk of stroke in patients with atrial fibrillation</td>
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<td></td>
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<td>IBIS</td>
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<td>Mclsaac score</td>
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<td></td>
<td>Reynolds risk calculator</td>
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<td></td>
<td>Wells’ criteria</td>
<td>Probability of pulmonary embolism</td>
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</table>
C) Tool user

The main user of tools, in general, was found to vary. Some tools are designed for use by physicians, some are administered by health professionals while interacting with patients, and others are designed for patients to use alone. However, the risk factors, computation and risk value are consistent regardless of the user, so participants had differing opinions of who the main user of these tools should be.

i. Physician using the tool alone

Physician reported that they perform risk assessments on their own, with the available data.

“I spend a considerable amount of time before clinics calculating Framingham risk scores and documenting that all on my chart” [Edmonton, Academic]

“I often find that when I’m getting my cholesterol results back, that’s when I’m plugging in my risk calculator, so I may not even be discussing it with the patient.” [Toronto, Academic]

ii. Patient using the tool alone

Physicians were aware of the possibility of asking patients to complete self-administered risk assessment questionnaires though there were differing opinions as to whether it was appropriate to do or not.

“Do I get a sense that it’s better for patients to use the tools on their own and maybe bring their results in? Group consensus: No.” [Toronto, Academic]

“So I think that the idea of having patients fill out surveys before their physical exams...if that’s possible, if they could do that tool before they come in once a year or when they touch base with the doctors it would be great, as the homework is done beforehand and the time in the appointment can actually be spent more on counselling.” [Toronto, Community]

iii. Physician using the tool with the patient

Physicians have tended to complete tools during routine clinical encounters with patients,

“It’s usually me using it with the patient. I don’t tell them to go on-line to look it up.” [Toronto, Community]
“So when I use the paper one... I also go back and forth, sometimes I do use, like, on-line. But because I like visually doing it with the patient and then I give them the actual assessment so that they can take it home and see where their last readings are, where their goal is for their LDL, and it’s just a nice kind of diagrammatic view to physically give the patient to educate.” [Edmonton, Academic]

Some tools use risk variables from blood work and are therefore used by the physician once those values have been obtained. However, many other factors were identified which contribute to whether a physician uses a tool with a patient or whether the physician feels that a patient should use a tool alone. These are discussed further below in subsection 4) Physicians’ feedback on the attributes of an ideal risk assessment tool, on pg. 47.

3) Physicians’ perceptions on the benefits and shortcomings of risk assessment tools

Several themes pertaining to tools that are currently available and in use in clinical practice were brought up. Physicians’ opinions and considerations on the usefulness of tools, and reasons tools are not used were also discussed.

A) Explaining the impact of lifestyle choices on disease risk

Participants felt that one of the benefits of using risk assessment tools is to explain the impact of lifestyle choices on health risks,

“I think it’s really useful when you’re discussing...overall risks and trying to recommend lifestyle changes” [Toronto, Academic]

One version of the Framingham tool allows users to visualize the impact of a specific risk factor on disease risk,

“the patient can see very clearly. ‘Wow, smoking contributes a lot to cardiovascular risk, I do actually want to think about smoking cessation.’” [Edmonton, Community]

Some participants felt that the risk assessment tools could also help in goal-setting by patients,

“they can help provide impetus for change, and then people also want to, once they do make a change, they want to repeat the tool to see if the change is evident,” [Toronto, Academic]
B) Reassuring patients

Individualized risk estimation is a way “[patients] are reassured that the risk is lower than they thought, so that can be valuable in relieving anxiety and stress” [Toronto, Academic]

C) Starting a dialogue with patients

Several participants felt that risk assessment tools foster, “the opportunity to have a dialogue about risk” [Edmonton, Academic] and, “[initiate] that discussion in terms of what their risk factors are” [Toronto, Community].

Using a risk assessment tool was felt to stimulate shared discussions with patients,

“The tool itself may not have been that accurate...but it was enough to open up [a] shared discussion.” [Edmonton, Community]

“It’s an opportunity...for communication...any bit of information that we feel is valid, that can be used to discuss with a patient is an educational moment and potentially a motivator.” [Edmonton, Academic]

D) Patient empowerment

Many participants stated that tools help patients understand risk-related health information so that they can make their own informed decisions:

“I want to engage them in the discussion and have them make an informed decision, so I talk about risk in that context quite a bit, if the patient has a choice in...of course the patient always has a choice, but if I want them to decide for themselves on certain things.” [Toronto, Academic]

“I think some of them give more objective numbers that then you can discuss with the patient...so I think it can empower them in terms of sort of putting a number to it, however accurate that number may be.” [Toronto, Community]

However, it was felt that one of the challenges of educating a patient about disease risk is conveying numerical risk information because patient numeracy varies widely.

“I work in [city name]. it’s a large variety of people like from different cultures and different education and different backgrounds, so it’s very challenging to put something complicated to them, so I just go by what they can understand, like, not something complicated with figures” [Toronto, Community]
E) Directing discussions around risk

Some participants felt that risk assessment tools can help to focus a discussion with a patient,

“I do it in real-time with the patient, and it usually stops a lot of the meandering dialogue that you’d otherwise engage in. So I find it just focuses the dialogue, and it very often helps.” [Toronto, Community]

However, this opinion was not shared by everyone,

“I guess on the other hand it might bring up a lot more other issues that they weren’t originally aware of and the discussion might actually take more time and be less directed.” [Toronto, Community]

F) Useful as a guide for physicians

Many participants considered risk assessment tools useful in supporting their own clinical decisions:

“I think it’s a nice guide for physicians a lot of the times, too” [Toronto, Academic]

“I don’t use it necessarily to 100% determine what I’m going to do, I just use it as another sort of part of my clinical assessment to decide what I want to do,” [Edmonton, Community]

G) Making decisions about further screening and interventions

Participants felt that a major reason risk assessment tools are used is because they can help patients and physicians come to a consensus around making screening and intervention decisions,

“a hereditary breast cancer screening tool is useful to say, “Well, you shouldn’t be doing the normal thing,” right? I mean, of course you can get the same thing from family history, right, but it took a little bit more weight value to say, “Listen, you’re not like all the other little bears, you’re different, your risks are higher, and we should do something different for you because your mom died at 32 of breast cancer. We should be MRI-ing your breast.”” [Edmonton, Community]

“You’re trying to make a decision, right, are we going to do a mammogram or not, or are we going to look at HMG-CoA or not, let’s look at your risks, and if you’re above average for a North American compared to the data it really almost solidifies the conversation and helps make a decision, helps the patient come to a decision.” [Toronto, Community]
The impact of making more accurate screening decisions by using risk assessment tools was also felt to have the potential of making screening more cost-effective,

“Similarly I think FRAX and stuff like that are useful because they can cut down on unnecessary screening, and so if patients are worried about osteoporosis and all the radiology forms say repeat in one year - which is totally not evidence-based - so then you can run the FRAX score with them and you can say, “Well, actually you really don’t need to have bone density done,” so we save $500 on an unnecessary test, and the patient still understands that I do take their risk of osteoporosis seriously, right?” [Edmonton, Community]

However, many participants felt that using a risk assessment tool might not have much value without an actionable intervention,

“Some people would like to know what their risk is, but does the fact that modern medicine has no specific approach to the condition, does that negate why are you screening?” [Edmonton, Academic]

4) Physicians’ feedback on the attributes of an ideal risk assessment tool

Focus group discussions highlighted aspects of tool design that make them easy to use, as well as desired features for future risk assessment tools.

A) Scope for EMR Integration

Many participants felt that the integration of risk assessment tools with EMR systems would allow them to be used more frequently. Participant experiences with EMR-embedded versions of the Framingham risk calculator served as a discussion point around issues with EMR integration. The following suggested features would improve the usefulness of risk assessment tools.

i. Tools should be able to automatically extract relevant information from the EMR

Some EMR systems have the ability to load patient data directly into embedded tools. Having this “auto-populate” function would mean that users of embedded tools would not have to manually enter each variable into a risk assessment tool.
“I find our computer one very annoying because you have to open it in a separate tab to your chart and thus you have to bounce back and forth and remember things like an HDL of 1.31...?” [Edmonton, Academic]

“It’d be nice if it did auto-populate,” [Toronto, Academic]

ii. Tools should have a mechanism for dealing with missing information

Most tools do not function unless all variable fields have been filled. Participants expressed a desire for tools to function without all the information.

“And so a tool in an EMR that is populated from information from the EMR that still works if information is missing, you know, I think would be useful,” [Edmonton, Community]

“There are some free [tools] on the Internet. [Patients] don’t have the blood pressure, necessarily, the cholesterol numbers, they’re actual real height and weight, so if those numbers were pulled out of the EMR and answered those questions then the patient could actually then interact and answer their own questions.” [Toronto, Community]

iii. Tools should have the flexibility for revisions and upgrades as new research emerges

Participants had a strong desire for tools to be adaptable to new research about risk factors for chronic diseases. For example, although the Framingham risk model has been upgraded to account for the impact of ethnicity on cardiovascular risk, most EMR-embedded Framingham tools have not been updated with the latest risk model.

“one thing...that’s really important for these tools - and it’s a frustration that we have and why I often am a little leery about EMR-implanted tools - is that, as we know, medicine changes, new research comes out, guidelines change. Is this a program that’s dynamic so that if a ground-breaking study comes out on breast cancer three months after it’s been implanted, does that then get incorporated and change the actual software within the EMR? Because very quickly it can become obsolete if it’s not dynamic.” [Edmonton, Academic]

B) User-interface attributes

Several comments pertained to opinions about the user-interface of risk assessment tools.

i. Need for user-friendly tool development

Some newer risk assessment tools compute risk for multiple chronic diseases. While discussing
one such all-in-one tool, participants felt that although hypothetically intriguing, it could overburden the user with excessive and unnecessary risk information. The importance of a user-centered approach to tool development was highlighted.

“Like, I don’t want everything to be integrated and blah-blah-blah, I think that’s too complicated. I don’t know for me or for patients or what my hang-up is, but I’d want them individual, like, what’s my risk for colon cancer, what’s my risk for heart disease, what’s my risk for diabetes.” [Toronto, Academic]

“it’d be really interesting to see what people actually want themselves, whether or not they actually want this information...would it be helpful for them, or if they wanted more targeted things, ‘I just want to know about heart disease,’ right, or, ‘I just want to know cancer risk, I don’t care about anything else,’ it would be interesting to see what people want to get to.” [Toronto, Community]

ii. Minimize the number of steps needed to complete a risk calculation

A design aspect that was raised by several participants was the number of steps, and consequently the amount of time it takes to complete a risk calculation. As one participant said,

“one of the reasons Framingham’s being cited here often is that for many of us within the room it is within the EMR, it’s two clicks,” [Toronto, Community]

iii. Tools should be able to display risk estimates as a visual graphic

For physicians who use risk assessment tools to explain disease risk to patients, many felt that graphical displays would help in communicating risk.

“There was one Framingham score I found where it did show graphs, and my patients really liked that, or it really impacted them a bit more and got the points across, and that’s how much that red...these people dying versus that much, you know, if you quit smoking.” [Edmonton, Community]

iv. Tools should generate a printer-friendly output

Some participants prefer to use paper-based tools because it allows their patients the flexibility of take it home and review it adequately. Participants who use computer-based tools all agreed that it is important to be able to print the risk assessment tool output to give to the patient.
“I would welcome future tools that are...printable so you can share it with patients if you want a printable version for the patients.” [Toronto, Academic]

v. Tools should be tailored to a patient’s level of literacy

Whether the target user of a tool is a healthcare professional or patient, participants agreed that patients need to be engaged for tool information to be useful. However, patient engagement is dependent on literacy and numeracy.

“I think it sort of depends on the education level of the patient as well, if you feel that they’re well-educated enough that they can sort of distinguish the relevant information and sort of not become increasingly anxious when they find out certain things that are sort of not in their favour, then you’re more likely to be telling the patient that, you know, ‘Why don’t you go and have a look at it?’” [Toronto, Community]

vi. Tools should allow for user interaction

User interactivity is a feature that is available on some web-based tools. The ability to manipulate risk factor values and view the changes in disease risk could help to better understand how a particular lifestyle habit might influence risk. One participant felt this would help physicians engage patients more in risk discussions.

“I think about a patient of mine...who, you know, obsesses about numbers, his blood pressure numbers...Somebody like that would be ecstatic about a tool that he could kind of manipulate and be able to say, ‘If I could get my blood pressure down to this and my weight up to that,’ that this is what would happen” [Toronto, Community]

vii. Tools should trigger risk assessment reminders

Some EMR systems trigger reminders to perform a risk assessment as patient record data is updated during an appointment.

“But I mean if there was a way of incorporating that and saying that certain levels of morbidity trigger certain things to happen that might be useful, you know?” [Edmonton, Community]
Participants felt this would be a helpful feature as long as it was sensitive to contraindications and did not infringe on their own clinical intuition. As one participant said, “do you need a tool for that or just a little bit of common clinical sense?” [Edmonton, Community]

Another participant echoed, “you would have to be able to turn it off, because I don’t want screens popping up telling me that my man is at 80% risk of developing prostate cancer when I know he’s going to die in a year from his COPD” [Edmonton, Academic].

viii. Tools should provide a prioritized summary of relative risks for multiple diseases

Participants expressed concern over the increasing complexity of risk assessment tools. It was suggested that such tools produce a risk summary.

“I would anticipate that if you were screening a lot of different things that you’d very quickly probably end up only picking out the one or two things that seemed to be useful, like maybe the Framingham component,” [Toronto, Community]

“I mean in some ways having a report card or something where you might just be able to synthesize it, maybe that would... I don’t know how that would work, but I do think that there’s a... you take the most important risk and you deal with that,” [Toronto, Academic]

ix. Tools should provide clinical practice guidelines along with the risk estimates

One participant suggested that risk assessment tool outputs should have the relevant clinical practice guideline recommendations available to compare results to.

“when I use a FRAX tool I’m pulling it up through the Internet Explore on the computer - that’s not embedded in our EMR - but I get a number, and ... if the numbers do show up it’s really important that...the latest guidelines of how to use and interpret that number pulls up too.” [Toronto, Community]

C) Concerns

i. Implication for patient insurability

Risk assessments and screening programs could identify asymptomatic, “at risk” individuals who could be stigmatized by employers and insurance companies, a concern noted by some
physicians. The feeling is reflected in the following statement:

“But I think even if you have the tool and the tool says there’s a 90% chance you’re going to get diabetes, that’s really close to 100% and life insurance or health insurance may just come in and say, ‘Well, your premiums are going to be higher because of the 90%.’”  
[Toronto, Community]  

While this information may be protected by doctor-patient confidentiality rules if collected in primary care settings, such a concern may be warranted for insurance-based risk assessments conducted to determine whether an individual would qualify for insurance.

**ii. Validity of the risk calculation methodology**

A significant point that arose in focus group discussions surrounded the importance of the proven validity of a risk algorithm in influencing whether a physician feels comfortable using it.

“the underlying idea here is that we need to recognize the limitations of a score when we run it, and Framingham’s nice because there’s a lot of weight behind it…”  
[Edmonton, Community]  

“it means a lot to us to know where that information is coming from, and whether or not we can feel comfortable in trusting [it]...to our patients to recommend it to them.”  
[Toronto, Community]  

In summary, physicians’ awareness and appraisal of current risk assessment tools generated the following conclusions:

1) Physicians’ are aware of the concept of risk assessment, some of the popular risk assessment tools and their critical role in calculating chronic disease risk.

2) Current patterns of use include physician-administered risk assessments in the clinical setting or interactive risk assessment during physician-patient encounters. Physicians acknowledged the rare use of patient self-administered risk assessment methods.

3) Physicians were unanimous in appraising the benefits of risk assessment tools; they are seen as instrumental in risk identification, risk communication and risk management.
4) Physicians “wish list” for the development of future risk assessment tools included characteristics such as a user-friendly interface, ability to produce a risk summary in numerical as well as graphical formats, and the flexibility to integrate with EMR systems.

4.4.2 Physicians’ outlook on the implementation of risk assessment in family practice settings

Participants also voiced their perspectives on the future of risk assessment and possible modes of adopting them into routine clinical practice settings.

1) Implementation of tools

A) Readiness to adopt computer-based risk assessment tools into routine clinical practice

Participants were enthusiastic about tool integration with EMRs but wary of proposed systems that incorporate multiple functions such as multiple disease risk calculations and computer-generated screening recommendations.

“Now, past trying it, the utility would really remain to be seen, but I think if part of the goal is, you know, would you be willing to try something like that, then I’d be interested, you know, I’d like to sort of see what it does and what information it gives us,” [Edmonton, Academic]

“with regards to feasibility of implementing these tools in your practice, first of all do you think your practice is ready to take on a computer-based tool?
Yes. Yeah.
Please God!” [Edmonton, Academic]

B) EMR Interoperability

Integration of risk assessment tools into the EMR system was a central feature that many participants desired. Several EMR systems are used in family practices. From a system-level perspective, risk assessment tool integration with different EMR systems will be essential.

“With respect to implementation, the issue will be that there are different systems that people are using, right? So, you know, Nightingale will be different from Practice Solutions…” [Toronto, Academic]
2) Administering roles

A) Patient self-administration of risk assessment tools

Participants from a number of practices felt that patients could complete the risk assessment tool using a computer either in the waiting area of the clinic or at their home.

“And not as many offices will have a patient-accessible computer in the waiting room, but that’s actually probably something that most of us will be looking at. You guys don’t have, at the moment, for patient self-check-in or anything?” [Toronto, Community]

“You could even have something where patients fill in something on a tablet in the waiting room that populates our electronic record and creates a score and helps focus your time on modifiable risk factors, so that could actually save time if it was well-designed.” [Edmonton, Community]

B) Risk assessment tools administered by allied health professionals

Allied health professionals may also be tool users, as one participant said,

“it wouldn’t necessarily be myself that would need to do [a risk calculation], it could be...our nurse practitioner, it could be another allied health care worker that could facilitate that,” [Edmonton, Community].

3) Operational considerations

A) Coupling risk assessment to the annual physical examination

Physicians saw greater importance to using risk assessment tools during annual physical examinations in the future, with a view to focus more on prevention and risk management.

“I think a lot of us are feeling this way, that the annual physical is going to sort of change into the screening and prevention visit, and once we can sort of move away from feeling like we have to do a full physical into doing a preventative care visit, being able to do a lot more discussion around risk is, I think, the time management’s going to change because that’s going to become the focus of a once-yearly 30-minute visit to just go over risk and screening.” [Toronto, Academic]

B) Risk estimates should prompt initiation of formal screening procedures

Risk assessment as a method for making decisions about whether to screen, or “pre-screening”, was raised as a major rationale for risk assessment tool use in family practices.
“I appreciate the pre-screening idea as a rational approach to screening. I mean, really what we’re doing with screens is taking a population where we know our baseline population risk is unacceptable and attempting to reassure people that their risk is lower, or work them up further, and so getting a...pre-test probability or a better idea of a pre-test probability before they go into that is completely in-line with the reason we do screening in the first place. I think it’s exciting” [Edmonton, Community]

C) Monitoring individuals identified as high-risk

The role of risk assessment tools as a component of disease prevention and management programs was also discussed. Without external support to assist individuals in making lifestyle modifications, participants felt that the impact of risk assessment would be limited.

“I think that in terms of patients making changes, especially in lifestyle, I find the most effective thing is either them seeing, for instance, a dietician who follows them and sees them monthly, or me following up on them and having them come back in...Like, everybody knows they shouldn’t smoke, that they need to lose weight, that they need to exercise, but few people are able to put that into action without motivation from an outside source,” [Toronto, Community]

D) Training to enhance risk communication skills

Risk communication is an associated skill that risk assessment tool use demands. As one participant said, “there needs to be a bit of an educational component that goes along with [risk assessment tools], and how to communicate risk, because communicating risk is a tricky endeavour,” [Toronto, Academic]. Another said,

“I don’t know what the [...] residency or even medical school program is like in terms of teaching physicians how to communicate risk and how to, you know, go through relative risk and absolute risk and all of this kind of thing with patients, but I certainly didn’t get any formal training in that, and I think that it would be incredibly helpful,” [Toronto, Academic]

In conclusion, risk assessment is hypothesized to become the main facet of annual clinical visits, thereby elevating the significance of developing well-integrated, user-centric, accessible risk assessment tools with a formalized role in disease prevention.
4.5 Key informants’ opinions and recommendations

The “key informants” focus group took place with three FPs who work in a community-based clinic. They have expertise in area of eHealth; all are strong proponents of the use of EMR and health information systems, having chaired numerous conferences on eHealth-related topics, and are involved in related research. Experts’ opinions concurred with many of the opinions expressed in other focus groups, and also provided additional insights into the design and implementation of risk assessment tools.

Regarding the issue of developing a tool that is adaptable to new research findings, some skepticism was expressed: “And then so you say, ‘We’ll change that for you,’ but what about the forty-two installs that you just did yesterday? Are you going to go back and change those, too?”

However, a proposed solution to deal with necessary system updates is one that has been suggested for managing EMR systems. A centralized information management and support service, operating via a cloud-based network could be used to maintain tool currency.

“you need some kind of centralized rules engine, perhaps. And then you’ve gotta start thinking about mounting some kind of a site that manages that and it has to be secure, and there has to be a committee that looks after what changes and who changes and why it’s changed, and then there has to be some way of recording all that bureaucracy, and then you have to hire somebody to look after bringing the people together to make those decisions.”

“I think as you start thinking about more cloud-based computing, that kind of centralization does make some level of sense.”

A limitation of networked health information systems is the obstacles related to security.

“there’s huge privacy challenges - like, you have to be on secure networks, or encryption, you would have to re-key the whole thing - but that way you could have a centralized rule set which people could compare against, and they could choose to connect to that or not connect to that.”

Additionally, integrating a tool into an EMR system would require that the tool be “interoperable” with different EMR brands, each with unique interfaces, structures and security
issues.

“there’s a number of different platforms that are used out there in the EMR world, on the order of forty, so when you start thinking about providing sort of universal access to a tool like this you’d have to be thinking about having some kind of interface wizard genius individual - a whole army of them, actually - to be able to implement this.”

The discussion also touched on design aspects of risk assessment tools that should be considered to improve usability. One participant had spoken about research into health management systems and patient motivation. He said, "they found the only way to improve outcomes were to have people use it in a checklist fashion, so you had to face the checklist, you had to do the checklist, otherwise it didn’t change behaviour."

The notion of risk assessment tools integrated with health management systems to provide screening reminders once patient data has been entered into an EMR was echoed by participants, but with the stipulation that, “[there’s] the situation where you may have something fire that says, ‘You should be doing this test on this individual,’ but in fact there’s reasons, really good, independent of the algorithm, to not do it on that particular patient for whatever reason, yet later at a time down the road you may find yourself trying to defend that decision, right?” A method for addressing the discrepancy between clinical intuition and guideline-based tool recommendations may be needed.

It was also mentioned that clinic-wide adoption of the risk assessment tool would be important for maintaining standard of care:

“There’s also a liability risk in terms of so if you do this and let’s say you have clinic like this where, say, three out of the four docs use it and one of the four docs doesn’t even though it’s embedded in our system, does that put them in a situation where they’re liable for not practising a certain standard of care that we’ve now assumed within our circle of trust within our clinic?”

In summary, the key informants raised several points about developing a risk assessment tool that is to be integrated with an EMR system. Centralization of information management and
support through tool developers would be essential to maintaining a risk model that is up-to-date with research and clinical guidelines. However, an off-site management network also raises the issue of security. This is further complicated by the need for risk assessment tool components to be compatible with multiple brands of EMR systems. Regarding the user-interface, it was felt that a checklist design of presenting risk assessment results could be helpful in facilitating behaviour change. It was mentioned that a potentially useful feature of an EMR-embedded tool would be automated reminders, triggered by patient data entry. However, this needs to be developed within the context of a physician’s own clinical expertise. How computer-based tools impact what is considered standard of care will also be an issue that requires further discussion.

4.6 Usability testing of computer-based risk assessment tool

Usability testing sessions evaluated an EMR-embedded version of the Framingham risk calculator for accessibility, ease-of-use, organization of subject matter, and functionality. The EMR system, OSCAR, was chosen because it is an open-source EMR system for which a trial version is freely available online. Five FPs participated in usability testing. Pooled participant demographics are presented in Table 4.2 pg. 33.

Participants were prompted to complete a series of tasks and ‘think aloud’, describing their actions and decisions on-screen. The feedback was recorded and grounded theory methods were used to qualitatively analyze audio-recorded transcripts using thematic analysis. Transcripts were analyzed for evidence supporting and substantiating themes that emerged from analysis of data from the focus groups and interview with key informants.

Themes arising from the usability interviews were organized into two categories, those pertaining to the design and usability of the OSCAR-embedded Framingham risk assessment
tool, and those related to FPs’ opinions of risk assessment with a tool.

4.6.1 Design and usability of the OSCAR-embedded Framingham risk assessment tool

Usability testing participants were asked to focus their descriptions of experiences using the embedded risk assessment tool rather than the layout of the EMR system. Several points were raised about the usability and layout of the risk calculator interface. The Framingham tool is accessible from the OSCAR patient file screen (see Figure 4.1 pg. 59).

**Figure 4.1 Patient encounter screen in OSCAR**

Participants felt the calculator menu was not immediately obvious and expressed frustration with the location of the menu: “*Which center of the screen? Here?*” Once selected, the risk calculator opened up in a new window. This presented many challenges for participants because it meant that they needed to switch between windows to view the patient file and calculator.

The new calculator was already pre-populated with data values that were not those of the patient file that they were currently evaluating. This was a source of confusion among all participants:
“Okay, so he’s 52. I don’t know, are the numbers already entered in drawn from... like, do I assume that his systolic blood pressure is in fact 140, or am I supposed to enter it in?”

“So when I open the Framingham risk calculator it has actually a systolic blood pressure in there. Is this just a general template or is the information in here correct? The systolic blood pressure is 140 and it has some different values than what I saw on the July 19th labwork. So do you want me to... like, what are these values here from?”

Furthermore, there was no way to auto-populate the risk assessment tool with risk factor values directly from the patient file open in the EMR. As a result, some participants switched back and forth to retrieve values from the patient file and enter them into the tool.

“I’ll probably have to minimize one window whilst I have open the lab documents on the other slash because this is not – as I was mentioning – super-friendly about transposing the data.”

A few participants instead opted to write down all of the risk factor values on a piece of paper and then enter this information into the tool.

“And having to write it out and then transfer, it’s almost a waste of my time because I had to write on here and then transfer back into the computer.”

As was expressed in focus groups, the number of steps to complete a risk calculation is very important to physicians, who would like to complete the process in a timely manner. The “number of clicks” it takes to complete this is important, as one participant expressed:

“A single click doesn’t work, a double-click doesn’t work.”

With regards to the display of risk information (shown in Figure 4.3 pg.62), participants did not find the presentation format easy to understand. A summary statement was provided at the bottom of the screen with a risk value for coronary heart disease alone and for coronary heart disease and stroke. This did not make the risk value that was desired readily apparent. As one participant said,

“it seems that in the summary it’s made it says that this man has a 7.5% risk of any sort of... oh, of specifically coronary heart disease in the next ten years - not for this man, sorry, for his age group - and that for his risk factors his... of coronary heart disease and stroke is 8.9%.”
The risk value was presented as a percent risk in a table. Many participants said that they would prefer a qualitative risk statement (for example, your risk is moderate), rather than a numerical value, although some also acknowledged that having a numerical value could be beneficial.

“I think what I tend to do is I’m more interested in the word, low, moderate and high...”

One participant stated that he would prefer graphs rather than a risk table: “Framingham calculators that I’ve seen have always been in tables...But you know, I think patients love graphs, they absolutely love graphs. It makes more sense, it’s a little bit more intuitive, and it’s easier to interpret.”

Following the completion of the usability test tasks, participants were asked to comment on their experience. In comparing experiences with computer-based risk assessment tools to paper-based tools, nearly all participants spoke positively of paper-based formats of risk assessment tools. One reason for this is that paper-based tools were felt to be conducive to patient engagement:

“If I’m typing on a computer and not really engaging the patient then they’re not going to take responsibility for their own health. So I don’t find a computer like this for me to type and tell them just a number, I don’t think that they’re convinced, whereas if we give them a piece of paper then they’ll actually go home and make the diet and exercise changes and be motivated to cut down salt and potentially start treatment if required.”

“I have a calculator on my computer but I usually like to do it paper, and I usually take it with me to see the patient, and circle it, and then I give it to them so that they know what my aim is and why my aim is the way it is.”
Figure 4.2 Framingham risk calculator in OSCAR

Figure 4.3 Risk information displayed in the risk calculator window
Participants felt that using a risk assessment tool with a patient is, “a good way to start conversations.” One participant said, in reference to a paper-based Framingham score sheet used, “So I’ve got all of that information there, and I’m just used to calculating it manually so I can actually physically show it to the patient as well.”

It was further clarified that, “It’s not so much that I’m uncomfortable with the computer as I find that a patient really likes to take home something. They can put this on their fridge and they’ve actually really thoroughly understood the different factors for coronary artery disease because I’ve asked them to do and add the score with me, we worked through the together”.

This sentiment was echoed by another participant, who suggested that computer-based tools would be acceptable if they could be printed out:

“So, like, if we went through all of this thing, and then there’s just, like, somewhere along here just there’s, like, a button that says, like, “Print patient handout,” or something like that, and then maybe that would allow those people to still have something to give to the patient, something for them to read through, because you can provide educational material on the sheet as well.”

Ultimately, participants concluded that many of the usability issues that arose were due to lack of familiarity with the EMR system:

“I think part of it is that I’m not familiar with the OSCAR system...if it was in PSS I probably would have been better about entering things and knowing where to get information.”

“I think it just mostly has to do with what you’re used to.”

Regarding broader opinions about risk assessment tools and their impact on physician practices, some participants made it clear that computer-based tools will not replace clinical intuition and physician autonomy:

“I think this is the way that people think computers or programs or, you know, that some algorithm’s going to make life easier for me. Nah.”

“So as I say, they’re nice tools but I don’t think they should be forced or, you know, mandatory, because I think a lot of the time what experienced clinicians - including the
health professionals - they’re often picking up, ‘Oh, this person hadn’t been here for five years. Why are they really here?’”

It was also mentioned that risk assessment tools might begin to play a larger role in the routine of annual physical exams, that “maybe this would become part of our, you know, screening preventative health exams, where they have to enter these risk calculators before they come and sit before us, and then we can have a discussion around it.”

In summary, usability issues related to the importance of designing a system with an intuitive feel. Tools should be readily apparent on the screen, operational within the same window, allow for auto-population of patient data from the EMR only when the user has requested it, and the “number of clicks” it takes to complete a calculation should be minimal. Maintaining patient engagement in the EMR-era is a major concern for FPs, and participants explained that paper-based tools were still fundamental to this. Furthermore, computer-based tools require a degree of familiarity for physicians to feel comfortable using them.

4.7 A framework of awareness and perspectives on the usefulness, usability and feasibility of implementation of health risk assessment tools in family practice

The fourth study objective, outlined in Chapter 2, aimed to use the data from this study to synthesize a framework of FPs’ awareness, and perspectives on the usefulness, feasibility of implementation and usability of health risk assessment tools for chronic diseases. As data was coded and analyzed, several themes emerged. Interrelationships between themes were deconstructed and reassembled during axial coding, and themes were categorized according to study objective (categories of awareness, usefulness, feasibility of implementation and usability). Themes common to multiple categories were grouped together. As selective coding proceeded, the core theme of EMR integration was found to be common among all categories. Participants
were aware of a health risk assessment tool because it was integrated into their EMR system. Participants found tools that were integrated into their EMR system to be useful because integration would allow several current and potential features of EMRs to be applied to risk assessment tools. These included autopopulation of the tool with EMR data, and the triggering of reminders for risk assessments. This sentiment was most strongly felt regarding the feasibility of implementation. By integrating risk assessment tools into an EMR, it was felt that implementation of a tool into clinical workflow would be much more probable. It was also felt that the usability of risk assessment tools would stand to benefit from EMR integration because it would make tools more accessible, easy to use and seamless with the computerization of the clinical encounter.

The framework is presented in the form of a Venn diagram to highlight the interrelatedness of themes within and between each circle (see Figure 4.4 pg. 66). Themes from the focus groups, discussion with key informants and usability testing sessions were cross-verified for overlap and triangulated (see Figure 4.5 pg. 67). Data from the demographic and opinion surveys was not included in the triangulation of data because the survey questions were closed-ended questions, and therefore, themes could not be conceptualized from responses. A revised framework, outlining the relationship between awareness, usefulness, usability and feasibility of implementation, and intersecting at EMR integration, is presented in Figure 4.6 on pg. 68. It shows themes colour-coded according to data source thereby adding the aspect of triangulation to the framework.
Figure 4.4 A framework outlining the interrelationship of awareness, and recommendations and considerations on the usefulness, usability and feasibility of implementation of risk assessment tools.

**Usefulness**
- Clinical practice guidelines should be provided with risk assessment results
- Tool should trigger screening recommendations
- Tools should trigger risk assessment reminders
- Tools should present a risk assessment summary

**Usability**
- Interactive
- User-friendly
- Minimal number of steps to calculate risk
- Interface should be tailored to patient literacy level
- All information available on a single screen
- Readily-apparent risk assessment result
- Ability to autopopulate with EMR data
- Training for risk communication may be needed
- Checklist presentation format
- Visual risk presentation format
- Printable risk assessment results

**Awareness**
- EMR integration
- Tools should be interoperable with different EMR brands
- Tool is well-validated and cited

**Feasibility of Implementation**
- Tools should be upgradable as new research emerges
- Risk assessment tools used by allied health professionals
- Issue of physician autonomy versus a standardized practice over use of risk assessment tools
- Coupling use of tools with annual physical exam
- Mechanism for dealing with missing information
Figure 4.5 Triangulation of themes from focus groups, key informants discussion and usability testing
Figure 4.6 A framework highlighting the interrelatedness of awareness, and opinions on the usefulness, usability and feasibility of implementation of risk assessment tools, as triangulated with the perspectives of focus groups participants, key informants and usability testing participants.
4.8 Summary

Several important themes were identified in this study. The FPs who participated in this study stated that they perform risk assessments on a daily basis. Oftentimes this is in the form of an annual physical exam, although sometimes, risk assessment is patient-initiated. Physicians have varying ability in conveying risk information to patients. Risk is most often communicated qualitatively either to provide a most basic understanding to patients whose literacy is varied, or, as one participant admitted, because they themselves struggle to communicate risk percentages. Physicians are aware of risk assessment tools, especially the Framingham tool. However, few others were known by participants, and even fewer used by them. The mode of administering tools differs between physicians; some prefer to use them on their own while others use them with patients. Several benefits of risk assessment tools were identified by participants, including for explaining the impact of lifestyle changes on disease risk, making screening and intervention decisions, and starting a dialogue with patients about risk. Furthermore, EMR integration with features such as auto-population of patient data from the EMR file and several usability features were identified. Key informants provided details about the implementation of risk assessment tools in EMR systems. Usability testing explored aspects that improve tool accessibility and functionality.
Chapter 5
DISCUSSION

5.1 Summary of main study findings

This qualitative study using focus groups and usability testing revealed that FPs are broadly aware of the importance of risk assessment though they haven’t been uniformly using a variety of risk assessment tools. There has been a consensus, however, that FPs acknowledged the value and benefits of using risk assessment tools. The study also identified a number of reasons for the limited practice of performing risk assessments using risk assessment tools. This study has brought out a several suggestions to develop an ideal risk assessment tool and FPs’ willingness to integrate risk assessment tools into their clinical practice. A number of these themes warrant further discussion.

To our knowledge, this is the first study to directly solicit FPs’ opinions on the use of risk assessment tools through employing a combination of qualitative data collection methods including focus groups, expert opinions and usability testing. Previous studies in this area, by Halas et al., and Ahmad et al., have focused on the opinions of FPs of the usability of risk assessment tool prototypes. Another study by Ahmad et al., looked at the use of risk assessment tools in family practice for guiding discussions on psychosocial health risks with patients. Here, we focus broadly on the area of risk assessment and chronic disease prevention.

5.2 Awareness of risk assessment tools

A systematic review of risk assessment tools for cardiovascular disease, cancer and diabetes, presented in Appendix 1.3 pg. 103, was undertaken in preparation for this study. The review identified 60 different tools with an interface that could be used by an FP. However, participants in our study were aware of only a small fraction of these. All 30 participating physicians knew
about the Framingham tool. Twenty-four participants knew about the FRAX tool for calculating risk of bone fracture. Nine FPs with expertise in fields such as oncology, knew about specific cancer risk calculators (Gail model, Colorectal Cancer Risk Assessment Tool etc.).

Physician awareness of risk assessment tools was heavily influenced by clinical evidence of their validity as well as promotion by healthcare organizations. One participant said, “Framingham’s nice because there’s a lot of weight behind it”. The Framingham tool is referred to in the Canadian CHD guidelines, the FRAX tool is widely endorsed by the WHO and referenced in the Canadian osteoporosis guidelines, and the Gail model was developed by the National Cancer Institute and used to define breast cancer risk in related screening guidelines. Despite evidence supporting the validity of many of the tools identified in the review, health promotion campaigns and physicians’ education by professional organizations will be essential to increase physician awareness about risk assessment tools. Furthermore, the integration of the Framingham tool in several EMR systems likely contributes to its widespread use over other cardiovascular disease risk assessment tools.

5.3 Usefulness of risk assessment tools

The survey results (Table 4.3.1 pg.34) showed that participants felt that risk assessment tools are very useful for FPs, supporting the original hypothesis proposed in the second study objective. This observation was further supported by specified benefits of using risk assessment tools described during the focus groups and usability testing sessions.

An incomplete understanding of risk

While the concept of risk is clear to many physicians, there has been significant confusion in deciphering numerical estimates of risk and conveying its significance to patients. As one
participant said, “Saying to someone they’ve got a 20% chance in the next five years... Like, how do you actually convey to people what is really meant by risk?” This is consistent with earlier findings that FPs may not understand how to convey risk information to laypeople\textsuperscript{29,30}, and may explain why some physicians feel more confident communicating risk qualitatively rather than quantitatively\textsuperscript{29}.

**Lack of wider popularity**

There is also a recurring theme of translating knowledge about risk into the practice of formal risk assessment in daily clinical practice. Survey responses indicated that participants were only “somewhat likely” to use a risk assessment tool with patients during an appointment, despite the expressed sentiments that risk assessment tools are helpful in starting a dialogue about risk factors, communicating risk information to patients, and explaining the impact of lifestyle choices on disease risk\textsuperscript{92}.

The “knowledge translation deficit” of a reluctance to implement best practice principles was noted in earlier studies\textsuperscript{51}, and has been attributed to various theoretical and practical reasons. Risk assessment tool use may require users to know the origin of the specific risk assessment tool and trust the validity of the risk model employed in its design. This is one reason why the Framingham tool is widely accepted; it has been validated in numerous populations and cited widely. One participant said, “But overall I think I do trust the value, maybe too much, I don’t know. I don’t question the number”. However, it was emphasized, by participants in this study, that tools are used only to support clinical expertise rather than replace it.

Low usage of risk assessment tools in the context of a patient encounter was likely due to the fact that some tools, like the Framingham tool, require specific information such as cholesterol and triglyceride values that may not be available at the time of initial assessment (blood work results
return to the physician after the appointment). Reasons based on the usability of tools may also contribute to this, as explained below (see Usability Section 5.4 pg. 75).

**Risk assessment tools on clinical workflow**

Participants seemed convinced that risk assessments are effective for the efficient identification of chronic disease risk but they seem unsure if they necessarily save time. Most participants felt that risk assessment tools may “somewhat” improve patient flow during an appointment [median 3.0, IQR (2,3.75)]. They also expressed mixed responses as to whether risk assessment tools might save time by helping focus discussions on relevant risk factors. This ambivalence was noted by Sposito et al., who surveyed physicians about their attitudes and adherence to the use of cardiovascular risk calculators. In this international sample, 48% of respondents indicated that they regularly used a cardiovascular risk calculator. The vast majority of these users used the Framingham tool (85%). Of those who did not use risk calculators regularly, the two major reasons indicated were that it takes too much time, or that it does not add value to the clinical evaluation. Participants in this study explained that it is important for computer-based tools to be quickly accessible from their computer desktop or EMR and this may be the reason for the perception about the time-saving ability of risk assessment tools.

**Risk as a form of discrimination**

One implication of tool-based risk assessment that was raised by a focus group participant was the issue of patient insurability and employment discrimination based on risk assessment results. It is possible that insurance companies could misinterpret or misrepresent numerical risk information without adequate clinical justification. Similar concerns have arisen regarding discrimination by health insurance providers on the basis of genetic susceptibility to cancer. However, there is little evidence at the present time to substantiate that this has indeed been
happening. In fact, in the United States, the Health Insurance Portability and Accountability Act (HIPAA) and Genetic Information Non-discrimination Act (GINA) proscribe discrimination on the basis of genetics by health insurance companies and employers. In Canada, however, there are no specific regulations over the use of genetic information by private industries although the Privacy Act regulates use of health information by the Canadian government. Without reconsideration, the lack of regulation may have far-reaching consequences on whether patients feel comfortable having their risk assessed, and therefore impact the uptake and use of risk assessment tools by FPs in Canada.

**Computerization of risk assessment tools and risk assessment-based recommendations**

In the current study, there were references by multiple participants and experts about the need to integrate risk assessment tools with health information systems. It was suggested that risk assessment tools should form a component of screening reminder systems and support informed decision-making around lifestyle modification. Screening tools, thus, could be considered computerized clinical decision support systems (CCDSS). CCDSSs are defined as "active knowledge systems which use two or more items of patient data to generate case-specific advice". Risk assessment tools use patient data to generate a case-specific risk profile, and some do provide advice based on this information. For example, the Prostate Cancer Assessment Tool by Karakiewicz et al. computes an individual’s risk of developing prostate cancer and provides personalized, risk factor-specific recommendations, such as, “Be sure to limit the amount of high-fat foods from animal sources and concentrate on a diet that includes vegetables, fruits and grains.” Some studies have shown that computerized reminder systems improve practitioner identification of at-risk behaviours and screening-related outcomes. However there is not enough evidence that demonstrates improvement in patient health outcomes when using CCDSSs.
5.4 Usability of risk assessment tools

Usability testing revealed that current participants had a relative preference for using paper-based risk assessment tools even if a computer-based one was available within their EMR. A number of reasons were identified for this preference. Firstly, paper-based tools seem to allow for more face-to-face dialogue, enabling an interactive physician-patient encounter.

“\textit{I think that \textquote{it\textquot;}} important rather than just being the doctor that\textquote{\textquot;lecturing them you need to involve them. You can lecture somebody. Are they going to retain it? Probably not as much as if you actually, like, have an interactive discussion, which something like a paper-based thing sometimes affords a little bit more easy.}”

Participants also believed that, with paper-based tools, they would have something to give to patients at the conclusion of an appointment. One participant summed up the theme as following: “\textit{I like being able to print useful things in... I think every patient should leave with something when they leave the doctor\textquote{s} office...}”. Participants also believed that paper-based tools provide more information. One participant exclaimed, “\textit{the reason I love the paper one is it actually has more detail on it}”.

A comparison of the user-interface of paper-based tools and computer-based tools seems to support this prevailing attitude. For example, when comparing the paper-based Framingham risk score sheet to the web-based Framingham calculator (Figure 5.1 and Figure 5.2, respectively), basing the comparison on recommended criteria for effective communication of risk\textsuperscript{16,21}, several usability differences stand out, as summarized in Table 5.1 on pg. 77.
Figure 5.1 Paper-based Framingham risk score sheet

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Age</th>
<th>Years</th>
<th>LDL Pts</th>
<th>Chol Pts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>30-34</td>
<td>-1</td>
<td>[1]</td>
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<tr>
<td></td>
<td></td>
<td>35-39</td>
<td>0</td>
<td>[0]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>40-44</td>
<td>1</td>
<td>[1]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>45-49</td>
<td>2</td>
<td>[2]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>50-54</td>
<td>3</td>
<td>[3]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>55-59</td>
<td>4</td>
<td>[4]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>60-64</td>
<td>5</td>
<td>[5]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>65-69</td>
<td>6</td>
<td>[6]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>70-74</td>
<td>7</td>
<td>[7]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 2</th>
<th>LDL - C</th>
<th>(mg/dL)</th>
<th>(mmol/L)</th>
<th>LDL Pts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>&lt;160</td>
<td>&lt;4.11</td>
<td>-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>160-199</td>
<td>4.15-6.17</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>200-239</td>
<td>5.18-8.21</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>240-279</td>
<td>6.22-7.24</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>≥280</td>
<td>≥7.24</td>
<td>[2]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 3</th>
<th>HDL - C</th>
<th>(mg/dL)</th>
<th>(mmol/L)</th>
<th>Chol Pts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>&lt;35</td>
<td>&lt;0.90</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>35-44</td>
<td>0.91-1.16</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>45-49</td>
<td>1.17-1.29</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>50-59</td>
<td>1.30-1.55</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>≥55</td>
<td>≥1.55</td>
<td>-1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 4</th>
<th>Blood Pressure</th>
<th>Systolic (mm Hg)</th>
<th>Diastolic (mm Hg)</th>
<th>Pts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>&lt;120</td>
<td>&lt;80</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>120-129</td>
<td>80-84</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>120-129</td>
<td>85-89</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>120-129</td>
<td>90-99</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>≥160</td>
<td>≥100</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 5</th>
<th>Diabetes</th>
<th>LDL Pts</th>
<th>Chol Pts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>0</td>
<td>[0]</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>2</td>
<td>[2]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 6</th>
<th>Smoker</th>
<th>LDL Pts</th>
<th>Chol Pts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>0</td>
<td>[0]</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>2</td>
<td>[2]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 7</th>
<th>Adding up the points</th>
<th>LDL Pts</th>
<th>Chol Pts</th>
<th>10 Yr CHD Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LDL-C or Chol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HDL - C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blood Pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Smoker</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Point total</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 8</th>
<th>(determine CHD risk from point total)</th>
<th>LDL Pts</th>
<th>Chol Pts</th>
<th>10 Yr CHD Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LDL-C or Chol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HDL - C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blood Pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Smoker</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Point total</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 9</th>
<th>Comparative Risk</th>
<th>Average</th>
<th>Average</th>
<th>Low**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age (years)</td>
<td>10 Yr CHD Rate</td>
<td>10 Yr Hard CHD Rate</td>
<td>10 Yr CHD Rate</td>
</tr>
<tr>
<td></td>
<td>Risk</td>
<td>Risk</td>
<td>Risk</td>
<td></td>
</tr>
<tr>
<td>30-34</td>
<td>3%</td>
<td>1%</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>35-39</td>
<td>5%</td>
<td>4%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>40-44</td>
<td>7%</td>
<td>4%</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>45-49</td>
<td>11%</td>
<td>8%</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>50-54</td>
<td>14%</td>
<td>10%</td>
<td>8%</td>
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<td>55-59</td>
<td>16%</td>
<td>13%</td>
<td>7%</td>
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</tr>
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<td>60-64</td>
<td>21%</td>
<td>20%</td>
<td>9%</td>
<td></td>
</tr>
<tr>
<td>65-69</td>
<td>25%</td>
<td>22%</td>
<td>11%</td>
<td></td>
</tr>
<tr>
<td>70-74</td>
<td>30%</td>
<td>25%</td>
<td>14%</td>
<td></td>
</tr>
</tbody>
</table>

*Hard CHD events exclude angina pectoris

**Low risk was calculated for a person the same age, optimal blood pressure, LDL-C 100-129 mg/dL, or cholesterol 160-199 mg/dL, HDL-C 45 mg/dL, for men or 55 mg/dL, for women, non-smoker, no diabetes

Risk estimates were derived from the experience of the Framingham Heart Study, a predominantly Caucasian population in Massachusetts, USA.

**Figure 5.2 Computer-based Framingham tool**

*From http://hp2010.nhlbihin.net/atpiii/calculator.asp (National Cholesterol Education Program)*

**Table 5.1 Comparison of the paper-based Framingham tool and the web-based Framingham tool based on criteria for effective risk communication**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Paper-based Framingham</th>
<th>Web-based Framingham</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact of each risk factor on disease risk should be apparent</td>
<td>-each risk factor is presented with the contribution to disease risk for every value</td>
<td>-the impact of an individual risk factor on disease risk is not apparent</td>
</tr>
<tr>
<td>Risk value input and output should be on the same page</td>
<td>-all risk factors and their contribution are presented on the same page as the 10-year risk score</td>
<td>-the entered information is presented along with the 10-year risk</td>
</tr>
<tr>
<td>Use visual aids</td>
<td>-coloured gradients indicate higher and lower relative risk</td>
<td>-no graphical display</td>
</tr>
<tr>
<td>Present a comparison of individual risk to average risk</td>
<td>-available in step 9 of paper-based tool</td>
<td>-not available without further reading</td>
</tr>
</tbody>
</table>
The single most important aspect of usability for a risk assessment tool is the accessibility of the user-interface. It needs to be simple and intuitive, requiring minimal technical knowledge. Interactivity of the user-interface was suggested as a method to improve usability and a way to help physicians involve patients in the risk assessment process. However, a study of static versus interactive decision aid interfaces for conveying statistical information found that, though users found the interactive tool visually appealing, they were less likely to interpret information correctly and were more distracted during tool use\(^{100}\). Risk assessment calculations should be completed within a few steps. This could be facilitated by enabling the risk assessment tool to be auto-populated with patient data from the EMR system, keeping risk factor input and disease risk output on the same screen, and employing strategies to enhance the conveyance of risk information (i.e. visual aids, qualitative statements, comparison with average risk).

### 5.5 Feasibility of implementation

Research exploring the implementation of complex interventions into clinical practice has highlighted the importance of tailoring interventions to practice styles and workflow patterns\(^{101}\). Studies on the implementation of CCDSSs have shown that poor integration of new tools into clinical workflow lead to a failure of the practitioner to use the tool\(^{39,102}\). It has been noted that, through adopting new technologies, physicians want to save time, improve efficiency, enhance their interaction with patients and improve outcomes\(^{103,104}\).

A recurring theme that emerged in the analysis was the importance of seamlessly integrating risk assessment protocols into family practice settings of different types. Despite the acknowledgement of a need for the wider use of EMR-embedded risk management tools, implementation has been hampered by problems at the local level (i.e. lack of uniformity in individual clinics) and system level (i.e. funding). Family practice settings vary widely in their
setup (solo vs. group, urban vs. rural, academic vs. community, small vs. large) and each clinic may choose different risk assessment tools, different types of EMR systems, different computer software and hardware, depending on their needs and resources\textsuperscript{105,106}. For example, there are over 35 different EMR vendors in Canada, and over 300 in the United States\textsuperscript{107,108}. These differences create a logistical challenge in terms of creating a risk assessment program with built-in flexibility for integration with any and all computer systems, platforms, programming languages and end-user literacy.

The challenge is not unique to the adoption of risk assessment tools; it pervades all aspects of EMR adoption. Insights gained from the process are essential in the context of introducing risk assessment tools to family practitioners at a wider level. Routine use of risk assessment tools is contingent on the tailoring of tools to the unique workflow of a clinic, and EMR integration is crucial to accomplish this goal. Hillestad et al., made a strong case about the benefits of EMR implementation in improving outcomes in chronic disease management\textsuperscript{109}. EMR-embedded risk assessment tools could facilitate the clinical process at each and every step including history taking\textsuperscript{110}, application of clinical practice guidelines, improving guideline adherence and developing personalized risk management plans based on individual needs\textsuperscript{111-113}. Participants felt that tools were helpful in supporting their own screening and intervention decisions, such as whether a woman should have a mammogram. This is also supportive of a previous study finding that general practitioners find tools helpful in making clinical decisions\textsuperscript{114}. Integrating risk assessment tools with EMRs, however, may lead to unintended consequences. Studies on CCDSSs identified a concern that increased dependence on such tools might replace physicians’ clinical skills from decision-making\textsuperscript{39,106,115,116}. 
Working with professional bodies and clinical practice guideline committees to disseminate the value of routine use of risk assessment tools in family practice settings would be helpful to convey an unequivocal message to FPs about the value of routinely using standard risk assessment tools. Convincing software developers to design risk assessment programs that are compatible with different types of computers, platforms and EMR systems is also essential to accomplishing the goal.

5.6 Strengths and limitations

This study provides preliminary insights of FPs’ current practices, opinions and outlook about the use of risk assessment tools. It has confirmed some of the themes identified in earlier studies and brought out significant new evidence that has previously been postulated. Some of the key strengths and limitations of the study are further discussed below.

As preliminary work toward this study, a review of risk assessment tools was conducted (see Appendix 1.3 pg. 103). We sought to create a compendium of chronic disease risk calculators that an FP could use without requiring statistical software or a background in statistics. As a consequence, many validated risk assessment models were excluded, such as the Claus model for breast cancer risk, because they did not have a usable interface. Several more risk assessment models with user-friendly interfaces were excluded because they were not relevant to FPs. For example, tools that calculate cancer metastatic risk and therapeutic side effect risks were excluded because of their specialist orientation. Also, only tools for computing chronic disease risk were included; those for acute conditions, such as risk of bone fracture, were excluded. Focus groups revealed that participating FPs, however, were most aware of risk assessment tools for acute conditions and less so of those for chronic diseases.
The main study design, methods and data analysis were guided by established theoretical foundations. Health behaviour change theory from the theoretical perspective of symbolic interactionism was used to guide the development of the main research questions. This study used the technique of data triangulation to confirm core themes using multiple sources of data. Perspectives from participants in focus groups, key informants and usability testing were used for comparison and cross-verification of findings to result in broader understanding of concepts relating to FPs’ opinions of risk assessment tools. Analysis was conducted using grounded theory to generate themes from analysis of collected data. The Strauss and Corbin approach to grounded theory is a rigorous, systematic method of conducting and analyzing qualitative research\textsuperscript{60}. This was selected because it was considered to be the most appropriate method for addressing the specific objectives of the current project.

Another study aspect which warrants discussion is the use of qualitative methods and its implications on the generalizability of results. Our study collected data from 25 FPs that participated in focus groups, and cross-validated the data using additional information from another set of five FPs during usability testing sessions. It should be noted that the notion of sample size is applied differently while conducting qualitative research, and the adequacy of sample size is assessed using parameters such as saturation, a method by which sampling is deemed adequate based on the observed recurrence of themes during data collection\textsuperscript{79}. This was monitored during data collection, and also further scrutinized during data analysis using grounded theory’s constant comparative approach. The coders came to the agreement that saturation had been reached and determined that the sample size was adequate to provide credible results.
The usability testing conducted in this study is analogous to the first phase of usability testing in relation to Systems Development Life Cycle (SDLC), as outlined by Kushniruk and Patel\textsuperscript{117}, shown in Figure 5.3.

**Figure 5.3- Usability testing in relation to the phases of the system development life cycle (SDLC)\textsuperscript{77}**

Five participants took part in usability testing with the OSCAR EMR system. The recommended sample size for usability testing of a complex intervention is five to eight participants, with the first five users identifying more than 70% of usability issues\textsuperscript{118-120}. According to the SDLC model, the first phase of usability testing involves an exploratory needs assessment, which was done here. The next steps would be to engage in phase two and three of the SDLC which involve the analysis of specific user requirements and design of a prototype. The usability testing, in this case, helped to supplement focus group themes, by employing a specific platform from which to elicit user experiences, however, further testing with a prototype tool would yield more relevant data.
It is essential to note that the “timing” of the study may have imposed some bias, known as a “cohort” effect. The study was carried out during 2011-2012, which could be seen as a time of transition when EMR implementation and computerization is beginning to take hold in the daily operations of family practices. Some of the findings such as physicians’ preference for paper-based assessment tools and infrequent use of web-based tools could be explained by various aspects of this transitory effect.

Furthermore, the representativeness of these results is limited by the fact that only two locations (Ontario and Alberta) were sampled from. Another study limitation that emerged during the recruitment of practices was that several family practices were in the process of adopting EMRs. As a result, all practices had adopted EMRs by the time data was collected, and therefore the results from this study did not capture the perspectives of FPs on computer-based health risk assessment tools that do not have an EMR in their practice. For reasons of feasibility and accessibility, the practices involved in this study were academic and community-based practices with affiliations to the respective universities in Toronto and Alberta, and as a result the opinions of family physicians from unaffiliated practices were not obtained.

5.7 Next steps

The findings from this study offer preliminary insights into research on computer-based health risk assessment tools. Future research in this area may take several forms. It has been alluded to from the commencement of this study that a major element that must be further investigated is the perspectives of patients. Given the patient-centered orientation of healthcare today, a supplemental investigation into patient perspectives will contribute to an understanding of user-centered tool development and administration, and reveal themes pertaining to the role of risk assessment tools in the self-management of health. Another direction which these study findings
point to a need to develop a standardized protocol for appraising web-based risk assessment tools. The review conducted in this study showed that computer-based risk assessment tools have been proliferating without appropriate checks and balances. Information from this study could be useful in developing a critical appraisal tool for evaluating current or future risk assessment tools. Furthermore, these results have heuristic value in terms of informing FPs about risk assessment in general and use of risk assessment tools in particular. This could be accomplished through presenting these findings at professional meetings and publishing in scientific journals.

5.8 Implications for future research and practice

Results of this study will make a contribution to what we know about the design of risk assessment tools and facilitating their use among physicians. Chronic disease prevention will continue to assume great importance across all aspects of healthcare, with a focus on identifying high risk individuals, early diagnosis and preventive intervention. Risk assessment tools are a critical element of these efforts, and our study will contribute to the development, evaluation and implementation of various risk assessment tools.

The study findings bring to light a crucial point about the importance of implementation of tools in influencing awareness, usefulness and usability. EMR integration was felt to be vital by participants in this study because of the acute impact that EMRs have had on clinical workflow and access to patient information. Computer-based management of health information is becoming commonplace among family practices in Canada, and future instruments targeted at family practices will need to be adaptable to a computerized clinical practice.

Risk assessment is one of the key activities in primary care, hence, much of the focus of our research has been confined to exploring FPs’ perspectives and attitudes in primary care settings.
However, risk assessment is an all pervasive theme that is equally important for a variety of other professionals including specialists as well as allied health professionals. Disease-specific and problem-oriented risk assessment tools would be helpful in training allied health workers in anticipating and monitoring for complications in community settings (e.g. risk of falls among elderly, treatment non-adherence among diabetic patients or lowering mortality among individuals with chronic respiratory diseases).

This study was funded as part of a larger initiative by Cancer Care Ontario (CCO) and Public Health Ontario to develop and implement an Ontario-based health risk assessment tool highlighting the impact of lifestyle and behaviour life expectancy. Manuel et al., published a life expectancy calculator targeted for the Ontario public. The tool relates life expectancy to demographic information, smoking, diet, physical activity and stress. Based on the most comprehensive, valid Ontario data available, the calculated estimate provides the most accurate and personalized estimation of life expectancy. This life expectancy calculator, compared to the chronic disease risk assessment tools discussed in this study, more directly addresses the impact of lifestyle choices on risk of mortality; however it does not compute specific disease risks and does not address the impact of family history, disease history, comorbidities, and genetic and environmental factors on life expectancy.

5.9 Knowledge translation

The Canadian Institute of Health Research defines knowledge translation (KT) as “a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically-sound application of knowledge to improve the health of Canadians, provide more effective health services and products and strengthen the health care system”. This definition is further refined to include the identification and involvement of stakeholders and end-users throughout the
research process, termed integrated KT\textsuperscript{123}. To place this research in the integrated KT context, this study was funded by the key stakeholder, Cancer Care Ontario and involved the target users (i.e., family physicians), from the outset, thereby involving the end-users in the research process. The lack of research on risk assessment tools in primary care demanded preliminary studies to highlight the needs and feasibility of tool use, as was done here. The results of this study will be published in a peer-reviewed journal and presented at academic conferences. The results have been shared with key decision makers at Cancer Care Ontario and the Ontario Institute for Cancer Research. Both organizations have expressed an interest in supporting continued research in this area, which may take the form of applying these study findings to the development of an Ontario-centric risk assessment tool.

5.10 Summary

This study revealed several practical themes relating to health risk assessment tool use. Participants were aware of a handful of risk assessment tools for chronic diseases but used only the Framingham tool regularly in practice. A major reason for this is that the Framingham tool is integrated into several different brands of EMR systems. EMR integration emerged as a core theme relating to usefulness, usability and implementation of tools. Recommendations related directly to EMR integration to enhance clinical efficiency. Tool integration may also facilitate making personalized recommendations based on individual risk calculations, as in CCDSSs. Nevertheless, “tangible” risk outputs, in the form of printable sheets, were still felt to be valuable in maintaining face-to-face dialogue. This study examined various aspects of risk assessment tools by FPs, documenting their needs and identifying desired components for designing new risk assessment tools and introducing them to clinical practice.
Chapter 6
CONCLUSION

This study was based on the premise that FPs play a crucial role in early detection and preventive intervention of chronic diseases. Risk assessment is central to this process. The manner in which risk assessment is practiced varies considerably, and poor risk communication may leave the patient with vague information given that not all FPs feel confident with risk communication. Risk assessment may benefit from the individualization of assessment via a health risk assessment tool.

A systematic review of the literature revealed an array of paper-based and web-based risk assessment tools for cancer, cardiovascular disease and diabetes. Over half of the identified tools computed cancer risk. Awareness and opinions on the usefulness, usability and feasibility of implementation were further solicited during focus groups, conducted with FPs and experts in the area of eHealth. These revealed that FPs are aware of several risk assessment tools for acute conditions, like risk of bone fracture, but are otherwise unaware of tools for chronic disease risk, with the exception of the Framingham risk calculator for cardiovascular disease risk and the Gail model for breast cancer risk. A few reasons contributing to the disparity between tool awareness and availability were noted. Popularity of tools seems to be a direct result of how well tools are cited and promoted. The Framingham and Gail risk assessment tools are widely cited in published literature. The Framingham tool is also integrated into and interoperable with different brands of EMR systems, making it easily accessible to most physicians.

This study found that the purpose for using these tools is wide and varied. Screening, decision-making and conveyance of risk information are just a few of the identified uses. Participants also commented on the desired features of future risk assessment tools. They suggested that tools
should display risk in a visual format, generate a printer-friendly output, trigger risk assessment reminders, and provide screening recommendations with the risk estimate.

Themes pertaining to the usability and implementation of risk assessment tools emerged during focus groups, key informant discussions and usability testing. Computerization of clinical practices via the implementation of EMR systems was felt to be inevitable and so several suggestions regarding usability and implementation, in relation to EMR integration, were made. Data should be autopopulated from the patient EMR file to the risk assessment tool. Patient health and risk information should be available on a single screen, and the user-interface should be interactive, allowing for the manipulation of risk factor values and the recalculation of risk. It is also necessary that risk models be upgradable to correspond with evolving research data.

In the future, the principal user of risk assessment tools may not be physicians. Tool users might also include allied health professionals and patients themselves. However, little research has been done on specific user groups and further studies on the opinions of patients and allied health professionals will be needed to better understand these perspectives.

This study presents a unique viewpoint on the use of risk assessment tools by FPs. Awareness, usefulness, usability and the feasibility of implementing tools into clinical practice rests at the intersection of integrating tools into a computerized clinical practice and continuing to offer patient-centered care. As more tools are developed, a clear understanding of the end goal for risk assessment tools needs to be established to mediate their future development.
References


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85. Charmaz K. Premises, principles, and practices in qualitative research: revisiting the foundations. *Qualitative health research.* Sep 2004;14(7):976-993.


Appendix
Appendix 1.1- QUOROM Diagram of Risk Assessment Tool Review Search Strategy

- 3079 citations identified from MEDLINE
- 2060 citations identified from EMBASE
- 3021 citations identified from Web of Science
- 214 citations identified from CINAHL
- 969 citations identified from Cochrane Central Register of Controlled Trials

9343 citations identified

- 8738 titles/abstracts identified through database searching
- 8650 excluded based on title/abstract

- 98 full text articles screened for inclusion/exclusion criteria
- 43 secondary full text articles screened for inclusion/exclusion criteria

- 141 full text articles assessed for eligibility based on inclusion/exclusion criteria

- 60 tools identified from 91 articles

- 605 duplicates removed

- 98 full text articles screened for inclusion/exclusion criteria
- 43 secondary full text articles screened for inclusion/exclusion criteria
- 141 full text articles assessed for eligibility based on inclusion/exclusion criteria

- 60 tools identified from 91 articles

- 605 duplicates removed
Appendix 1.2- Sample Search Strategy

Database: Ovid MEDLINE(R) <1946 to March Week 2 2012>
Search Strategy:

--------------------------------------------------------------------------------
1     tool.mp. (196913)
2     exp Algorithms/ (139631)
3     models, theoretical/ or models, statistical/ (140603)
4     1 or 2 or 3 (444974)
5     exp Neoplasms/ (2298877)
6     exp Diabetes Mellitus, Type 2/ (69616)
7     exp Cardiovascular Diseases/ (1695163)
8     5 or 6 or 7 (3919078)
9     exp Risk Assessment/ (143847)
10    4 and 8 and 9 (3079)
**Appendix 1.3- Pre-Screening Health Risk Assessment Tools for Average-Risk Individuals (N=60)**

*Blank cells indicate that information was either inaccessible or unavailable*

**Table 1: Breast Cancer**

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<thead>
<tr>
<th>Name</th>
<th>Source Reference</th>
<th>Target Audience</th>
<th>External Validation</th>
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<th>Model</th>
<th>Medium</th>
<th>Risk Factors</th>
<th>Risk Presentation Format</th>
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</thead>
<tbody>
<tr>
<td><strong>National Cancer Institute Breast Cancer Risk Assessment Tool (BCRAT)</strong></td>
<td>Gail, Brinton et al., 1989; Gail, Constantino et al., 2007(^{124,125})</td>
<td>White Females + African American Females</td>
<td>Yes</td>
<td>Case-control data from Breast Cancer Detection Demonstration Project (BCDDP) + Women’s Contraceptive and Reproductive Experiences (CARE) Study + US Surveillance Epidemiology and End Results Program (SEER) + Study of Tamoxifen and Raloxifene (STAR) trial</td>
<td>Gail Model 1 + Gail Model 2</td>
<td>Web-based: <a href="http://www.cancer.gov/bcrisktool/">http://www.cancer.gov/bcrisktool/</a></td>
<td>Age at menarche First degree relatives Number of breast biopsies Age at first live birth Ethnicity</td>
<td>Chance of developing disease over time span % 5 year risk-individual/avg. % lifetime risk-individual/avg. Numerical/Verbal</td>
</tr>
<tr>
<td><strong>FHAT</strong></td>
<td>Gilpin, Carson et al., 2000(^{126})</td>
<td>Females</td>
<td>Retrospective cohort study of Ontario Familial Breast Cancer Registry</td>
<td>Family History Assessment Tool</td>
<td>Paper-based (score sheet)</td>
<td>Personal history of breast cancer Age of onset Family history of breast or ovarian cancer (first-degree relatives)</td>
<td>Probability of developing breast or ovarian cancer</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>Source Reference</td>
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<td>External Validation</td>
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<tr>
<td>IBIS tool</td>
<td>Tyrer, Duffy et al., 2004[127]</td>
<td>British Females</td>
<td>Yes</td>
<td>Retrospective cohort study of UK National Health Statistics data and data drawn from[128][131]</td>
<td>Tyrer-Cuzick Model</td>
<td>Web-based <a href="http://www.ems-trials.org/riskevaluator/">http://www.ems-trials.org/riskevaluator/</a></td>
<td>Age at menarche, Parity, Age at first child, Age at menopause, Height (premenopausal), BMI (post-menopausal), Use of hormone replacement therapy, Atypical hyperplasia, Lobular carcinoma in situ, Breast cancer family history (first-degree relatives), Ovarian cancer family history, BRCA 1 and 2 mutation frequency by age</td>
<td>Cumulative lifetime risk of developing disease, % risk after 10 years, $ lifetime risk, with and without BRCA1 or BRCA2 gene mutation, each risk presented along with population risk</td>
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### Table 2: Cervical Cancer

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<th>Risk Factors</th>
<th>Risk Presentation Format</th>
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</thead>
<tbody>
<tr>
<td>Pittsburgh Cervical Cancer Screening Model</td>
<td>Austin, Onisko et al., 2010(^{133})</td>
<td>Females</td>
<td>Retrospective cohort study of &gt;400 000 pap tests from Magee Women’s Hospital of UPMC</td>
<td>Pittsburgh Cervical Cancer Screening Model PCCSM</td>
<td>Computer-based</td>
<td>Personal HPV vaccination history Pap-test history histopathology</td>
<td>Relative risk of histopathologically verifiable CIN2, CIN3, AIS, and CxCa conditions</td>
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### Table 3: Colorectal Cancer

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<th>Risk Factors</th>
<th>Risk Presentation Format</th>
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</thead>
<tbody>
<tr>
<td>Colorectal Cancer Risk Assessment Tool (CCRAT)</td>
<td>Freedman, Slattery et al., 2009&lt;sup&gt;134&lt;/sup&gt;</td>
<td>White Males and Females</td>
<td>Yes</td>
<td>Case-control study (primary data collection)</td>
<td>CCRAT</td>
<td>Web-based <a href="http://www.cancer.gov/colorectalcancerrisk/">http://www.cancer.gov/colorectalcancerrisk/</a></td>
<td>Age&lt;br&gt;Familial history of CRC (first degree relatives)&lt;br&gt;Personal history of sigmoidoscopy and colonoscopy&lt;br&gt;History of polyps&lt;br&gt;Dietary intake (multivitamins, red meat, vegetable and fruit consumption)&lt;br&gt;Alcohol intake&lt;br&gt;BMI&lt;br&gt;Smoking history&lt;br&gt;Use of NSAIDS&lt;br&gt;Physical activity&lt;br&gt;Menopause status&lt;br&gt;Hormone replacement therapy</td>
<td>Probability of developing colorectal cancer (relative risk)</td>
</tr>
<tr>
<td>Colorectal Cancer Prediction Model (CCPM)</td>
<td>Driver, Gaziano et al., 2007&lt;sup&gt;135&lt;/sup&gt;</td>
<td>Male</td>
<td>Retrospective cohort study&lt;br&gt;Physicians Health Study</td>
<td>CCPM</td>
<td>Paper-based: Risk score (see publication)</td>
<td>Age&lt;br&gt;Alcohol use&lt;br&gt;Smoking status&lt;br&gt;BMI</td>
<td>Probability of developing colorectal cancer over 20 years</td>
<td></td>
</tr>
<tr>
<td>Risk Scoring Index</td>
<td>Impierale, Wagner et al., 2003&lt;sup&gt;136&lt;/sup&gt;</td>
<td>White, Black and Hispanic Males and Females</td>
<td>Yes</td>
<td>Cross-sectional study (primary data collection)</td>
<td>Risk of Advanced Proximal Neoplasia Index</td>
<td>Paper-based (score sheet)</td>
<td>Age&lt;br&gt;Sex&lt;br&gt;Most advanced distal findings (polyps)</td>
<td>Scoring system for Risk Index stratified by risk factors&lt;br&gt;Probability of low risk patients developing advanced proximal neoplasia</td>
</tr>
<tr>
<td>Name</td>
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<tr>
<td>Selva Score</td>
<td>Selvachandran, Hodder et al., 2002&lt;sup&gt;137&lt;/sup&gt;</td>
<td>Males and Females</td>
<td>Yes</td>
<td>Prospective cohort study (primary data collection)</td>
<td>Paper-based pre-procedural questionnaire, 4-pages long</td>
<td>Age, Sex, Blood per rectum, Change in bowel habit, Perianal symptoms, Abdominal symptoms, Weight loss, Loss of appetite, Tiredness, Family history, Relative medical history</td>
<td>Weighted risk score</td>
<td>Probability of having colon cancer given colorectal symptoms</td>
</tr>
<tr>
<td>Ma, Sasazuki et al., 2010&lt;sup&gt;138&lt;/sup&gt;</td>
<td>Japanese Males</td>
<td>Yes</td>
<td>Retrospective cohort study of Japanese Public Health Cohort II</td>
<td>Paper-based (score sheet)</td>
<td>Age, BMI, Alcohol consumption, Smoking status, Physical activity level</td>
<td>Probability of developing colorectal cancer over 10-year period</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brazer, Pancotto et al., 201&lt;sup&gt;139&lt;/sup&gt;</td>
<td>Males and Females</td>
<td>Yes</td>
<td>Prospective cohort study (primary data collection)</td>
<td>Paper-based nomogram (see publication)</td>
<td>Age, Sex, Fecal Occult Blood Test, Hematocrit, Indication for colonoscopy (GI bleeding, diarrhea, abdominal pain, iron deficiency, family history, IBD)</td>
<td>Probability of developing colorectal cancer (absolute risk)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>QCancer-Colorectal</td>
<td>Hippisley-Cox, 2012&lt;sup&gt;140&lt;/sup&gt;</td>
<td>British Males and Females</td>
<td>Yes</td>
<td>QResearch database</td>
<td>Web-based: <a href="http://www.qcancer.org/colorectal/">http://www.qcancer.org/colorectal/</a></td>
<td>Age, Sex, Alcohol status, Family history, Bleeding (y/n), Abdominal pain (y/n), Loss of appetite (y/n), Weight loss (y/n), Anemia (y/n)</td>
<td>Percent risk over 2 years</td>
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</table>
Table 4: Gastro-esophageal Cancer

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<th>Risk Presentation Format</th>
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</thead>
<tbody>
<tr>
<td>QCancer-Gastro-esophageal</td>
<td>Hippisley-Cox, 2011(^\text{141})</td>
<td>British Males and Females aged 30-84</td>
<td>Yes</td>
<td>QResearch database</td>
<td>Web-based: <a href="http://www.qcancer.org/gastro-oesophageal/">http://www.qcancer.org/gastro-oesophageal/</a></td>
<td>Age, Sex, Smoking status (y/n), Hematemesis (y/n), Dysphagia (y/n), Abdominal pain (y/n), Loss of appetite (y/n), Heartburn, Weight loss (y/n), Anemia (y/n)</td>
<td>Percent risk over 2 years</td>
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Table 5: Lung Cancer

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<tbody>
<tr>
<td>Deng, Kimmel et al., 2009</td>
<td></td>
<td>White Males and Females</td>
<td>Yes</td>
<td>Retrospective multi-study design: Cancer Prevention Study (CPS-II) cohort study M.D. Anderson Lung Cancer Case-Control study</td>
<td>Two-Stage Clonal Expansion TSCE Model</td>
<td>Computer-based</td>
<td>Smoking history Genetic Susceptibility by blood sample assay</td>
<td>Probability of developing lung cancer</td>
</tr>
<tr>
<td>Lung Cancer Risk Assessment Tool</td>
<td></td>
<td>Males and Females</td>
<td>Yes</td>
<td>Carotene and Retinol Efficacy Trial (CARET) RCT study data</td>
<td>Web-based <a href="http://www.mskcc.org/mskcc/html/12463.cfm">http://www.mskcc.org/mskcc/html/12463.cfm</a></td>
<td>Web-based</td>
<td>Age Sex Asbestos exposure Smoking history (duration, number of cigarettes daily, and time since quitting)</td>
<td>Probability of developing lung cancer within 10-year period (absolute risk)</td>
</tr>
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<td>Name</td>
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<tr>
<td>Fears, Guerry et al., 2006(^{145})</td>
<td>White Males and Females</td>
<td></td>
<td>Case-control study data (primary data collection)</td>
<td></td>
<td>Web-based: <a href="http://www.cancer.gov/melanomarisktool/Index.aspx#q1">http://www.cancer.gov/melanomarisktool/Index.aspx#q1</a></td>
<td>Geographic location in USA Sex Race Age</td>
<td>Probability of developing lung cancer within 5-year period (% absolute risk)</td>
<td></td>
</tr>
<tr>
<td>Brief Skin Cancer Risk Assessment Tool (BRAT)</td>
<td>Glanz, Schoenfeld et al., 2003(^{146})</td>
<td>Males and Females</td>
<td>Does not state how algorithm was created Apart of Skin Cancer Awareness, Prevention and Education (Project SCAPE)</td>
<td></td>
<td>Paper-based (score sheet)</td>
<td>Childhood residence Hair color Freckles Sunburn history Prior skin cancer Ability to tan Skin color Tendency to burn Large moles</td>
<td>Score Index &gt;30 high risk Probability of developing melanoma (absolute risk)</td>
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### Table 7: Ovarian Cancer

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<tbody>
<tr>
<td>QCancer- Ovarian</td>
<td>Hippisley-Cox, 2012¹⁴⁸</td>
<td>British Females</td>
<td>Yes</td>
<td>QResearch database</td>
<td>Web-based: <a href="http://www.qcancer.org/ovary/">http://www.qcancer.org/ovary/</a></td>
<td></td>
<td>Age</td>
<td>Percent risk of having undiagnosed ovarian cancer</td>
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<td>Family history (y/n)</td>
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<td>Rectal bleeding (y/n)</td>
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<td>Postmenopausal bleeding (y/n)</td>
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<td>Abdominal distension (y/n)</td>
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<td>Loss of appetite (y/n)</td>
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<td>Weight loss (y/n)</td>
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<td></td>
<td></td>
<td></td>
<td>Anemia (y/n)</td>
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<tr>
<td>OCRA- ovarian cancer risk assessment</td>
<td>Ronco, 2011¹⁴⁹</td>
<td>130 American Females</td>
<td>Prospective study</td>
<td>Paper-based (equation)</td>
<td>Menopausal status (y/n)</td>
<td>Serum prealbumin</td>
<td>Serum CA-125</td>
<td>Risk score</td>
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¹⁴⁸ Hippisley-Cox, 2012
¹⁴⁹ Ronco, 2011
## Table 8: Prostate Cancer

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<th>Risk Presentation Format</th>
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<tbody>
<tr>
<td>PCPT risk calculator</td>
<td>Thompson, Aukerst et al., 2006&lt;sup&gt;150&lt;/sup&gt;</td>
<td>Males</td>
<td>Yes</td>
<td>Prostate Cancer Prevention Trial (PCPT) study data</td>
<td>PCPT risk model</td>
<td>Web-based: <a href="http://deb.uthscsa.edu/URORiskCalcPages/uroriskcalc.jsp">http://deb.uthscsa.edu/URORiskCalcPages/uroriskcalc.jsp</a></td>
<td>Age, Race, PSA level, Family history of prostate cancer, History of digital rectal examination (DRE), Prostate biopsy history</td>
<td>Probability of developing prostate cancer via positive biopsy detection (percent risk in 2x2 table format)</td>
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<tr>
<td>ERSPC risk calculator</td>
<td>van Vugt, Roobol et al., 2011&lt;sup&gt;151&lt;/sup&gt;</td>
<td>White Males</td>
<td>Yes</td>
<td>European Randomized study of Screening for Prostate Cancer (ERSPC) data</td>
<td>ERSPC risk model</td>
<td>Web-based: <a href="http://www.prostatecancer-riskcalculator.com">http://www.prostatecancer-riskcalculator.com</a></td>
<td>Age, Family history of prostate cancer, Urinary symptoms</td>
<td>Probability of developing prostate cancer (percent risk)</td>
</tr>
<tr>
<td>Eastham, May et al., 1999&lt;sup&gt;152&lt;/sup&gt;</td>
<td>Males</td>
<td>Cross-section</td>
<td>study (primary data collection)</td>
<td>Paper-based nomogram (see publication)</td>
<td>PSA level</td>
<td>Probability of positive prostate biopsy (percentage on graph)</td>
<td></td>
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<tr>
<td>CAPRI test</td>
<td>Optenberg, Clark et al., 1997&lt;sup&gt;153&lt;/sup&gt;</td>
<td>White or African American Males</td>
<td>Yes</td>
<td>Retrospective cross-sectional data</td>
<td>CAPRI model</td>
<td>Paper-based (see publication)</td>
<td>Age, Race, PSA level, DRE</td>
<td>Probability of positive prostate biopsy (odds ratio)</td>
</tr>
<tr>
<td>neURon</td>
<td>Kalra, Togami et al., 2003&lt;sup&gt;154&lt;/sup&gt;</td>
<td>Males</td>
<td>Yes</td>
<td>Retrospective case-control data from various samples</td>
<td>neURon computational software</td>
<td></td>
<td>Age, Race, Family history, International Prostate Symptom Score (IPPS), DRE, Complexed PSA, Total PSA</td>
<td>Probability of positive prostate biopsy (odds)</td>
</tr>
<tr>
<td>PCAT</td>
<td>Karakiewicz, Benayoun et al., 2005&lt;sup&gt;155&lt;/sup&gt;</td>
<td>Males</td>
<td>Yes</td>
<td>nested case-control study (primary data collection)</td>
<td>Web-based: <a href="http://www.prostatecancer.ca/assessment/Default.aspx">http://www.prostatecancer.ca/assessment/Default.aspx</a></td>
<td>Age, Total PSA, Percent free PSA, DRE</td>
<td>Risk of positive prostate biopsy (percent)</td>
<td></td>
</tr>
<tr>
<td>Name</td>
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<tr>
<td>Prostate Calculator</td>
<td>Porter, Gamito et al., 2005</td>
<td>Males</td>
<td>Yes</td>
<td>Cross-sectional data from Tyrol PSA Screening Project</td>
<td>Neural network</td>
<td>Web-based: <a href="http://www.prostatecalculator.org/trus.htm">http://www.prostatecalculator.org/trus.htm</a> l</td>
<td>Age, Total PSA, PSA density, Gland volume, DRE, TRUS</td>
<td>Probability of positive prostate biopsy</td>
</tr>
<tr>
<td></td>
<td>Suzuki, Komiya et al., 2006</td>
<td>Japanese Males</td>
<td>Cross-sectional data (primary data collection)</td>
<td>Paper-based nomogram (see publication)</td>
<td>Age, Total PSA, Percent free PSA, DRE, Prostate volume</td>
<td>Probability of positive prostate biopsy</td>
<td></td>
<td></td>
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<td></td>
<td>Chun, Steuber et al., 2006</td>
<td>Males</td>
<td>Prospective cohort data (primary data collection)</td>
<td>Paper-based nomogram (see publication)</td>
<td>Age, Total PSA, Percent free PSA, DRE, Sampling density</td>
<td>Probability of positive prostate biopsy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sunnybrook Prostate Cancer Risk Calculator</td>
<td>Nam, Toi et al., 2007</td>
<td>Males</td>
<td>Prospective cohort data (primary data collection)</td>
<td>Web-based: <a href="http://sunnybrook.ca/content/?page=OCC_prostateCalc">http://sunnybrook.ca/content/?page=OCC_prostateCalc</a></td>
<td>Age, Ethnicity, Family history of prostate cancer, Urinary symptoms, Percent free PSA, Total PSA, DRE</td>
<td>Probability of presence of prostate cancer (percent risk)</td>
<td></td>
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<td>Name</td>
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<tr>
<td>PancPro</td>
<td>Wang, Chen et al., 2007&lt;sup&gt;160&lt;/sup&gt;</td>
<td>Males and Females</td>
<td>Yes</td>
<td>National Familial Pancreas Tumor Registry</td>
<td>Computer-based</td>
<td></td>
<td>Family history of pancreatic cancer, Pancreatic cancer diagnosis, Age at diagnosis, Current age</td>
<td>Probability of developing pancreatic cancer</td>
</tr>
<tr>
<td>QCancer-Pancreatic</td>
<td>Hippisley-Cox, 2012&lt;sup&gt;161&lt;/sup&gt;</td>
<td>British Males and Females</td>
<td>Yes</td>
<td>QResearch database</td>
<td>Web-based: <a href="http://www.qcancer.org/pancreas/">http://www.qcancer.org/pancreas/</a></td>
<td></td>
<td>Age, Sex, Smoking status (y/n), Diabetes (y/n), Pancreatitis (y/n), Abdominal pain (y/n), Loss of appetite (y/n), Weight loss (y/n), Difficulty swallowing (y/n), Constipation (y/n), Heartburn (y/n)</td>
<td>Percent risk over 2 years</td>
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</table>

Table 9: Pancreatic Cancer
### Table 9: Diabetes

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<tr>
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<tr>
<td>Diabetes PhD</td>
<td>Eddy and Schlessinger, 2003</td>
<td>American Males and Females</td>
<td>UK Prospective Diabetes Study (UKDPS) Diabetes Prevention Program (DPP) Diabetes Control and Complications Trial (DCCT)</td>
<td>Archimedes Model</td>
<td>Web-based <a href="https://www.diabetesarchive.net/phd/profile/default.jsp">https://www.diabetesarchive.net/phd/profile/default.jsp</a></td>
<td>Age Sex Family history Race/Ethnicity Models disease progression</td>
<td>% 30-year risk of developing diabetes in statement</td>
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<tr>
<td>Name</td>
<td>Source Reference</td>
<td>Target Audience</td>
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<tr>
<td>DPoRT</td>
<td>Rosella, Manuel et al., 2010&lt;sup&gt;165&lt;/sup&gt;</td>
<td>Canadian Males and Females</td>
<td>Yes</td>
<td>National Population Health Survey (Canada)</td>
<td>Computer-based</td>
<td></td>
<td>Age, Height, Weight, Chronic conditions, Ethnicity, Immigration status, Educational achievement, Household income, Alcohol consumption, Physical activity</td>
<td></td>
</tr>
<tr>
<td>ARIC</td>
<td>Chambers, Folson et al., 2003&lt;sup&gt;167&lt;/sup&gt;</td>
<td>American Males and Females</td>
<td>Yes</td>
<td>Atherosclerosis Risk in Communities Study</td>
<td>Web-based: <a href="http://www.aricnews.net/riskcalc/html/RC1.html">http://www.aricnews.net/riskcalc/html/RC1.html</a></td>
<td></td>
<td>Age, Sex, Race, Smoking status (y/n), Total cholesterol, HDL, Systolic BP, Antihypertensives (y/n), Diabetes status</td>
<td>% risk over 10 years</td>
</tr>
<tr>
<td>AusDrisk</td>
<td>Schwartz, Li et al., 2009&lt;sup&gt;168&lt;/sup&gt;</td>
<td>Australian Males and Females</td>
<td>Adapted from FINRISK Study data</td>
<td>Adapteed FIND RISC model</td>
<td>Web-based: <a href="https://www.ausdrisk.com/register/">https://www.ausdrisk.com/register/</a></td>
<td></td>
<td>Age, Sex, Ethnicity, Place of birth, Family history of diabetes, History of high blood glucose, Antihypertensives, Smoking status, Dietary vegetable consumption, Physical activity, Waist</td>
<td>Risk score over 5 years Coloured graph</td>
</tr>
<tr>
<td>Name</td>
<td>Source Reference</td>
<td>Target Audience</td>
<td>External Validation</td>
<td>Data Sources</td>
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<tr>
<td>FINDRISC Score</td>
<td>Lindstrom, 2003</td>
<td>Finnish Males and Females</td>
<td>Yes</td>
<td>Finnish Diabetes Prevention Study</td>
<td>Paper-based (questionnaire)</td>
<td></td>
<td>Age, BMI, Waist, Antihypertensives, History of high blood glucose, Physical activity, Diet</td>
<td>Risk score over 10 years</td>
</tr>
<tr>
<td>German Diabetes Risk Score</td>
<td>Schulze, 2007</td>
<td>German Males and Females</td>
<td>Yes</td>
<td>EPIC-Postdam Study cohort</td>
<td>Web-based: <a href="http://drs.dife.de/en">http://drs.dife.de/en</a></td>
<td></td>
<td>Age, Sex, Abnormal blood sugar, Height, Waist, Family history, Physical activity, Diet, Alcohol, Smoking status (y/n)</td>
<td>% risk over 5 years</td>
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<tr>
<td>Diabetes Risk Score</td>
<td>Wilson, 2007</td>
<td>American Males and Females</td>
<td>Yes</td>
<td>Framingham Offspring Study</td>
<td>Paper-based (score sheet)</td>
<td></td>
<td>Age, Sex, BMI, Systolic BP, HDL cholesterol, Triglycerides, FPG</td>
<td>% risk over 8 years</td>
</tr>
<tr>
<td>Name</td>
<td>Source Reference</td>
<td>Target Audience</td>
<td>External Validation</td>
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<tr>
<td>Bozorgmanesh, 2011</td>
<td>Tehran Lipid and Glucose Study</td>
<td>Paper-based (score sheet)</td>
<td>Systolic BP</td>
<td>Family history</td>
<td></td>
<td></td>
<td>% risk over 6 years</td>
<td></td>
</tr>
<tr>
<td>Cambridge Diabetes Risk Score</td>
<td>Griffin, 2000</td>
<td>British Males and Females, 40-64 years old</td>
<td>Yes</td>
<td>Ely Study, Wessex Study</td>
<td>Paper-based (score sheet)</td>
<td>Age, Sex, BMI, Smoking status (y/n), Family history, Antihypertensives, Corticosteroids history</td>
<td>Absolute risk of diabetes</td>
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<tr>
<td>Balkau, 2008</td>
<td>DESIR study cohorts</td>
<td>Paper-based (score sheet)</td>
<td>BMI</td>
<td>Waist circumference, Smoking status (y/n), Hypertension (y/n), FPG, Family history</td>
<td></td>
<td></td>
<td>Probability of diabetes over 9 years</td>
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<tr>
<td>Simmons et al., 2007</td>
<td>EPIC-Norfolk study</td>
<td>Paper-based (equation and score sheet)</td>
<td>Age, Sex, Antihypertensives (y/n), BMI, Family history, Diet</td>
<td>Risk score for developing diabetes</td>
<td></td>
<td></td>
<td>At risk of diabetes (y/n)</td>
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<tr>
<td>Herman et al., 1995</td>
<td>Second National Health and Nutrition Examination Survey (NHANES II)</td>
<td>Paper-based (score sheet)</td>
<td>Age, Sex, Obesity, Race, Family history, Physical activity</td>
<td>At risk of diabetes (y/n)</td>
<td></td>
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<td>Name</td>
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<tr>
<td>Framingham Heart Model Risk Calculator 1991 and 1998 versions (ATP-III)</td>
<td>Wilson, D’Agostino et al., 1998</td>
<td>American Males and Females (Age 20-59)</td>
<td>Yes</td>
<td>Framingham Heart Study</td>
<td>Web-based</td>
<td>Framingham Heart Study Model</td>
<td>Male sex, Age, Systolic blood pressure, Antihypertensives (Y/N), Smoking status, Total cholesterol, HDL cholesterol, BMI, Diabetes mellitus (Y/N)</td>
<td>Risk Value tables for CHD, % Risk score 2/10 year CHD</td>
</tr>
<tr>
<td>UKPDS</td>
<td>Stevens, Kothari et al., 2001</td>
<td>White, Afro-Caribbean and Asian-Indian Patients with type II diabetes</td>
<td>Yes</td>
<td>UK Prospective Diabetes study</td>
<td>Web-based</td>
<td></td>
<td>Age at diagnosis of diabetes, Sex, Ethnicity, Smoking status, HbA, Systolic blood pressure, Total cholesterol : HDL cholesterol ratio</td>
<td>10-year % risk overlaid on bar graph, no legend</td>
</tr>
<tr>
<td>PROCAM</td>
<td>Assman, 1993</td>
<td>German Males and Females</td>
<td>Yes</td>
<td>Prospective Cardiovascular Munster Study</td>
<td>Web-based</td>
<td></td>
<td>Age, Sex, Diabetes status (y/n), Smoking status (y/n), Family history of anamnesis, Systolic BP, Weight, Height, Antihypertensives (y/n)</td>
<td>% risk over 10 years compared to average person, Risk dial</td>
</tr>
<tr>
<td>SCORE</td>
<td>Conroy, Pyorala et al., 2003</td>
<td>European Males and Females</td>
<td>Yes</td>
<td>Systematic Coronary Risk Evaluation Study</td>
<td>Web-based</td>
<td></td>
<td>Age, Sex, Total Cholesterol, Systolic BP</td>
<td>% risk over 10 years</td>
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<td>Name</td>
<td>Source Reference</td>
<td>Target Audience</td>
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<td>EthRisk (BRHS)</td>
<td>Brindle, May et al., 2006</td>
<td>British Males and Females</td>
<td>Yes</td>
<td>British Regional Heart Study</td>
<td>Modified Framingham model</td>
<td>Web-based: <a href="http://www.epi.bris.ac.uk/CVDethrisk/">http://www.epi.bris.ac.uk/CVDethrisk/</a></td>
<td>Ethnic Group, Age, Sex, Systolic BP, Total cholesterol, HDL cholesterol, Smoking status (y/n)</td>
<td>% risk over 10 years</td>
</tr>
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<td>Reynold's Risk Score</td>
<td>Ridker, Buring et al., 2007</td>
<td>American Females</td>
<td>Yes</td>
<td>Women’s Health Study</td>
<td>Web-based:</td>
<td>Age, Sex, Smoking status (y/n), Systolic BP, Total cholesterol, HDL, High-sensitivity C-reactive protein, Family history of MI</td>
<td>% risk over 10 years, Colour-coded bar graph</td>
<td></td>
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<tr>
<td>QRisk2</td>
<td>Hippisley-Cox, Coupland et al., 2007</td>
<td>British Males and Females</td>
<td>Yes</td>
<td>The Health Improvement Network (THIN) Database</td>
<td>Web-based:</td>
<td>Age, Sex, Smoking status (y/n), Diabetes status, Family history of heart disease, Antihypertensives, Postal code, BMI, Systolic BP, Total cholesterol, HDL, Ethnicity, Rheumatoid arthritis, status, Chronic Kidney disease, Atrial fibrillation</td>
<td>% risk over 10-years, Smiley face diagram</td>
<td></td>
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<tr>
<td>Name</td>
<td>Source Reference</td>
<td>Target Audience</td>
<td>External Validation</td>
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<tr>
<td>ASSIGN modified with Scottish Heart Health Extended Cohort (SHHEC) and Dundee Coronary Heart Risk-Disk</td>
<td>de la Iglesia, Potter et al., 2011&lt;sup&gt;184&lt;/sup&gt;</td>
<td>British Males and Females</td>
<td>Yes</td>
<td>THIN Database</td>
<td>ASSIGN model-</td>
<td>Web-based: <a href="http://assign-score.com/estimate-the-risk/">http://assign-score.com/estimate-the-risk/</a></td>
<td>Age, Sex, Smoking frequency, Family history of CVD, Diabetes status (y/n), Postal code, Total cholesterol, HDL cholesterol, Systolic BP</td>
<td>% risk over 10 years</td>
</tr>
<tr>
<td>CUORE</td>
<td>Palmieri, 2011&lt;sup&gt;183&lt;/sup&gt;</td>
<td>Italian Males and Females</td>
<td>Yes</td>
<td>Progetto CUORE</td>
<td>Computer-based</td>
<td>Age, Systolic BP, Diastolic BP, Total cholesterol, HDL cholesterol, Smoking status (y/n), Antihypertensives (y/n)</td>
<td>Risk score</td>
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<td>Source Reference</td>
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<tr>
<td>Harvard Disease Risk Index</td>
<td>Colditz and Rosner, 2000\textsuperscript{186}</td>
<td>Males and Females</td>
<td>Yes</td>
<td>SEER data</td>
<td>Web-based</td>
<td><a href="http://www.diseaseriskindex.harvard.edu/update/english/index.htm">http://www.diseaseriskindex.harvard.edu/update/english/index.htm</a></td>
<td>N/A</td>
<td>Verbal, overlaid on a seven-level colour gradient vertical bar graph from green as low risk to red as high risk</td>
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<td>Know Your Number/BioSignia Inc</td>
<td>Zhou, Hu et al., 2009\textsuperscript{187}</td>
<td>Males and Females</td>
<td>Yes</td>
<td>Framingham Heart Study, National Health and Nutrition Examination Survey, NHANES I</td>
<td>Computer-based</td>
<td>N/A</td>
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Appendix 3.1- Letter of Invitation

Dear Dr.____________,

Dr. Eva Grunfeld, Director of Research at the Department of Family and Community Medicine, and I are working on a project to develop a web-based health risk assessment tool for chronic diseases.

Health risk assessment tools (a.k.a. ‘risk calculators’) calculate an individual’s risk of developing a condition over a specified time period. You may be familiar with the Framingham Risk Calculator which was developed using cardiovascular risk data from the Framingham Heart Study.

One of the components of our project involves conducting one 1-hour focus group with 5-8 family physicians per group to learn more about how they view health risk assessment tools and what they perceive the benefits and limitations of implementing such tools in practice are. This would be followed by one-on-one appointments with 2-3 individual family physicians who have not participated in a focus group, at a later date, to conduct usability testing using a risk calculator that is currently in practice.

I would be interested in getting the perspective of family physicians from _______.

The busy practices of family physicians would likely prevent us from setting up an isolated focus group session, so we were hoping that we could hold the focus group at lunchtime rounds or a similar occasion. Would you know of any venues or opportunities during which members of the _______ family practice unit might be willing take part in this research?

We would provide an honorarium of $200 to your unit for future

We appreciate your help and look forward to hearing from you,

Sincerely

Teja Voruganti
Project Co-Investigator

Dr. Eva Grunfeld
Principal Investigator
Appendix 3.2- Recruitment Flyer (on letterhead)

STUDY TITLE: Family Physicians’ Perspectives on Computer-based Health Risk Assessment Tools for Chronic Diseases

PRINCIPAL INVESTIGATOR: Dr. Eva Grunfeld

Department of Family and Community Medicine
University of Toronto
500 University Avenue, 3rd floor
Toronto, Ontario M5G 1V7
Telephone: (416) 978-7951

ASSOCIATE INVESTIGATORS: Teja Voruganti, Dr. Donna Manca, Dr. John McLaughlin,
Dr. Mary Ann O’Brien and Dr. Sharon Straus

BACKGROUND:
Health risk assessment tools (a.k.a. ‘risk calculators’) calculate an individual’s risk of developing a condition over a specified period of time. You may be familiar with the Framingham Heart Attack Risk Calculator which was developed using risk data from the Framingham Heart Study.

As primary care practices are the ideal setting to implement chronic disease prevention strategies, health risk assessment tools could potentially play a larger role in mediating dialogue between family physicians and patients about the impact of lifestyle choices on chronic disease susceptibility through personalized risk estimation. Studies have shown that personalized information can have a greater impact on an individual’s motivation to make healthier lifestyle choices.

OBJECTIVES:
This study will seek family physicians’ views regarding awareness, perceived usefulness, feasibility and usability of health risk assessment tools for chronic diseases in clinical practice.

OPPORTUNITY FOR PARTICIPATION:
Focus group: We would like to hold a focus group with 7-8 family physicians from the Women’s College Hospital primary care practice unit.

Length: approx. 1 hour in length
Discussion Topic: The usefulness and feasibility of implementing health risk assessment tools for chronic diseases in clinical practice. A two-page survey will also be filled out.
Date, Time and Location: A time and location will be set that is convenient for all participants; possibly during a lunch hour. Refreshments will be provided.

Usability study: We would also like to conduct individual usability studies, distinct from the focus groups, with 2-3 family physicians using a currently available online health risk assessment tool.

Length: approx. ½ hour in length
Involvement: Use an online health risk assessment tool to complete a series of prompted tasks. A two-page survey will also be filled out.
Date, Time and Location: A time and location that is convenient for each participant will be arranged.

IMPLICATIONS:
We hope to use the views gathered from your participation to develop a health risk assessment tool for multiple chronic diseases that is better suited to family physicians.

COMPENSATION:
Your family practice unit will be compensated with a $200 honorarium for participation in a focus group and with $100 for each usability study participant. Thank you for your consideration. If you have any questions, please contact the study coordinator, Teja Voruganti, at teja.voruganti@utoronto.ca or (416) 978 4242.
Appendix 3.3- Demographic and Opinion Survey

Study Title: Family Physicians’ Perspectives of Computer-based Health Risk Assessment Tools for Chronic Diseases

Principal Investigator: Dr. Eva Grunfeld
Department of Family and Community Medicine
University of Toronto
500 University Avenue, 3rd floor
Toronto, Ontario M5G 1V7
Telephone: (416) 978-7951

Co-Investigators: Teja Voruganti, Dr. Donna Manca, Dr. John McLaughlin, Dr. Mary Ann O’Brien and Dr. Sharon Straus

Thank you for participating in this study. Health risk assessment tools calculate an individual’s risk of developing a disease over a period of time using risk prediction models derived from epidemiological data of disease incidence. Using information about an individual’s risk factors, risk prediction can present individuals with personalized risk information.

This survey asks for demographic information and your opinions about computer-based health risk assessment tools. Please complete it now and return it to the study investigator.

1. Age ____________ (years)                       2. Sex: □ Female    □ Male

3. What year did you graduate from medical school?       ______/_______/______
Year       Month       Day

4. Where is your practice located?  ____________________

5. What is the approximate size of your patient roster?  ____________________

6. Do you receive support from nurse practitioners or allied health professionals in your practice? (Please circle one)
   Yes    No

For questions 7-14, please circle the number that best corresponds to your opinion.

7. How comfortable are you using computers?

   Not Comfortable    Somewhat Comfortable    Extremely Comfortable
   1                   2                     3                     4                     5

(Please turn over)
8. In your opinion, how useful are computer-based health risk assessment tools for patients?

Not Useful  Somewhat Useful  Very Useful

1  2  3  4  5

9. In your opinion, how useful are computer-based health risk assessment tools for family physicians?

Not Useful  Somewhat Useful  Very Useful

1  2  3  4  5

10. How often do you use instruments like health risk assessment tools in your practice to provide information to patients?

Not Often  Sometimes  Very Often

1  2  3  4  5

11. How likely are you to use health risk assessment tools with patients during appointments?

Not Likely  Somewhat Likely  Very Likely

1  2  3  4  5

12. How likely are you to discuss risk assessment results with a patient during an appointment?

Not Likely  Somewhat Likely  Very Likely

1  2  3  4  5

(Please continue on next page)
13. In your opinion, will computer-based health risk assessment tools improve patient flow?

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<tr>
<th>Not Likely</th>
<th>Somewhat Likely</th>
<th>Very Likely</th>
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14. Would you be more likely to use a risk assessment tool if it was embedded in your Electronic Medical Record (EMR) system than if it was available as a stand-alone program?

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<th>Less Likely</th>
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<th>More Likely</th>
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</table>

15. Are you aware of any of the following computer-based health risk assessment tools? (Please check all that apply)

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>
| ☐   | ☑  | Gail Model/Breast Cancer Risk Assessment Tool
| ☐   | ☑  | Framingham Heart Calculator/Cardiovascular Disease Risk Assessment Tool
| ☐   | ☑  | FRAX/Fracture Risk Assessment Tool
| ☐   | ☑  | Prostate Cancer Prevention Trial Risk Calculator
| ☐   | ☑  | Liverpool Lung Project Risk Assessment Tool
| ☐   | ☑  | Other: ____________________________________________________

(Please list)

| ☐   | ☑  | Not aware of any

Thank you. Please return this form to the study investigator.
Appendix 3.4- Focus Group Guide

Study Title: “Family Physicians’ Perspectives on Computer-based Health Risk Assessment Tools for Chronic Diseases”

PRINCIPAL INVESTIGATOR: Dr. Eva Grunfeld
Department of Family and Community Medicine
University of Toronto
500 University Avenue, 3rd floor
Toronto, Ontario M5G 1V7
Telephone: (416) 978-7951

ASSOCIATE INVESTIGATORS: Teja Voruganti
Dr. Donna Manca
Dr. John McLaughlin
Dr. Mary Ann O’Brien
Dr. Sharon Straus

Introduction and Disclaimer

Thank you for agreeing to participate in our study aimed at investigating family physicians attitudes on the use of health risk assessment tools in primary care settings.

Please sign the written consent form now. You will be requested to complete a short demographic and opinion survey at the conclusion of the focus group. Please remember that your participation in today’s study is entirely voluntary. Today’s group discussion will be led by co-investigator, Teja Voruganti. Dr. O’Brien, will be assisting with note-taking but not participating in discussion. The approximate duration of this focus group is one hour.

As a reminder, today’s session is being audiotaped. During the discussion, please refer to yourself by your first name when speaking so that we can identify the speakers on the audio recording. No individual names will appear in the typed record.

Your opinions gathered here today will be compiled and used to develop a framework of family physicians’ perspectives of chronic disease health risk assessment tools.

The discussion is expected to last one hour long. For your time here, a $200 honorarium will be given to your family practice unit.

Thank you, your participation is appreciated.
Part A- Physician Awareness

Patients often come to their family physician with questions about their chance of getting a chronic illness in the future.

1. As a family physician, how do you engage in risk assessment with your patients about chronic disease risk factors?
   Prompts: decision aids used, specificity of the discussion (numerical or verbal in nature, what kinds of health problems, how often)

   If necessary, hypothetical scenario: White female, aged 42 comes for annual check-up, has heard a friend just had a heart attack and is interested in knowing her risk of having one.

2. How much time do you spend with a patient in the context of pre-screening for chronic diseases?

3. Have you heard of any computer-based tools developed to assess chronic disease risk factors?
   Prompts: risk calculators like Framingham risk calculator, Gail model, paper-based, computer-based

4. Have you used any computer-based tools in your practice?
   Prompts: which tools, how are they used

Part B- Usefulness of Tools

1. What is your opinion about computer-based tools?
   Prompts: likes, dislikes, are they useful, do they take too long to use, how do you use it (do you use it yourself or with the patient during an appointment?), helpful?

   If necessary:
   Many calculators exist online or in paper format and are used in a variety of contexts. A typical risk calculator, like the Framingham Risk Calculator available online, requires you to input a patient’s characteristics like age, family history, diet etc. and, using data from previous studies on risk factors and disease incidence, calculates an individual’s risk value, such as “a risk of 1 in 1000”.

   If necessary:
   If an individual is obese, weight can influence cardiovascular disease, diabetes and cancer. However, currently available tools do not account for the influence of risk factors on multiple diseases or the effect of risk factors on other risk factors.

   Continue:
   We would like to develop a computer-based, composite health risk assessment tool that integrates multiple risk factors, including comorbidities, to compute the risk of a single disease.
This would be used as a pre-screening tool for chronic diseases such as diabetes, cardiovascular disease and cancer.

2. What is your opinion about the need for such a “super tool”?
   Prompts: likes, dislikes, helpfulness, focussed discussion? Multiple disease risks?

3. How do you see yourself using such a tool?
   Prompts: used just by physician or with a patient, allied health professional

   If necessary:
   Our aim is for this tool to be used with patients to help convey specific, individualized risk information, and recommendations that may motivate individuals to make better lifestyle choices.

4. Do you think this tool will help you clarify lifestyle choices and their impact on disease risk for your patient?

5. Do you think such a tool would help with shared decision-making?
   Prompts: decisions to screen, trust the information from risk calculators? Utility vs. harm, usefulness despite a lack of interventions to reduce risk

Part C- Feasibility of Tools

1. Would your practice be ready to implement the use of a composite tool (i.e. one that integrates multiple risk factors)?
   Prompts: do you think such a tool is practical, does your practice have the facilities (i.e. computer in each exam room) to make use of this tool

2. How do you think having such a tool would affect the amount of time you spend with a patient? If necessary:

3. What barriers do you perceive might prevent implementing a health risk assessment tool in your practice?
   Prompts: time, clinical facilities for prevention

4. If it was available, would you use it?

Closing

Thank you for participating in this study. Please remember that everything that was said here today is confidential. Please take the remaining time to complete the demographic survey and then when you leave, please return the survey and consent form to me.

Your participation today will help us better understand the usefulness and feasibility of health risk assessment tools in primary practice.
Appendix 3.5- Timeline for Focus Group Discussion

Study Title: “Family Physicians’ Perspectives on Computer-based Health Risk Assessment Tools for Chronic Diseases”

PRINCIPAL INVESTIGATOR: Dr. Eva Grunfeld
Department of Family and Community Medicine
University of Toronto
500 University Avenue, 3rd floor
Toronto, Ontario M5G 1V7
Telephone: (416) 978-7951

ASSOCIATE INVESTIGATORS: Teja Voruganti
Dr. Donna Manca
Dr. John McLaughlin
Dr. Mary Ann O’Brien
Dr. Sharon Straus

Focus Group Timeline Expected Time

Obtain written consent from each participant 5 minutes
Introduction 2 minutes
Part A- Physician Awareness 10 minutes
Part B- Usefulness of Tools 15 minutes
Part C- Feasibility of Tools 15 minutes
Survey 10 minutes
Closing Remarks 3 minutes
Appendix 3.6- Usability Testing Structured Interview Guide

Study Title: “Family Physicians’ Perspectives on Computer-based Health Risk Assessment Tools for Chronic Diseases”

Associate Investigators: Teja Voruganti, Dr. Donna Manca, Dr. John McLaughlin, Dr. Mary Ann O’Brien and Dr. Sharon Straus

Principal Investigator: Dr. Eva Grunfeld

Usability Testing Interview Guide

Introduction and Disclaimer

Thank you for agreeing to participate in our study aimed at evaluating the usability of a chronic disease health risk assessment tool. I, Teja Voruganti, will be your study leader and will conduct this usability test with you. ________ will be taking notes but not participating in the usability test. If you have any questions, please don’t hesitate to ask me.

Please sign the informed written consent form. Please remember that your participation in today’s study is entirely voluntary. You are free to withdraw at any time. This usability test should take approximately ½ an hour. You will be requested to complete a two-page demographic and opinion survey at the conclusion of this usability test.

As a reminder, today’s session is being audiotaped. A transcript will be made of the audio recording and used only for data analysis. No individual names will appear in the typed record. Points that you make may be quoted in future reports or publications that come from this study. If you do not wish to be quoted, please inform the study investigator.

Your opinions gathered here today will be compiled and used to develop a framework of family physicians’ perspectives of chronic disease health risk assessment tools. Your family practice unit will be compensated with $100 for your participation in today’s study.

Again, thank you, your participation is appreciated.
Instructions

The Framingham Coronary Heart Disease Risk Assessment Tool is an example of a computer-based risk calculator. Health risk assessment tools, which include risk calculators, compute an individual's risk of developing a condition over a specific time period. Risk calculators project an individual's risk based on study data of risk factors and incidence of disease. In this calculator, data from the Framingham Heart Study is used.

We will present you with a hypothetical case scenario using data from an electronic health record system and ask you to complete a series of tasks.

As you complete the tasks, we would like you to “think aloud”, describing what you are doing. If there are things that you like, dislike, or feel you are not able to do, please say so. Please be very specific when describing your motions on screen.

Since the main objectives of this study are to examine risk calculators, please focus your comments on the usability of the risk calculator, not the electronic health record. Your perspective will help to design a health risk assessment tool that is tailored to family physicians like you.

If you have any questions, please let me know.

Hypothetical Scenario

A patient comes in for an annual check-up. You ask about health. He tells you that he tries to maintain good physical health and diet. He tells you that his father suffered a mild heart attack at age 68 and was afterwards diagnosed with coronary heart disease. He would like to know his risk of developing the disease himself.

Prompt: Please open OSCAR on the computer desktop. This is your electronic medical record (EMR) system. It stores your patient medical records, billing information and scheduling information. Please log in by entering the username and passwords as they appear on-screen.

Prompt: You have a patient booked currently named Mark Johnson. Please find the appointment. Select the letter ‘E’ (for Encounter) to the right of the name. Please take a minute to examine the patient profile on the right and left sidebars of the screen.

Prompt: In the center of the screen, click the drop-down menu entitled “Calculators” and select Framingham/UKDPS Search Engine. Your task is to calculate your patient’s Framingham risk score based on the July 19 lab results.
**Prompt:** Please open this lab report under documents on the left side of the screen. Using this information, please enter your patient’s information into the risk calculator. Press calculate. What is your patient’s 10-year risk of coronary heart disease?

You and the patient read the screen. He tells you that he actually no longer smokes. He asks how this information will affect his risk.

**Prompt:** Please calculate his new risk and explain how his risk has changed. Please describe your experience using the interface between the calculator and the patient record. Please describe your opinion of the visual interface for communicating the risk information to you.

**Prompt:** The patient appointment is now finished. Please close all the windows and return to the desktop screen. Please describe your experience finding and exiting the risk calculator and EMR.

**Prompt:** Thank you. That concludes this scenario.

**Closing**

Thank you for participating in this study. Please remember that everything that was said here today is confidential.

Your participation today will help us better understand the usability of health risk assessment tools in primary practice.
Appendix 3.7- Screen-shot Framingham Risk Calculator on OSCAR EMR

**Figure 1- Risk Factor Input Screen**

![Image of Risk Factor Input Screen]

**Figure 2- Results Screen**

![Image of Results Screen]

You are using the Framingham Risk Calculator, intended for patients with no history of diabetes. Is the patient diabetic?

- **Your Details**
  - This calculator is for use only in primary prevention, and should not be used for individuals with known heart disease.
  - Age: [ ]
  - Sex: [ ] Male, [ ] Female
  - Systolic BP: [ ] mmHg
  - Smoker? [ ] Yes, [ ] No, or ex-smoker
  - Current Smoker: [ ]
  - Total Cholesterol: [ ] mmol/L, [ ] HDL Cholesterol: [ ] mmol/L
  - [Calculate]

**Your Results**
Appendix 3.8- Coding Guide

1) Logistics of Implementation- statements regarding the planning and organization of incorporating risk assessment tools into clinical practice
   1A) EMR Integration- statements regarding the incorporation of risk tools into EMR
   1B) Smartphone Integration- statements regarding the incorporation of risk tools on smart phones
   1C) Readiness- statements regarding the readiness of practices to implement risk assessment tools
   1D) Patient self-check in- implementing self-check in kiosks for patients in waiting rooms or at home

2) Physicians’ Current Practices- what is done at present by physicians in their clinical practice, within the context of risk assessment
   2A) Assessing patient risk- statements regarding the evaluation of a patient’s risk at a typical appointment; procedures, practices, frequency etc.
   2B) Current methods of communicating risk- how do physicians convey risk information to their patients
   2C) Opportunistic risk assessment- statements regarding the assessment of patient risk whenever the occasion arises; for example, if a patient, who hasn’t been to the doctor in a while, comes in with a specific request
   2D) Users of risk assessment tools in practices currently- who uses the tool in clinical practice at present
      2Di) Patient using the tools alone
      2Dii) Physician using the tool with a patient
      2Diii) Physician using tools alone
      2Div) Employers using tools to assess employee health

3) Practice Level - specifics about an individual clinical practice
   3A) EMR- statements regarding the EMR system at the level of a clinical practice, impacting all physicians within that practice
      3Ai) EMR Availability- are EMR systems available in the practice
      3Aii) EMR Integration- are risk assessment tools (in general) integrated into the EMR system; is there the ability to complete a risk calculation within the EMR system

4) Risk Assessment Tools- statements regarding the assessment of risk with a risk calculation instrument
   4A) Current Tools- statements regarding risk assessment tools that are currently used
      4Ai) Physicians’ Opinions on current tools
         4Aia) Positive opinions- regarding current tools
         4Aib) Negative opinions- regarding current tools
4Aic) Considerations- impartial thoughts about tools

4Aii) Tools currently used- statements regarding what tools are currently used
  4Aii(a) EMR-integrated risk assessment tools
  4Aii(b) Web-based risk assessment tools
  4Aii(c) Stand-alone computer-based tools
  4Aii(d) Paper-based tools
  4Aii(e) Phone-based tools

4B) Super Tool
  4Bi) Physicians’ Opinions on super tool
      4Bia) Recommendations- suggestions or desires for super tool
      4Bib) Positive opinions- regarding super tool
  4Bic) Negative opinions- regarding super tool
  4Bid) Considerations- impartial thoughts to take into account regarding super tool
  4Bii) Willingness to use super tool
  4Biii) Challenges discussing a tool yet to be developed

4C) Past Tools- statements regarding risk assessment tools no longer used

4D) Physician Awareness of Risk Assessment Tools- statements regarding what risk assessment tools participants know about

4E) Frequency of use of risk assessment tools- how often are risk assessment tools used in practice (speaking either generally or specifically)

5) System-level- Statements regarding risk assessment tools in the healthcare system

  5A) Change in the annual physical examination- a notion that discussed the changes of annual physical exams to annual prevention and screening exams; less touching, less physical measurement. Has implications for risk assessment with tools as they may become much more important to this type of annual checkup.

  5B) Risk calculators and clinical practice guidelines- several clinical practice guidelines have mentioned and indicate use of risk calculators to compute risk cut-offs for making screening or intervention decisions.

  5C) Risk communication requires training- risk communication requires knowledge and understanding of statistics and current research. Some physicians find this process difficult without assistance. It was also expressed that more training on communicating risk information to patients is required in school.
Appendix 3.9 – Sample Informed Consent Form/Information Sheet and Approval Notices

**CONSENT TO TAKE PART IN A RESEARCH STUDY**

**Participant Information**

**STUDY TITLE:** Family Physicians’ Perspectives of Computer-based Health Risk Assessment Tools for Chronic Diseases

**PRINCIPAL INVESTIGATOR:** Dr. Eva Grunfeld
Department of Family and Community Medicine
University of Toronto
500 University Avenue, 3rd floor
Toronto, Ontario M5G 1V7
Telephone: (416) 978-7951

**ASSOCIATE INVESTIGATORS:** Teja Voruganti
Dr. Donna Manca
Dr. John McLaughlin
Dr. Mary Ann O’Brien
Dr. Sharon Straus

**STUDY SPONSOR:** Population Studies Network, Cancer Care Ontario

*NOTE: This is a sample consent form. Focus group or usability testing-specific information will be indicated with ‘[ ]’ square brackets. Actual consent form will only include information relevant to the data collection method used.*
PART A

RESEARCH STUDIES- GENERAL INFORMATION

1. INTRODUCTION

You have been invited to take part in a research study. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not.

This study is being conducted to investigate family physicians’ views on the usefulness and feasibility of health risk assessments tool for chronic diseases. This information will help you decide if you want to be part of the study or not. It tells you what will happen and about any inconveniences or risks you may encounter. There is also a complete description of the study.

Please read this carefully. Take as much time as you like. Mark anything you don’t understand, or what could be explained better. After you have read it, please ask questions about anything that is not clear.

The researcher will:

- Discuss the study with you
- Answer your questions
- Be available during the study to deal with problems and answer questions

PART B

EXPLAINING THIS STUDY

2. WHY IS THIS STUDY BEING DONE?

Research studies are done in order to gather new information that may help other people with similar situations to yours.

In this study, we want to determine family physicians’ awareness and perspectives on the usefulness and feasibility of computer-based health risk assessment tools for chronic diseases.

3. WHY I AM BEING ASKED TO JOIN THIS STUDY?

You are being asked if you would like to take part in this research study because you are family physician.

4. HOW LONG WILL I BE IN THIS STUDY?

You will participate in a [focus group/usability test] that is expected to last [one hour/half an hour].

5. HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

A total of sixty family physicians will participate in this study from primary care practices in Toronto, Ontario and Edmonton, Alberta. Participants will be asked to participate in either a
6. HOW IS THIS STUDY BEING DONE?

This study is being conducted in Toronto, Ontario and Edmonton, Alberta. The study involves participation in a [focus group/usability testing interview]. You are being asked to participate in a [focus group with family physicians from your practice location/usability study]. The discussion will be led by an experienced researcher.

The [discussions/session] will be tape-recorded. [Please refer to yourself by your first name during the discussion. This will maintain your anonymity in the audio recording]. Your remarks and comments will remain confidential. No names will appear on typed transcripts.

7. WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you want to be in the study, you need to sign this consent form. You will be asked to participate in a [focus group discussion/usability study]. [Discussion topics will address family physician awareness and perceived usefulness and feasibility of health risk assessment tools for chronic diseases/You will participate in a usability test in which you will be asked to complete a series of tasks using the Framingham Heart Risk Calculator, an online tool used to calculate an individual’s risk of having a heart attack].

8. ARE THERE RISKS TO THIS STUDY

There are no identifiable risks to this study. You do not have to answer those questions that you find uncomfortable.

9. WHAT HAPPENS AT THE END OF THIS STUDY?

Please do not discuss the contents of this [focus group/usability test] so as to maintain the confidentiality of all that was said.

Points that you make in [focus group discussions/usability studies] may be used verbatim in study reports and/or publications, quoted anonymously. By signing this consent form, you authorize us to use quotes anonymously for reports or publications that result from this study. If you do not wish for things you say to be used in future reports/publications, please let the study investigator know.

The results of this study will be made available to the public (i.e. through journal publication and presentations to health professionals). However, your identity will never be known by anyone outside of the research group.

10. WHAT ARE MY RESPONSIBILITIES?

As a participant you will be required to:

- Sign consent form
- Participate in [focus group/usability study]
Follow the directions of the study investigator
Complete the demographic and opinion survey

11. CAN I BE TAKEN OUT OF THE STUDY WITHOUT MY CONSENT?

Yes. If you are having difficulty taking part in the [focus group discussion/usability test], the study leader will recommend that you stop participating.

12. WILL IT COST ME ANYTHING?

Compensation
Your family practice unit will be given a $200 honourarium for use in future research-related activities if you are a participant in a focus group. A $100 honourarium will be provided to your family practice unit for your participation in a usability testing study.

Research Related Injury
If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your participation in the study and agree to participate as a subject. In no way does this waive your legal rights nor release the Principal Investigator, the research staff, the study sponsor or involved institutions from their legal and professional responsibilities.

14. WHAT ABOUT MY RIGHTS TO PRIVACY?

Your personal information will be confidential. Your name will not be used at all in the study records. Instead, you will be identified only with your first name and assigned participant identification number. If the results of this study are presented in a meeting, or published, nobody will be able to tell that you were in the study.

[Although it cannot completely guarantee that other participants in focus group discussions will maintain confidentiality, your confidentiality during the focus group discussion will be protected as much as possible. At the beginning of the focus group discussions, a request that other participants refer to you by your first name will be made. This will be done to respect your privacy and that everything that is said during the discussion remains confidential.]

The [discussion groups/usability test] will be tape-recorded. Your remarks and comments will remain confidential. Some of your quotations may be used in publications, but your name will not be used. Any quotations will remain anonymous.

Audio recordings and transcripts will be kept for five years in a secure area such as a locked file cabinet and office. Only the research staff will have access to them.

Points that you make in [focus group discussions/usability test] may be used anonymously in study reports and/or publications. By signing this consent form, you authorize us to use quotes anonymously for reports or publications that result from this study. If you do not wish to allow what you say in this group to be published in study reports or publications, please let the study investigator know.
The representatives from the following organizations may inspect and receive information about the study to make sure all of the information is correct. All of these people have a professional responsibility to protect your privacy.

These groups are:

- University of Toronto Research Ethics Board
- Toronto Academic Health Sciences Network (TAHSN) Research Ethics Board
- Markham-Stouffville Hospital Research Ethics Board
- University of Alberta Human Research Ethics Board

### 15. WHAT IF I WANT TO QUIT THE STUDY?

If you choose to participate and later decide to change your mind, you can say so and stop participating at any time. A decision to stop being in the study will not affect your employment, professional or personal relationships. All data collected up to the date you withdraw your consent will remain in the study record.

### 16. DECLARATION OF FINANCIAL INTERESTS

The sponsor (Cancer Care Ontario) is paying the study doctor and/or the study doctor’s institution to conduct this study. The amount of this payment is sufficient to cover the costs of conducting the study.

### 17. WHAT ABOUT QUESTIONS OR PROBLEMS

For further information about this study, call Dr. Eva Grunfeld. Dr. Grunfeld is in the Principal Investigator and is in charge of this study at this hospital. Dr. Grunfeld can be reached at (416) 978-7951.

Your Study Coordinator is Mr. Teja Voruganti. Should you have any questions or concerns, please contact the study coordinator at: (416) 978-4242.

### 18. WHAT ARE MY RIGHTS?

After you have signed this consent form, you will be given a copy. Participation in this study is entirely voluntary. You have the right to withdraw from this study at any time. Should you wish to withdraw from this study, all data collected up to the date you withdraw your consent will remain in the study record. You will not be asked to disclose any identifying information. All reasonable effort will be made to ensure that what you say in this study remains confidential and anonymous. Some things that you say as a participant may be anonymously quoted in reports or publications that come from this research. Should you not want your quotes to be used, please let the study coordinator know at any time prior, during or after the study.

In the next part you will be asked if you agree (consent) to join this study. If the answer is “yes”, you will need to sign the form.
PART C.

19. CONSENT FORM AND SIGNATURES

I have read all the information about this study, which is called:
Family Physicians’ Perspectives of Computer-based Health Risk Assessment Tools for Chronic Diseases

I have been given the opportunity to discuss it. All my questions have been answered. I am satisfied with the answers.

This signature on this consent form means that I agree to take part in this study.

__________________________________              ________________________              _____/___/____
SIGNATURE OF PARTICIPANT              NAME (PRINTED)             day  month year*

__________________________________        _________________________               _____/___/____
WITNESS TO PARTICIPANT                  NAME (PRINTED)                                  day  month year*
SIGNATURE

__________________________________          ________________________                        _____/___/____
SIGNATURE OF INVESTIGATOR                      NAME (PRINTED)                          day month year*

__________________________________________       ________________________                        _____/___/____
SIGNATURE OF PERSON                                  NAME (PRINTED)                          day month year*
CONDUCTING CONSENT DISCUSSION

*Note: Please fill in the dates personally

I WILL BE GIVEN A SIGNED COPY OF THIS CONSENT FORM.

Thank you for your time and patience!
PROTOCOL REFERENCE # 26877

September 26, 2011

Dr. Eva Grunfeld  
DEPT OF FAMILY & COMMUNITY MEDICINE  
FACULTY OF MEDICINE

Mr. Teja Voruganti  
DEPT OF FAMILY & COMMUNITY MEDICINE  
FACULTY OF MEDICINE

Dear Dr. Grunfeld and Mr. Teja Voruganti,

Re: Your research protocol entitled, "Family Physicians' perspectives on computer-based health risk assessment tools for chronic diseases"

ETHICS APPROVAL

Original Approval Date: September 26, 2011  
Expiry Date: September 25, 2012  
Continuing Review Level: 1

We are writing to advise you that the Health Sciences Research Ethics Board (REB) has granted approval to the above-named research protocol under the REB’s delegated review process. Your protocol has been approved for a period of one year and ongoing research under this protocol must be renewed prior to the expiry date.

Any changes to the approved protocol or consent materials must be reviewed and approved through the amendment process prior to its implementation. Any adverse or unanticipated events in the research should be reported to the Office of Research Ethics as soon as possible.

Please ensure that you submit an Annual Renewal Form or a Study Completion Report 15 to 30 days prior to the expiry date of your current ethics approval. Note that annual renewals for studies cannot be accepted more than 30 days prior to the date of expiry.

If your research is funded by a third party, please contact the assigned Research Funding Officer in Research Services to ensure that your funds are released.

Best wishes for the successful completion of your research.

Yours sincerely,

Judith Friedland, Ph.D.  
REB Chair

Daniel Gyewu  
REB Manager
September 13, 2011

Mr. Teja Voruganti  
Department of Family & Community Medicine  
University of Toronto  
Room 347  
500 University Avenue, Toronto,  
ON MSG 1V7

Dear Mr. Voruganti:

Re: Family Physicians’ Perspectives of Health Risk Assessment Tools for Chronic Diseases

The Research Ethics Board of Markham Stouffville Hospital has reviewed and approved the above study on **September 13, 2011**.

The quorum for approval did not include any member associated with this project.

If during the course of the research, changes in the approved submission or any new information that must be considered with respect to the study, these should be brought to the immediate attention of the Research Ethics Board.

All members of the Board wish you success in your research endeavours and look forward to continued follow-up regarding progress with this study.

Yours sincerely,

[Signature]

Dr. Henry Solow  
Chair, Research Ethics Board

HS/jb

c.  
Dr. Jane Philpott
Notification of REB Initial Approval

Date: 07 September, 2011
To: Dr. Eva Grunfeld
Re: 2011-0038-E
Family Physicians’ Perspectives of Health Risk Assessment Tools for Chronic Disease.
Sponsor: Population Studies Research Network - Cancer Care Ontario -
REB Review Type: Expedited
REB Approval Date: 07 September, 2011
REB Expiry Date: 07 September, 2012
Documents Approved:
- TAHSN Application Form - Initial REB Application Form ver: 08/30/2011
- Protocol - Detailed study Protocol ver: 
- Budget - Detailed study Budget ver: 
- Letter of Invitation - Letter of Invitation ver: 
- Flyer - Study Recruitment Flyer ` ver: 
- Survey - Focus Group Demographic Survey ver: 
- Interview Guides - Semi-structured Group interview guide ver: 
- Outline - Timeframe for Focus Group discussion ver: 
- Survey - Usability Testing Demographic Survey ver: 
- Interview Guides - Usability Testing Structured Interview Guide ver: 
- Consent Form - Informed Consent form/Information Sheet ver: 08/20/2011
- funding letter - Confirmation of Funding ver: 03/31/2011

The above named study has been reviewed and approved by the Women’s College Hospital (WCH) Research Ethics Board. WCH retains the authority to deny the implementation of REB-approved research protocols for reasons other than research ethics; such reasons may be administrative, programmatic, or resource-based in nature. Any additional approvals must be coordinated through the VP, Research Office prior to initiating research.

The quorum for approval did not involve any member associated with this project. If, during the course of the research, there are any serious adverse events, confidentiality concerns, changes in the approved project, or any new information that must be considered with respect to the project, these should be brought to the immediate attention of the WCH Research Ethics Board. In the event of a privacy breach, you are responsible for reporting the breach to the WCH Research Ethics Board and the WCH Corporate Privacy Officer (in accordance with Ontario health privacy legislation - Personal Health Information Protection Act, 2004). Additionally, the WCH Research Ethics Board requires reports of inappropriate/unauthorized use of the information.

If the study is expected to continue beyond the expiry date, you are responsible for ensuring the study receives re-approval. The WCH Research Ethics Board must be notified of the completion or termination of this study and a final report provided. As the Principal Investigator, you are responsible for the ethical conduct of this study.

Approval of this study by the WCH Research Ethics Board entails that this study complies with current legislation as outlined in the Ontario Personal Health Information Protection Act (PHIPA) and all policies and guidelines established by Women’s College Hospital.

Sincerely,

[Signature]

Dr. Miriam Shuchman, Chair, Women’s College Hospital Research Ethics Board
## Approval Form

<table>
<thead>
<tr>
<th>Date:</th>
<th>November 7, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator:</td>
<td>Donna Manca</td>
</tr>
<tr>
<td>Study ID:</td>
<td>Pro00025459</td>
</tr>
<tr>
<td>Study Title:</td>
<td>Family Physicians’ Perspectives on Computer-based Health Risk Assessment Tools for Chronic Diseases</td>
</tr>
<tr>
<td>Approval Expiry Date:</td>
<td>November 5, 2012</td>
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Thank you for submitting the above study to the Health Research Ethics Board - Health Panel. Your application, including revisions received October 31 and November 6, 2011, has been reviewed and approved on behalf of the committee.

A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. If you do not renew on or before the renewal expiry date, you will have to re-submit an ethics application. Approval by the Health Research Ethics Board does not encompass authorization to access the patients, staff or resources of Alberta Health Services or other local health care institutions for the purposes of the research.

Enquiries regarding Alberta Health Services administrative approval, and operational approval for areas impacted by the research, should be directed to the Alberta Health Services Regional Research Administration office, #1800 College Plaza, phone (780) 407-6041.

Sincerely,
Doug Gross, Ph.D.
Associate Chair, Health Research Ethics Board - Health Panel

*Note: This correspondence includes an electronic signature (validation and approval via an online system*