Patient Driven Clinical Decision Support Instrument for Predicting Cardiovascular Complications of Non-Cardiac Surgery - Creation, Implementation, and Evaluation

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Dedication

अज्ञानतिमिरान्धस्य ज्ञानाञ्जनशलाकया।
चक्षुरुन्मीलितं येन तस्मै श्रीगुरवे नमः॥

"My salutations to the Guru, who removes the darkness of ignorance from our blind (inner) eyes by applying the collyrium of their light of knowledge. By whom, our (inner) eyes are opened; Salutations to that Guru" - ||Guru Gita||

I lovingly dedicate this dissertation to my Gurus:
My parents, Sharda & Chander Mohan Manaktala; wife, Deepika; and advisor, Dr. Terrence Adam, who through their constant nurturing, support, and dedication, have shaped the course of my being.

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Chapter 1

1.1 Introduction

An estimated 6 million people in the United States undergo non-cardiac surgeries annually in the United States. Approximately one-fourth of these procedures include major intra-abdominal, thoracic, vascular, and orthopedic procedures known to be associated with significant perioperative cardiovascular morbidity and mortality (1). Results from several health quality improvement studies have concluded that patients with postoperative complications had a significantly higher chance of incurring readmission and its associated costs during readmission than patients without a complication and concluded that efforts to reduce postoperative readmissions should begin by focusing on postoperative complications (2-4). These facts underscore the need to endorse a standardized and evidenced based approach to pre-operative patient evaluation that provides an opportunity for any necessary medical interventions to stabilize patients prior to surgery.

About 51.4 million surgical procedures are performed every year in United States. Internists and family physicians are routinely consulted to evaluate patients prior to surgery. These pre-operative evaluations hold significant importance as they help the surgical and anesthesia providers get a clear perspective of a patient's current medical status. The goals for a preoperative evaluation are to evaluate the risk to patient's health from the anticipated procedure and mitigate any modifiable disease states and risk factors to their safest possible levels prior to the procedure to prevent perioperative morbidity.

Clinicians can optimally achieve these goals during the course of a pre-operative patient visit by (5,6)

- Comprehensively reviewing patient' past medical information to address key risk factors.
- Obtaining detailed patient history and body system assessments from detailed examination.
- Identifying unrecognized co-morbid disease and risk factors for medical complications during or after surgery.
- Optimizing the preoperative medical conditions like blood sugar levels, blood pressure etc.
- Recognizing and treating potential complications specific to the clinical scenario.
- Working effectively as a member of the preoperative team (including providers from other specialties like family and general medicine, surgical and anesthesia).
- Educating patients about the risks and benefits of planned procedures and involving them in informed decision making for surgery.
- Medication reconciliation and targeted advice on lifestyle, environmental, dietary and therapeutic modifications for the patient during their pre, peri and post-operative periods.

In an attempt to achieve these goals and standardize clinical practice recommendations, various medical organizations have provided guidelines to aid clinician efforts in their primary care and preoperative roles. The American College of Cardiology (**ACC**) Foundation and American Heart Association (**AHA**) have collectively engaged in assimilation and publication of clinical guidelines on cardiovascular medicine since 1980. The ACC/AHA Task Force on Practice Guidelines develops, updates, or revises guidelines, standards and policies for optimal care of patients with cardiovascular diseases and procedures. Starting from year 2002, ACC and AHA have consulted medical experts to examine subject specific data with an aim to formulate and publish guidelines on perioperative cardiovascular evaluation for non-cardiac surgery. ACC/AHA task force

reviews these guidelines annually, and to date have issued two updates in 2007 and 2009 (Focused update to include beta-blocker recommendations only) respectively (7,8). These guidelines provide clinicians with a framework for considering cardiac risk of non-cardiac surgery in a variety of clinical and surgical situations.

The latest iteration of perioperative guidelines for cardiovascular risk identifies key harbingers of significant cardiovascular morbidity and mortality (Table A.1 **Appendix 1**). When present, these cardiovascular risk factors place a patient in the High Risk for Surgery category.

1.1.1 Challenges in the Provision of Care

Despite the availability of expert recommendations and practice guidelines for risk stratification in the scientific literature, a variety of barriers prevent their effective utilization by the targeted audience, leaving significant room for improvement in the area of provider utilization (9). Some key problems include:

a. Out-of-date guidelines
b. Inadequate or lack of access to information
c. Lack of awareness, agreement, or self-efficacy
d. Lack of outcome expectancy; the inertia of previous practice; work burden
e. External barriers (10-12).

The effort to identify and manage clinical risk prior to surgery has the additional challenge of time constraints. Typically, the clinical workup prior to surgery includes a detailed history and physical examination completed 30 days prior surgery, due to

regulatory requirements enforced for billing purposes as well as to maintain the standard of patient care. These visits are typically focused on patient clinical conditions that may affect anesthesia and surgery, and are usually completed by a primary care provider or in an anesthesiology clinic. These medical assessments, often provided in conjunction with surgery specific patient education and assessment, creating additional intra-provider communication dependencies. In this window period in the immediate 30 days prior to surgery, patients may be at risk of developing exacerbations of their chronic medical conditions that may adversely contribute to peri and post- operative morbidity and mortality. As a result, it is important that patients have their assessments completed as close as possible to their surgery for accurate risk assessment, yet allow enough time to mitigate any clinical conditions to manage procedural risk. Frequently, there may be a need for diagnostic testing and specialty consultation before the surgical date to ensure appropriate care. Currently, there is a paucity of uniform clinical guidelines for optimizing the timing for pre-operative medical assessment, as patients with complicated histories often require a longer evaluation period prior to surgery, and could require multiple preoperative assessments to identify pertinent comorbidities and mollify chronic disease states that mat exacerbate prior to surgery (13,14). The effectiveness of these visits is clinically very important since relapse of a patient chronic condition prior to surgery has often been observed and subsequently required the procedure to be cancelled or rescheduled to a later date, leaving the assigned operating room slot go unused. Late surgical cancellations have been observed to adversely affect hospital revenues, since many operating rooms costs are fixed expenditures and the surgical procedures are often major hospital surgical revenue generators (15). Consequently, there is a critical need to

facilitate better preoperative planning. In particular, it is important to identify those patients most at risk of clinical decompensation prior to and after surgery (16,17).

1.1.2 Patient Driven Information Acquisition

There are several strategic advantages to having patients identify their own clinical risk factors, both in terms of patient education on their own clinical conditions and risk of complications, as well as potential cost savings with obtaining valid clinical information without the cost of provider mediation (18-20). Technologies like CDSS hold immense potential for enabling patients' access to higher tiers of the clinical knowledge pyramid (**Figure 1.1**), and gain from the collective wisdom of the scientific literature. Decision support tools that can offer patient driven information acquisition and self-assessment that can potentially help mitigate time pressures in the typical 30-day preoperative window by adding important triage data to better identify the at-risk populations.

The advent of personal health records has shown the potential to facilitate the creation of patient driven clinical information, however, the lack of direct connections with patient's electronic medical records pose a major limitation for their use. An additional question is

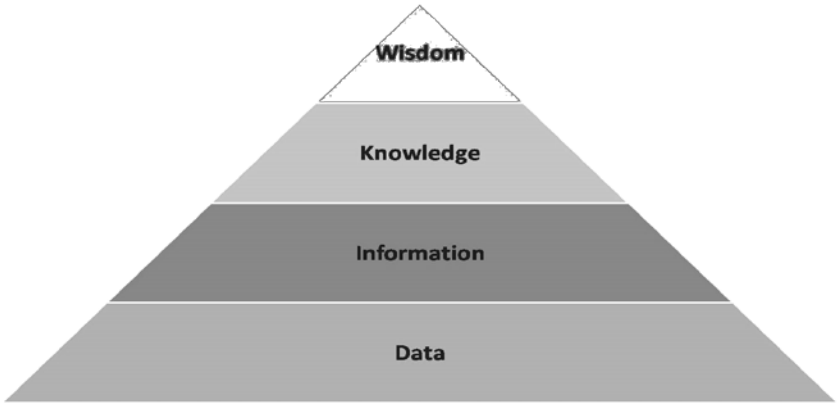

Figure 1.1 - Information Pyramid

whether patient self-identification of risk factors is valid for focused clinical assessments such as cardiac risk (19-24).

In order to address the above-mentioned critical needs of preoperative assessment, an evaluation of patient self-report data on cardiac risk could be validated against the current standard of clinical practice. The patient self-report data on perception and objective cardiac risk factors can be compared with the gold standard provider mediated revised cardiac risk index (RCRI). The selection of RCRI is justified since it is the most widely used clinical assessment that has been validated for use in planning pre-operative clinical interventions and it is well established in the existing clinical guidelines. The proposed study will be focused on using an established risk stratification scale, modified into descriptive disease elements and symptomatic verbiage to help improve patient understanding, with the goal of laying a solid foundation to develop preoperative cardiac risk decision support that can be integrated with novel technologies like e-surveys, and electronic medical records applications including personal health records, secured messaging and promote patient centric care.

1.1.3 Rationale for Use of Revised Cardiac Risk Index:

RCRI was chosen as the preferred risk index for the following reasons -

1. RCRI stems from Cardiac Risk Index, originally published in 1977, which was a first cardiac risk index and remained widely used till its revision in 1999. (25-27)
2. RCRI has consistently performed in repeated validation studies- It has been validated in at least 10 different studies on several thousand patients from different countries and populations.(26)

3. RCRI is to date the most popular and widely accepted risk index in the primary care clinician community. (28-30)
4. Beyond the risk of cardiovascular complications, RCRI has been observed to predict all cause peri-operative mortality – a feature that has not been validated for any other risk index.(26)
5. RCRI is the only risk index included in the most recent AHA clinical guidelines (2009) for assessing pre-operative risk of non-cardiac surgery.(7,8)
6. The included risk factors in RCRI are relatively straightforward and can be confirmed clinically with greater ease than the NSQIP model, which includes American Society of Anesthesiologists (ASA) Physical Status classification, is often criticized as unreliable and subjective (31).
7. The RCRI has better a predictive value than the original Goldman index or the Detsky modified risk index, and comparable accuracy with NSQIP model.(26)

In 2007, the American College of Cardiology/American Heart Association (ACC/AHA) issued perioperative guidelines for non-cardiac surgery (7), followed by a focused update on preoperative beta blockade in 2009 (8), and endorsed these guidelines to clinicians for estimating risk of major adverse myocardial events. These guidelines include a recommendation for the Revised Cardiac Risk Index (**RCRI**) (25) and also highlight a set of conditions, which, when present, are associated with significantly higher post-operative morbidity and mortality for patients (**Table- 6, Table A.2 Appendix 1**). These are the most updated clinical guidelines for preoperative assessment

and thus are a core resource for the knowledge base and prediction rules for the proposed study.

We developed a prototype of the decision support application guided by directives issued by the Office of National Coordinator (ONC) and the Health Information and Management Systems Society (HIMSS) Clinical Decision Support Workgroup and Task Force' guidelines on CDS implementation (32)

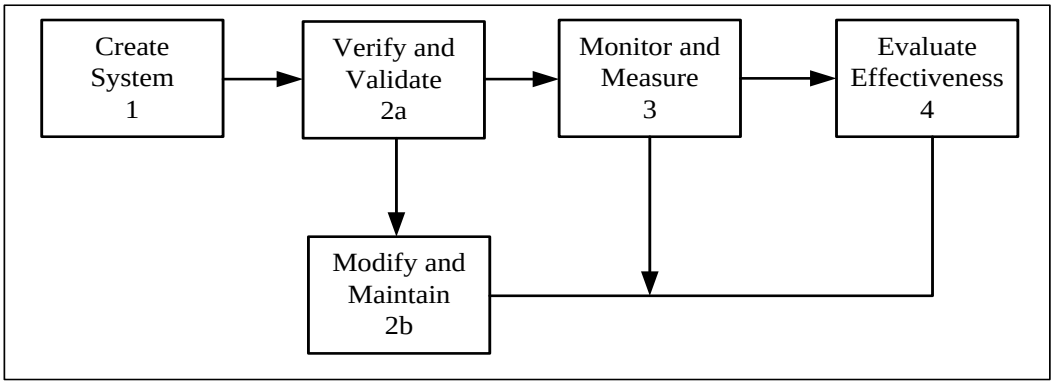

Figure 1.2 - HIMSS Model for Implementation of Clinical Decision Support Systems

1.2 Objectives

To use patient-driven clinical information to its optimal capacity, it is important to establish its validity and reliability. The need for patients to identify their clinical risk factors has been previously established in many studies of chronic disease (24,33-37). However, tools for patient self-identification of clinical risk factors have not always crossed directly from large research studies into use in clinical care (21,37).

At the end of this study, results from observations and analysis of the ensuing three studies would help create and validate a patient driven health information acquisition and

decision support tool, contribute to clarify provider experience and attitudes on the use of patient reported health information.

In the first study, to accurately assess and capture patient medical and surgical history, exercise tolerance, and cardiovascular risk perceptions, a survey instrument was developed in the form of a patient questionnaire. This questionnaire was developed by mapping recommendations of American Heart Association Guidelines for Pre-operative risk assessment of Cardiac complications for Non-Cardiac Surgery. Specific questions identifying each of the six revised cardiac risk index factors and a mapping algorithm was established to create patient generated RCRI scores. In addition to the objective cardiac risk factor assessment, questions were developed to identify patient cardiac risk perception on an ordinal scale. These results were then compared to relative levels of patient risk perceived by clinicians based on recommendations of the current clinical guidelines.

In summary, the ensuing chapters describe three focused studies to achieve the following objectives:

1. Creating foundation for a patient driven information acquisition tool based on recommendations of evidence based research (Study 1).
2. Examining and validation of patient reported self-assessment of pre-operative cardiac risk against gold standard provider assessment cardiovascular risk; compare patient risk perceptions to provider perceived risk for post-operative complications (Study 2).

3. Physician attitudes, satisfaction and ease of use for using the web based decision support. Barriers that providers face in the effective utilization of guidelines and evidence based practices (Study 3).

Chapter 2

Validation of Pre-operative Patient Self-Assessment of Cardiac Risk for Non-Cardiac Surgery: Foundations for Decision Support

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Objectives: To better characterize patient understanding of their risk of cardiac complications from non-cardiac surgery and to develop a patient driven clinical decision support system for preoperative patient risk management.

Methods: A patient-driven preoperative self-assessment decision support tool for perioperative assessment was created. Patient' self-perception of cardiac risk and self-report data for risk factors were compared with gold standard preoperative physician assessment to evaluate agreement.

Results: The patient generated cardiac risk profile was used for risk score generation and had excellent agreement with the expert physician assessment. However, patient subjective self-perception risk of cardiovascular complications had poor agreement with expert assessment.

Conclusion: A patient driven cardiac risk assessment tool provides a high degree of agreement with expert provider assessment demonstrating clinical feasibility. The limited agreement between provider risk assessment and patient self-perception underscores a need for further work including focused preoperative patient education on cardiac risk.

2. 1 Introduction

Surgical interventions provide opportunities for patients to alleviate potential morbidity and mortality. However, these procedures frequently result in cardiac, pulmonary, bleeding and infectious complications. Surgery is a frequent health care intervention with an estimated 6 million non-cardiac surgical procedures performed every year in the United States, with progressive growth in procedures noted each subsequent year (1,7). Approximately 25% of these procedures include major intra-abdominal, thoracic, vascular, and orthopedic procedures known to be associated with significant perioperative cardiovascular morbidity and mortality (8).

The American College of Cardiology/American Heart Association (ACC/AHA) issued perioperative guidelines for non-cardiac surgery in 2007(7), as well as a focused update on preoperative beta blockade in 2009 (8), and endorsed guidelines to direct clinicians to estimate the risk of major adverse myocardial events. These guidelines modified recommendations on the Revised Cardiac Risk Index (RCRI) (25,27) to highlight a set of conditions associated with higher post-operative morbidity and mortality for patients undergoing surgery. The primary risk factors of the RCRI include ischemic heart disease, compensated or prior congestive heart failure, cerebrovascular disease, diabetes mellitus requiring insulin, and renal insufficiency typically with a creatinine level of 2.0 or above (25).

Although the RCRI guidelines have been an important attempt to simplify preoperative risk assessment, it remains a significant challenge for clinical practitioners to provide proper evidence-based preoperative evaluations given the constantly changing clinical

evidence and the broad realm of specialty literature pertinent to preoperative testing and risk management (9-12,38,39). As surgical interventions continue to evolve with increasingly complex and costly procedures, there is a critical need to improve the preoperative assessment to effectively identify clinical risk factors and manage existing co-morbidities. In the perioperative window, from one month before to one month after the surgical intervention, targeted risk mitigation can be implemented to reduce surgical complication risk. In the context of growing surgical work volumes, there is a paucity of well-trained primary providers and preoperative assessment clinics to address patient needs with ongoing growth in the number of preoperative assessments (40,41), (42). An important partner for the surgical team is the patient, who ultimately has the most at stake from the surgical benefits and potential complications (21). Unfortunately, few tools are available for patients to self-identify surgical risk and empower them to work in tandem with multi-disciplinary surgical teams. Such tools could help patients become better informed of their surgical risk and address an important knowledge gap since most patients have limited recall of the risks and benefits of surgical interventions after completing the pre-operative clinical workup (19,43). In addition to the potential educational and clinical benefits to the patients, patient driven decision support tools could also be a cost-effective adjunct tool for surgical quality efforts including Accountable Care Organizations (ACO), medical homes, and other efforts to enhance clinical quality. Having effective patient driven clinical assessments can provide surgical providers a greater appreciation of surgical risks prior to their planned procedures and facilitate optimized multi-specialty care delivery.

Though patients may not fully understand all the details discussed with their providers prior to their surgical procedures, the informed consent process has been established to insure discussions of risk and benefits do take place. The preoperative care process makes it possible for patients to better understand any planned procedures by asking their providers targeted questions and facilitate their own information gathering. Prior studies on patient understanding of clinical risk focused on patient perceptions of risks and benefits, (18,19,22,43,44) but there is limited data on whether patient risk perceptions have a significant correlation with provider risk assessment. Such mutual understanding by both patients and providers is important to better manage potential complications that can occur during surgical procedures. When gaps in the patient and provider perceptions are present, this creates an important education opportunity to help patients fully appreciate the implications of any planned procedure.

2.2 Background

The identification and management of clinical risk prior to surgery occurs in the context of time constraints. Typically, the clinical workup prior to surgery is a full history and physical examination completed 30 days prior to surgery to fulfill regulatory requirements and to maintain clinical care standards. These preoperative visits focus on clinical conditions that may affect anesthesia and surgery and are usually completed by a primary care provider or in an anesthesiology clinic. Frequently, these medical evaluations are provided in conjunction with surgery specific patient education and assessment and coordinated with surgical, anesthesia and medical providers. In this 30 day preoperative window, the patient is at risk of having exacerbations of their chronic

medical conditions contributing to operative morbidity and mortality. As a result, it is important that patients have their assessments completed as close as possible to their surgery, yet it is important to allow enough time to mitigate any clinical conditions which may place the patient at increased clinical risk. Frequently, diagnostic testing and specialty consultation are required prior to the surgical date to insure appropriate care. Unfortunately, no clinical guidelines provide guidance on how to optimize pre-operative assessment timing. Patients with complicated medical histories often require a complicated evaluation and treatments prior to surgery that may involve multiple preoperative assessments in order to optimize their clinical conditions (19). The effectiveness of these visits is clinically important since the decompensation of chronic conditions just prior to surgery may lead to late cancellations resulting in unfilled operating room slots. Late surgical cancellations can have substantial adverse effects on hospital revenue since many operating rooms costs are fixed expenditures and surgical procedures generating substantial proportions of hospital revenue (17). To optimally deliver surgical care, preoperative planning and risk management capacity must be enhanced for those patients at risk of clinical decompensation prior to and after surgery (15).

Patient self-assessment software can potentially mitigate time pressures in the 30-day preoperative window by adding important triage data to better identify the at-risk population. Such tools would optimally be patient-driven since they are most aware of any new changes that occur prior to surgery. However, to use such patient-driven information collection systems, it is important to establish validity and reliability. The ability of patients to self-identify clinical risk factors has been previously established in

many studies of chronic disease (17,24,33-35). However, tools for patient self-identification of clinical risk factors have not translated efficiently from large research studies for use in clinical care. There are strategic advantages to having patients identify their own clinical risk factors both in terms of patient understanding of their own clinical conditions and to facilitate accurate clinical history data. In addition, a patient driven approach could potentially be used to reduce treatment costs by minimizing provider mediation to obtain medical information. Although personal health records have the potential to facilitate pertinent patient driven clinical data, the lack of effective direct connections to the patient's electronic medical record remains a major limitation. An additional question is whether patient self-identification of risk factors is valid for focused clinical assessments such as cardiac risk (36). In order to address some of the critical needs of preoperative assessment, a continuous improvement project was undertaken to assess if patient self-report data on cardiac risk could be validated against the current standard of clinical practice. Patient self-report data on cardiac risk perception and objective cardiac risk factors were compared with the provider mediated revised cardiac risk index assessment. The RCRI was selected for use since it is the most widely used clinical assessment that has been validated for use in planning pre-operative clinical interventions and is well established in existing care guidelines (26,28,30). The authors were motivated to use a widely used risk scale, modify it into descriptive disease elements and symptomatic verbiage to facilitate patient comprehension. The primary project goal is to create a valid and evidence-based foundation for a patient driven preoperative cardiac risk decision support tool for preoperative clinical decision making.

2.3 Methods

2.3.1 Study Design

A prospective, single center, hospital based observational study to evaluate an institutionally approved continuous quality improvement initiative was conducted at VA Medical Center (VAMC) in Minneapolis, Minnesota.

2.3.2 Site Description

A total of 309 patients, visiting the preoperative medicine clinic in the Department of General Medicine VAMC Minneapolis, during the study period were included. The Minneapolis Veterans Administration Hospital is a major referral site within the VA system and serves as a multiple surgical specialty site for the VISN 23 region. The VISN 23 clinical health care network serves more than 400,000 enrolled Veterans residing in the states of Iowa, Minnesota, Nebraska, North Dakota, South Dakota and portions of Illinois, Kansas, Missouri, Wisconsin and Wyoming. The preoperative medical clinic operated from the Minneapolis clinical site is a large preoperative medical site with 10 clinicians providing preoperative medical assessments.

2.3.3 Patient Selection

All patients, referred to the Pre-operative Medicine Clinic during the study period from 1 Dec 2011 to 28 February 2013 were eligible for the study. After excluding 3 patients who were not able to complete surveys and 5 patients who has incomplete surveys, a total of 301 patient surveys and medical records were analyzed for this study.

2.3.4 Cardiac Risk Tool Development

The survey tool used for this study was developed with a goal of enabling patients to complete this survey online through secured messaging at remote sites. The implementation of the survey with electronic messaging can help facilitate remote care and potentially enhance the ability to aggregate patient history and medical information with direct links to electronic patient medical records. (Figure 2)

To accurately assess and capture patient medical and surgical history, exercise tolerance, and cardiovascular risk perceptions, a survey instrument was developed as a 25-question assessment tool (Appendix A.3). The instrument was developed by mapping the American Heart Association Guidelines for Pre-operative risk assessment of cardiac complications of Non-Cardiac Surgery (Figure 4). Specific questions were developed to identify each of the six revised cardiac risk index factors and a mapping algorithm was established to generate a RCRI score with expert provider review. Where applicable, questions from established and validated patient instruments like Rose Questionnaire for ischemic heart disease; Questionnaire to Verify Stroke Free Status (QVSFS) for cerebrovascular disease; and Compendium of Physical Activity for exercise capacity, were modified and used to generate survey questions. In addition to the objective cardiac risk factor assessment, questions were developed to identify patient cardiac risk perception on a graded scale. These results were scored with a mapping algorithm to identify relative levels of risk perceived by the patients that reflected current clinical guidelines.

The development included iterative pilot surveys assessed by practicing preoperative medical providers and patients. The survey content was tailored for patient use with an approximate reading level of grade 7 by Flesch-Kincaid Readability analysis to facilitate patient use.

Figure 2.1 - Overview of Methods

Questions on important surgical contraindications including certain high risk surgical preclusion criteria, preexisting conditions, cardiovascular risk perception, exercise tolerance, and elements of the 6 revised cardiac risk index risk factors were adapted for patient use and incorporated into the instrument. The validity assessment in this paper focuses on the patient perception of their cardiac risk as well as patient self-reported cardiac history to assess tool reliability when compared to gold standard provider evaluation.

2.3.5 Statistical Analysis

Provider notes for each patient's preoperative medical visit were examined by assessing provider risk scoring and their objective cardiac risk assessment. Study data was analyzed using the SAS statistical package (Version 9.3, Cary, N.C.). A p-value of less than 0.05 was considered to be significant.

2.4 Results

In Table 1, the characteristics of the study patients included self-reported cardiac risk tool responders. Exercise tolerance was included in the table as it is an important predictor of cardiac risk with surgery and provides an important surrogate measure of the group cardiac risk.

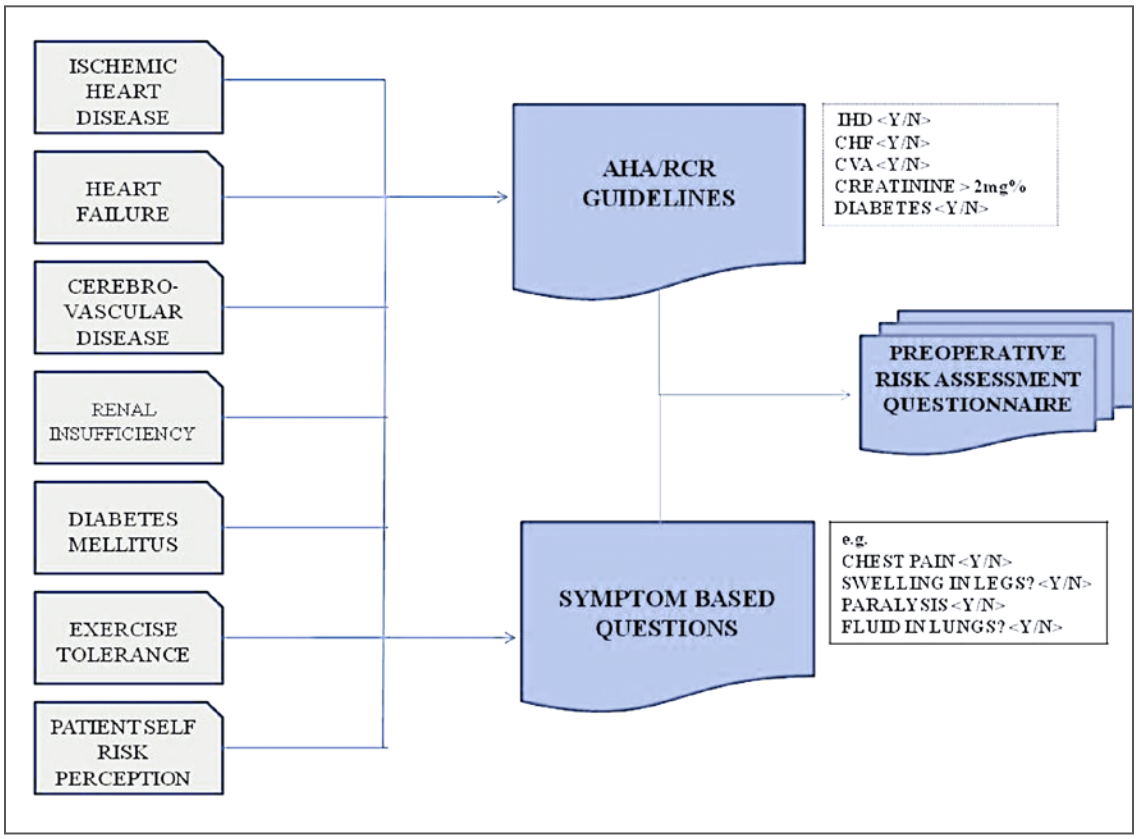

Figure 2.2- Overview of Questionnaire Development

Patient cardiac risk was evaluated using patient self-assessment tool responses, which were mapped and aggregated to create a revised cardiac risk index score. These results were compared with a clinical chart review of the final medical consultation reported risk completed by each patient's clinical provider during their preoperative visit. Patient self-

assessment was completed just prior to the planned preoperative clinical visit provided little likelihood of a change in clinical status between the time of the patient self-report and the medical provider's assessment. The risk factor results with aggregated scores are noted in table 2**.**

The patient self-report of their estimated cardiac risk with surgery is listed in Table 2. These results were compared with the clinical provider's estimate of operative cardiac risk documented in the clinical chart after the patient's routine preoperative medical visits was completed. The results were assessed for inter-rater reliability by calculating a kappa statistic (45). The Kappa Statistic (Weighted) for percent agreement between RCR Score generated from patient survey instrument and Chart review is 0.78 (95% C.I.0.72-0.85). These results demonstrated a substantial level of agreement between the two estimates of reported cardiac risk.

Age mean (± S.D.)	63 years (±12)
{Range}	{25 – 94 years}
Males *n* (percent)	290 (95%)
Exercise Tolerance (> 4 Mets) *n* (percent)	276 (93%)

Table 2.1 – Participant Characteristics

Risk Category	***n* (%)**
Low Risk	105 (35)
Intermediate Risk	178 (59)
High Risk	19 (6)

Table 2.2 - Risk categories for surgeries during study period

From Provider Report *n* (%)	Perceived Cardiac Risk	From Patient Report *n* (%)
236 (84)	**Low**	242 (86)
41 (15)	**Intermediate**	36 (13)
5 (2)	**High**	4 (1)

Table 2.3 - Perceived Risk of Cardiac Complication; Provider versus Patient Self Report

Calculated from Provider Notes, Chart Review *n* (%)	Revised Cardiac Risk Index Score	Calculated from Patient Surveys *n* (%)
209 (69)	**0**	211 (70)
64 (21)	**1**	60 (20)
16 (5)	**2**	23 (8)
7 (2)	**3**	4 (1)
3 (1)	**4**	2 (0.6)
2 (0.6)	**5**	1 (0.3)

Table 2.4 - Comparison of RCRI Scores - Patient self report and Provider Notes

In the comparison of the results, the agreement was assessed with a kappa statistic. As described in Table 2.4, the aggregate frequencies of cardiac risk perceptions were similar but demonstrated substantial disparities for inter-rater agreement between patient and providers. The calculated kappa showed that the patient's risk perception had poor level of overall agreement with physician perception of cardiac risk with a weighted Kappa score of only 0.18 (95% C.I. 0.04-0.31) with individual kappa for low, intermediate and high risk comparisons being 0.17, 0.08, and 0.21 respectively.

There were only 19 high risk procedures planned among the participating patients and most major surgical subspecialties were included in study with 105 of the planned

surgeries deemed to have low estimated cardiac risk and 178 of the procedures designated as intermediate (Table 2.3). Tables 2.5, identifies the types of procedures for which the patients were being evaluated. Cardiac surgeries were excluded as they received their preoperative assessment from the cardiothoracic clinical service lines at the clinical site of the study and practice guidelines assess risk for cardiac surgery differently than non-cardiac surgery.

Procedure Type	***n* (%)**
Orthopedic	89 (29)
Neurosurgery	38 (13)
Otolaryngology	34 (11)
General Surgery	32 (11)
Ambulatory	31 (10)
Urology	27 (9)
Ophthalmology	23(8)
Vascular	15(5)
Podiatry	7 (2)
Colorectal	2 (0.6)
Dental	2 (0.6)
Cardio-Thoracic	1 (0.3)
OB-GYN	1 (0.3)

Table 2.5 - Specialty Surgeries for Study Participants

2.5 Discussion

The results of the assessment of this quality improvement initiative provide two key insights on patient self-assessment of cardiac risk. The patient's self-assessment of their perceived pre-operative cardiac risk had poor agreement with expert clinical providers. In

contrast, the patient self-report of their primary cardiac risk factors showed substantial inter-rater reliability with the provider assessment. In addition, the patient self-reported risk data mapped well to the existing clinical standards of preoperative cardiac risk (Revised Cardiac Risk Index) demonstrating the feasibility of a patient driven approach. These findings provide important evidence that patients can adequately provide self-report data that can accurately estimate cardiac risk with surgical interventions. The ability of patients to self-report risk factors with similar results to the gold standard provider clinical assessment indicates that the development of decision support tools with patient driven interfaces may potentially be used for preoperative cardiac assessment. In contrast, patients appear less able to predictably provide an accurate perception of their pre-operative cardiac risk, which matches the gold standard assessment of their clinical providers.

There are a number of limitations to this evaluation. The sample size is relatively modest, which makes it difficult to ensure that the patient self-report of cardiac risk factors and self-perception data is a true representation of Veterans Administration preoperative patients. The data collected in the study focuses on a regional Veterans Administration pre-operative patient population and the data is generated from a single clinical practice site. It is unclear if these results could be extended to non-VA clinical sites given the predominant male distribution of the sample and mandates further study. Another limitation is the relative lack of high cardiac risk surgical procedures in the study population. It is unclear how patients perceive the risk of these procedures and correspondingly uncertain whether that perception can be detected in the objective risk

data related to procedures. Further assessment, including patients undergoing high-risk procedures, can be used to assess this aspect of the survey in future work.

The future work for the project, based on the findings to date, will focus on developing patient friendly computer interfaces in the secure messaging application. In addition, the survey tool will be used to pre-screen patients with high-risk characteristics to potentially receive high-risk assessments, which have been developed at the clinical site of this research project (16,17). Patient prescreening can be matched with protocols to preorder cardiac assessments when indicated. This could help improve clinical care coordination, particularly for those patients who have to travel hundreds of miles for their preoperative assessment as part of the national VA health care system.

2.6 Conflicts of Interest

The authors declare that they have no conflicts of interest in this research study.

2.7 Human Subjects Protection

The study was performed in compliance with the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects. Prior to commencement of this study, all selected patient records were de-identified and stored using institutionally recommended data security protocols. This study was carried out after receiving due approvals from the Institutional Review Boards at Minneapolis VA healthcare System and University of Minnesota.

Chapter 3

Diagnostic Characteristics of Patient Self-Assessment of Preoperative Cardiac Risk for Non-Cardiac Surgery - Foundations for Patient Driven Decision Support

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Patient self-assessment can potentially mitigate time pressures in the 30-day preoperative window by adding important triage data to better identify at-risk patients. However, to effectively harness such patient-driven capacity, it is important to establish its validity and reliability. We tested the reliability and validity of a patient self-report survey instrument and its concordance with gold standard clinician assessment for pre-operative cardiovascular risk evaluation. A total 314 surveys and their corresponding clinician evaluations were used for calculating patient and provider reported RCRI scores, risk perceptions, reliability and validity analyses. We concluded that patient self-reported RCRI risk factors (Ischemic heart disease, congestive heart failure, cerebrovascular accident, diabetes requiring insulin, and renal insufficiency) had a good and statistically significant overall accuracy, high specificity and negative predictive values compared to gold standard clinician evaluation.

3.1 Introduction

Surgery is a frequent health care intervention with an estimated 6 million non-cardiac surgical procedures performed every year in the United States, with progressive growth in the number of procedures noted each subsequent year (1). Preoperative medical evaluations have been a cornerstone of pre-surgical care planning and patient management. The clinical providers carry out these pre-operative evaluations guided by their medical knowledge, institutional policies and clinical practice guidelines. To address the challenge of standardizing the evaluation and management of perioperative cardiovascular complications of non-cardiac surgery, the American College of Cardiology/American Heart Association (ACC/AHA) issued perioperative guidelines for non-cardiac surgery in 2007(7), as well as a focused update on preoperative beta blockade in 2009(8)These guidelines modified recommendations on the Revised Cardiac Risk Index (RCRI) (25,27) to highlight a set of conditions associated with higher post-operative morbidity and mortality for patients undergoing non-cardiac surgery.

As surgical interventions continue to evolve with increasingly complex and costly procedures, there is a critical need to improve the preoperative assessment to effectively identify clinical risk factors and manage existing co-morbidities. In the typical perioperative window, from one month before to one month after the surgical intervention, targeted risk mitigation can be implemented to reduce surgical complication risk. In the context of growing surgical work volumes, there is a paucity of well-trained primary providers and preoperative assessment clinics to address patient needs with ongoing growth in the number of preoperative assessments (40-42).

An important partner for the surgical team is the patient, who ultimately has the most at stake from the surgical benefits and potential complications (21). Unfortunately, few tools are available for patients to self-identify surgical risk and empower them to work in tandem with multi-disciplinary surgical teams. Such tools could help patients become better informed of their surgical risk and address an important knowledge gap since most patients have limited recall of the risks and benefits of surgical interventions after completing the pre-operative clinical workup (19,43). In addition to the potential educational and clinical benefits to patients, patient driven decision support tools could also be a cost-effective adjunct tool for surgical quality efforts including Accountable Care Organizations (ACO), medical homes, and other efforts to enhance clinical quality. Having effective patient driven clinical assessments can provide surgical providers a greater appreciation of risks prior to their planned procedures and facilitate optimized multi-specialty care delivery.

Decision support tools that offer patient self-assessment can potentially help mitigate time pressures in the typical 30-day preoperative window by adding important triage data to better identify the at-risk populations. To use patient-driven clinical information to its optimal capacity, it is important to establish its validity and reliability. The ability of patients to self-identify clinical risk factors has been previously established in many studies of chronic disease (24, 33-37). However, tools for patient self-identification of clinical risk factors have not always crossed directly from large research studies into use in clinical care (21,37).

There are several strategic advantages to having patients identify their own clinical risk factors, both in terms of patient education on their own clinical conditions and risk of complications, as well as potential cost savings with obtaining valid clinical information without the cost of provider mediation (18-20). Technologies like clinical decision support systems (CDSS) hold immense potential to enable patients to access higher tiers of the knowledge pyramid thereby gaining from the collective wisdom of scientific

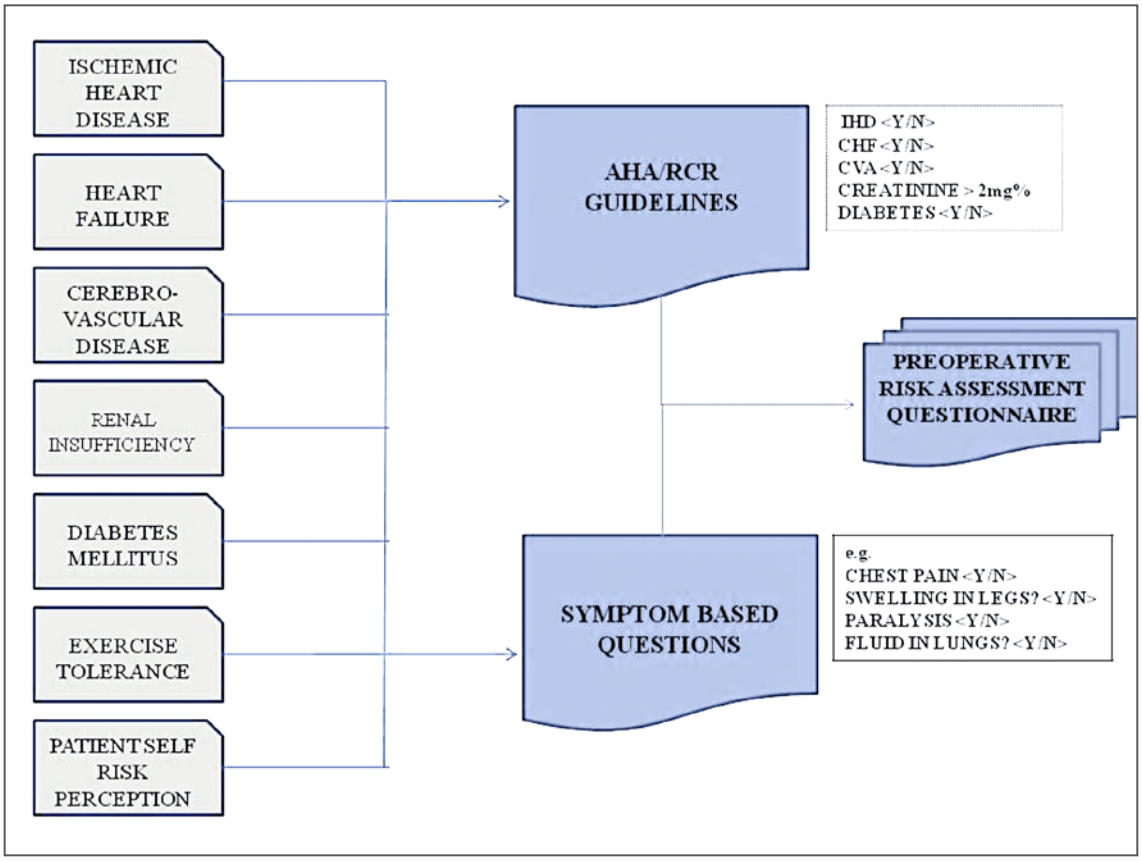

Figure 3.1 - Overview of Questionnaire Development

literature. This study aims to create and validate prediction rules to form the basis for a patient generated risk prediction tool for patient centric health care with timely stratification of preoperative risk.

3.2 Methods

3.2.1 Experimental Design - A prospective, single center, hospital based observational study was performed to evaluate the diagnostic characteristics of patient self-reported health information.

3.2.2 Site Description - The Minneapolis Veterans Administration Hospital is a major referral site within the VA system with care provision by multiple surgical specialties in the VISN 23 region. The VISN 23 clinical health care network serves more than 400,000 enrolled Veterans residing in the states of Iowa, Minnesota, Nebraska, North Dakota, South Dakota and portions of Illinois, Kansas, Missouri, Wisconsin and Wyoming. The preoperative medical clinic operated from the Minneapolis clinical site is a large preoperative medical site with 10 clinicians providing preoperative medical assessments.

3.2.3 Survey Design - To accurately assess and capture patient medical and surgical history, exercise tolerance, and cardiovascular risk perceptions; a survey instrument was iteratively developed in the form of a 25-point assessment tool. This instrument was developed by mapping the recommendations of American Heart Association (AHA) Guidelines for Pre-operative risk assessment of Cardiac complications of Non-Cardiac Surgery (8)The AHA recommends using the Revised Cardiac Risk Index (RCRI) (25) which stratifies cardiovascular complication risk based upon 6 key risk factors: history of coronary artery disease (CAD) or unstable angina, history of cerebrovascular accident, history of Congestive Heart Failure (CHF), diabetes mellitus requiring insulin for control, serum creatinine greater than 2mg/dL, and high risk surgical procedure. A questionnaire survey instrument was developed by modifying existing patient self-report instruments

including: Modified Rose Questionnaire for IHD (46, 47); Questionnaire to Verify Stroke Free Status (QVSFS) (48) for Stroke and Cerebrovascular accident (CVA); and Compendium of physical activity (49) to assess patient exercise capacity. Symptomatic questions were developed based on expert consensus when a suitable validated instrument was not available for a risk factor. After identifying each of the six revised cardiac risk index factors, a patient reported RCRI score was generated along with other patient reported health information such as cardiovascular and procedure history. In addition to objective cardiac risk factor assessment, questions were developed to identify patient cardiac risk perceptions on a graded scale. These results were scored with a mapping algorithm to identify the relative levels of risk perceived by patients while reflecting current clinical guidelines. The survey content was tailored for patient use with an estimated reading level of grade 7 by Flesch-Kincaid readability analysis to facilitate patient use. Questions on important surgical contraindications including certain high risk surgical preclusion criteria, pre-existing conditions, cardiovascular risk perception, exercise tolerance, and the elements of the 6 revised cardiac risk index risk factors were adapted for patient use and incorporated into the instrument.

3.2.4 Survey Validity - An intended referential was established along with the connotative meaning of each question to ensure that the respondents interpreted the questions as intended. The survey was developed while making broad consideration for the educational level of a wide range of participants but focused on those in the VA Medical Center, Minneapolis. The survey content was tailored for patient use with an estimated readability level < grade 8 on the Flesch-Kincaid Readability Scale (50,51), consistent with readability level of a high school graduate. The questionnaire was

designed and assessed to avoid biased wording, double negatives and leading questions to check for response bias. Closed ended questions were framed around almost all questions with ordered and partially ordered responses for most questions, to allow a continuum of responses and to facilitate ease and accuracy of responses (52). Survey length was kept at less than 25 questions that were spread over 3 letter-sized pages. Survey completion times were recorded during pre-testing in a sub-set of participants to ensure that the respondents are able to complete the questionnaire within a reasonable time frame. Pre-testing on a small sub-set of participants revealed that all participants were able to complete the survey within 3 to 4 minutes.

3.2.5 Data Collection – Patients checking in at the preoperative medicine clinic were asked to complete the survey questionnaires while they waited to be seen by their clinicians. Patients at the preoperative medicine clinic completed a total of 500 surveys during the study period. Since the survey development process was iterative, only 401 patients, who completed the finalized survey version, were included in the study. Patients visiting the preoperative medicine clinic in the Department of General Medicine VAMC Minneapolis during the study period were included in the study. Provider data was retrospectively collected from chart review of provider visit notes, problem list, drug list and surgical records of corresponding patients from the VistA electronic medical record system.

We excluded eighty-seven more patients that had missing or incomplete survey responses and for some cases incomplete or cancelled preoperative clinician evaluations. Thus, only the remaining 314 surveys and their corresponding clinicians evaluation were used for comparison of RCRI scores, risk perception, reliability and validity analyses.

3.2.6 Data Analysis - Descriptive statistics were used to tabulate patient demographics, cardiac risk self-perceptions, and cardiovascular risk profiles using SAS version 9.3 (SAS Institute Cary, NC). We evaluated the association between provider perceptions of patient risk, provider generated RCRI score with patient subjective perception of risk and RCRI scores generated by patient provided survey information. We calculated Cronbach's alpha to estimate the internal consistency of this survey.

3.3 Results

At the end of the study period we included study participants with ages ranging from 25 to 91, with an average age of 66 (±12.4) years for the study population. Typical for veteran populations (53)who constituted the majority of study participants, 9 out of 10 participants were males. Other details for patient demographic data is presented in table 3.2. The calculated standardized Cronbach's alpha (0.93) indicated that the survey had excellent internal consistency.

	Coronary Heart Disease	Congestive Heart Failure	Cerebrovascular Accident/Stroke	Diabetes requiring Insulin	Renal Insufficiency
n (%)	85 (21%)	28 (7%)	24 (6%)	38 (9%)	17 (4%)

Table 3.1 – Prevalence of provider diagnosed risk factors in study population

Males n (%)	Mean (±SD){Range}	25 - 44 years n (%)	45-64 years n (%)	65-80 years n (%)	> 80 years n (%)
381 (95%)	66 years (+12.4) {25-91}	35 (9%)	195 (49%)	128 (32%)	43 (11%)

Table 3.2– Gender and age distribution for study population

We also calculated frequencies and prevalence of cardiovascular risk factors outlines in the RCRI using descriptive statistics. We noted that coronary heart disease was the commonest risk factor with a prevalence of 21% (n = 85), followed by Diabetes requiring insulin 9%(n = 38), with renal insufficiency observed as least prevalent at 4% (n = 17) (Table 3.1).

To evaluate concordance between RCRI scores generated by patient provided information and comprehensive chart review and provider assessment, we created a comparison matrix (Table 3.3).

Patient RCRI	Provider RCRI Scores						
	0	1	2	3	4	5	
0	199	15	3	0	0	0	217
1	13	44	3	2	1	0	63
2	1	8	12	3	0	0	24
3	0	1	2	3	0	0	6
4	0	0	0	0	2	1	3
5	0	0	0	0	0	1	1
	213	68	20	8	3	2	314

Table 3.3 - Comparison Matrix of Patient Generated RCRI scores with Expert Provider Assessment {Absolute difference between provider generated and patient RCRI score: Green - zero, Yellow - One, Red - More than one}

This RCRI comparison demonstrated complete agreement between the patient and provider scores in 261 out the total 314 surveyed patients, with some level of disagreement in the remainder. This observation illustrates the fact that patient identified

risk factors and the generated RCRI scores were in 83% agreement. There were only a limited number of subjects (n = 8) for whom the absolute difference between patient driven and provider RCRI scores were greater than 1.

Risk Factor	**Odds Ratio (95% C.I.)**
Physician Diagnosed CAD	5.48* (2.51-11.95)
Physician Diagnosed CVA	2.6 (0.97-6.96)
Physician Diagnosed CHF	0.93 (0.2-4.2)
Physician Diagnosed Renal Insufficiency	Not significant
Diabetes requiring insulin (Self reported)	0.89 (0.25-3.16)
H/o of intra-cardiac device	1.84 (0.15-22.47)
H/o of CABG	8.53* (3.43-21.17)
H/o of Stress Test	0.89 (0.25-3.16)

Table 3.4 - What drives patient risk perception? Table shows association (odds ratio) between patients' self-perception of risk and physician diagnosed risk factors adjusted for age (* Indicates p-value < 0.05)

3.3.1 Patient Self-Perceptions of Cardiovascular Risk

To explore potential drivers of patient self-perceptions of cardiovascular risk, we evaluated the strength of association between patient self-perceived risk and gold standard physician diagnosed risk factors (Table 3.4). We noted that patients who had physician diagnosed CAD were 5 times more likely to perceive themselves as high risk for cardiovascular complications peri-operatively compared to patients who had a

negative history for physician diagnosed CAD, despite the nearly same risk of other factors such as renal insufficiency. Similarly, patients with physician reported history of CABG were 8 times more likely to consider themselves as high risk for cardiovascular complications peri-operatively compared to those who had not had a CABG. The perceived risk association for stroke, heart failure, diabetes requiring insulin and renal insufficiency, were however, statistically insignificant.

3.3.2 Validity of Patient Self-reported Health Information

We also performed an analysis of the operating characteristics for validity of patient self-diagnosis versus gold standard clinician diagnosis for peri-operative risk factors. As seen in table- 3.5, all patient self reported risk factors had a statistically significant overall accuracy of at least 0.93 compared to gold standard clinician evaluation. We also noted that all patient reported risk factors including coronary heart disease (CAD), cerebrovascular accident (CVA), diabetes and exercise tolerance had acceptable sensitivity values of 0.77, 0.83, 0.87, and 0.86 respectively. However, all five patient reported risk factors had high specificities, Negative Predictive Values (NPV) and positive Likelihood Ratios (LR +).

3.3.3 Clinician perception of patient risk for complications

The validation study by Goldman et al concluded that all risk factors (CAD, CVA, diabetes requiring insulin, CHF, renal insufficiency and high risk type surgery) had an equivalent contribution to the risk of post-operative cardiovascular complications after non-cardiac surgery (27). However, we observed that certain patient risk factors influenced clinician perceived risk more than the others. For example, we used logistic

regression to calculate odds ratios for evaluating the association between patient risk factors and provider perceptions of post-operative adverse cardiac events. We observed that after adjusting for age, providers perceived patients who reported a history CAD to be 9 times (95 % C.I. 4.98-16.45) higher risk of having a adverse cardiac event after surgery as compared to patients who had no history of heart disease. History of chest pain, history of CHF, presence of cardiac pacemaker or defibrillator, high-risk type planned procedure were among the other significant driver of clinician risk perception for their patients. (Table –3.6)

Patient Identified Risk Factor	**Sensitivity** (95% C.I.)	**Specificity** (95% C.I.)	**PPV** (95% C.I.)	**NPV** (95% C.I.)	**LR+** (95% C.I.)	**LR –** (95% C.I.)	**Overall Accuracy** (95% C.I.)
Ischemic Heart Disease	0.771 (0.66-0.85)	0.975 (0.94-0.98)	0.9 (0.79-0.95)	0.937 (0.9-0.96)	31.3 (14.08-69.85)	0.23 (0.15-0.36)	0.93 (0.9-0.95)
Congestive Heart Failure	0.6 (0.38-0.81)	0.969 (0.94-0.98)	0.579 (0.36-0.76)	0.972 (0.95-0.99)	19.6 (9.38-40.92)	0.412 (0.24-0.7)	0.94 (0.92-0.97)
Cerebrovascular Accident/Stroke	0.833 (0.6-0.94)	0.958 (0.92-0.97)	0.556 (0.36-0.78)	0.989 (0.96-0.99)	20.48 (11.33-37)	0.174 (0.06-0.48)	0.95 (0.92-0.97)
Diabetes Requiring Insulin	0.875 (0.69-0.95)	0.986 (0.96-0.99)	0.84 (0.65-0.93)	0.989 (0.96-0.99)	60.37 (22.55-161.59)	0.127 (0.04-0.36)	0.977 (0.96-0.99)
Serum Creatinine >2mg/dL	0.357 (0.16-0.61)	0.972 (0.94-0.98)	0.385 (0.17-0.64)	0.969 (0.94-0.98)	12.81 (4.8-34.14)	0.661 (0.44-0.97)	0.945 (0.92-0.97)
Physical Activity	0.867 (0.82-0.9)	0.64 (0.41-0.87)	0.976 (0.94-0.98)	0.123 (0.12-0.34)	2.31 (1.22-4.36)	0.212 (0.13-0.34)	0.855 (0.81-0.89)

Table 3.5 Diagnostic characteristics of Patient identified risk factors against gold standard expert clinician diagnosis (all p-values < 0.05)

Risk Factor	OR (95 % C.I.)
Age	1.07 (1.04-1.1)*
Patient reported history of CAD ψ	9.05 (4.98-16.45)*
Does walking at a normal pace give you chest pain?ψ	24.28 (5.63-104.57)*
Does walking fast uphill give you chest pain? Ψ	12.73 (4.45-36.34)*
Do you ever have any pain or discomfort in your chest? ψ	4.18 (2.18-8.03)*
Have you ever been told by a physician that you have had a stroke, mini-stroke, or transient ischemic attack (TIA)?ϕ	3.51 (1.54-8.01)*
Have you ever had sudden painless weakness on one side of your body? ϕ	2.2 (0.66-7.37)
Have you ever had sudden numbness or a dead feeling on one side of your body? Φ	2.33 (1.01-5.36)*
Have you ever had sudden painless loss of vision in one or both eyes? ϕ	2.13 (0.6-6.72)
Have you ever suddenly lost the ability to understand what other people are saying? Φ	1.87 (0.47-7.35)
Have you ever suddenly lost the ability to speak or write? ϕ	0.39 (0.04-3.38)
Have you ever been told by a doctor that you have congestive heart failure (CHF)?	10.74 (4.03-28.62)*
Do you have leg swelling due to fluid retention?	2.95 (1.44-5.98)*
Have you ever been told by a physician about or seen your lab results showing blood creatinine level greater than 2 mg/dL?	4.93 (1.55-15.65)*
Have you ever been on dialysis?	2.4 (0.53-11.18)
Do you use insulin for treatment of diabetes?	6.15 (2.64-14.31)*
Pacemaker or ICD (Defibrillator) placement	14.7 (2.24-97.5)*
Heart bypass Surgery (CABG)	3.84 (1.73-8.52)*
Cardiac Stress test (treadmill test)?	1.79 (1.01-3.18)*
Insufficient Exercise Capacity	2.33 (1.1-4.5)*
Patient Self Perception of Risk	3.6 (1.89-6.87)*
High Risk Procedures	10.55 (3.03-36.68)*
Intermediate Risk Procedures	1.69 (0.84-3.3)

Table 3- What drives clinician risk perception?

Association between provider perception for risk of cardiovascular complications and specific risk factors adjusted for age) {All number are odds ratios} [Questions for ψ – CAD, ϕ – Stroke, * Indicates p-value < 0.05]

3.4 Discussion

The results of this study provide key insights on the association between patient reported health information and expert clinician diagnosis of preoperative cardiovascular risk for patients undergoing non-cardiac surgery.

We investigated the concordance between RCR scores generated by gold standard provider assessment and patient self-identified risk factors, and generated RCRI scores were in near perfect (83%) agreement. We also concluded that patient reported coronary heart disease, congestive heart failure, presence of pacemaker or defibrillator, were perceived by provider to have higher risk for cardiovascular complications.

Upon examining the validity of patient reported health information, we concluded that patient self reported RCRI risk factors (Ischemic heart disease, congestive heart failure, cerebrovascular accident, diabetes requiring insulin, and renal insufficiency) had a good and statistically significant overall accuracy, high specificity and negative predictive values compared to gold standard clinician evaluation. This underscores the fact that detailed pre-operative testing, evaluation and resources can be reserved for patient who report to have these risk factors, potentially saving on hospital costs and clinician time and avoiding risk of unnecessary testing and assessment which may create iatrogenic risk of otherwise low risk patients.

The results from our study agree with a large body of scientific literature suggests that patient self-reported health information is a valid resource of information and holds immense potential for improving the provision of healthcare (18,24,33,37,46,54,55).

We acknowledge that there are number of limitations of this study. The study sample size is relatively modest, which makes it difficult to ensure that the patient self-report of cardiac risk factors and self-perception data is a true representation of Veterans Administration preoperative patients. The data collected in the study focuses on a regional Veterans Administration pre-operative patient population and the data is generated from a single clinical practice site. It is unclear if these results could be extended to non-VA clinical sites given the predominant male distribution of the sample, which mandates further study. Also since this was a self-administered survey, the authors could not assess behavioral factors like patient denial or over-report for subjective patient health perceptions, but the availability of provider assessment data on the patient risk factors allowed for within patient comparisons. The authors also limited their scope to the assessment for perioperative cardiovascular complications to minimize bias. Thus, patient and provider perceptions of post-operative risk that may also be driven by other risk factors and pathologies like gender, age, race, and other co-morbidities.

In conclusion we developed a patient self-report survey instrument that had excellent internal consistency. We also concluded that patient self-report is a valid resource for obtaining health information for preoperative cardiovascular evaluation.

Our future goals include validating our findings through a study extending to a larger, non-veteran population; develop and evaluate other risk factors (like respiratory, neurological and medication management components) from patient driven data

acquisition and management of perioperative risk and thus empowering patients to play a pivotal role in their health care decisions.

3.5 Conflicts of Interest

The authors declare that they have no conflicts of interest in this research study.

3.6 Human Subjects Protection

The study was performed in compliance with the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects. Prior to commencement of this study, all selected patient records were de-identified and stored using institutionally recommended data security protocols. This study was carried out after receiving due approvals from the Institutional Review Boards at Minneapolis VA healthcare System and University of Minnesota.

Chapter 4

Clinician Perceptions of Usefulness of a Patient Driven Decision Support Application: A Mixed Methods Evaluation

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Cardiovascular complications of non-cardiac surgery are an important concern for clinicians and patients. Patients are an important, but often under-utilized partner for the surgical team. We created a patient self-report instrument based on evidence-based preoperative cardiac assessment guidelines. We evaluated the usefulness of the patient self-report tool for pre-operative cardiac risk evaluation and assessed how the prototype met functional goals (features, format, and interface) and end users' perceptions of the facilitators and barriers to using the prototype at the point of care. We conducted a single center, cross-sectional mixed methods study to evaluate the provider perceptions of the tool's usefulness. We found that providers perceived patient-reported health information as significantly useful and view them as a valid resource of information for executing cardiovascular preoperative evaluations.

4.1 Introduction

An estimated 6 million non-cardiac surgical procedures are performed every year in the United States, with progressive growth in the number of procedures noted each subsequent year (1). Cardiovascular complications of non-cardiac surgery are a chief concern for clinicians and patients during preparation for surgery, given the relatively high rates of post-operative morbidity and mortality. Preoperative medical evaluations have been a cornerstone of pre-surgical care planning and patient management. The clinical providers who carry out these pre-operative evaluations are guided by their medical knowledge, institutional policies and clinical practice guidelines. There is a critical need to improve preoperative assessment to effectively identify clinical risk factors and manage existing co-morbidities while providing increasingly complex and costly surgical procedures. In the typical perioperative period, which is a 60-day window including the 30 days before and after the surgical intervention, targeted risk mitigation can significantly reduce surgical complication risk. In the context of growing surgical work volumes, there is a paucity of well-trained primary providers and preoperative assessment clinics to address patient needs with ongoing growth in the number of preoperative assessments(40-42). To address the challenge of standardizing the evaluation and management of perioperative cardiovascular complications, scientific bodies like the American Heart Association (AHA) and American College of Cardiology (ACC) periodically issue perioperative guidelines for non-cardiac surgery (7,8) These guidelines recommend established indices like the Revised Cardiac Risk Index (RCRI) which highlight conditions associated with higher post- operative morbidity and mortality for patients undergoing non-cardiac surgery (4,5).

An important but often underutilized partner for the surgical team is the patient, who ultimately experiences both the surgical benefits and potential risks of potential post-operative complications (21). Unfortunately, few tools are available for patients to self-identify surgical risk and empower them to work in tandem with multi-disciplinary surgical teams. Such tools could potentially help patients become informed about their surgical risk and address an important knowledge gap, since most patients have limited baseline understanding of the risks and benefits of surgical interventions after completing the pre-operative clinical workup (19,43). In addition to the potential educational and clinical benefits to patients, patient driven decision support tools could also be a cost-effective adjunct tool for enhancing surgical quality efforts.

4.1.2 Patient Driven Pre-operative Cardiovascular Risk Assessment-

Decision support tools that offer patient self-assessment can potentially mitigate time pressures in the typical 30-day preoperative window by adding important triage data to better identify the at-risk patients. To address the challenges and concerns faced by providers and patients, we created a patient self-report instrument based on evidence based guidelines and best clinical practices and mapped the content to patient comprehensible clinical problem and symptomatic verbiage.

In two separate studies, we established the concordance of patient self-reported information collected using this survey, and tested the validity of patient self-reported health information against gold standard combination of comprehensive chart review information and provider assessment in two separate studies (56,57)

4.1.3 Usefulness of patient Self Reports

The Technology Acceptance Model (TAM) is an information systems theory that models how users come to accept and use a technology (10). The model suggests that the actual use of a technology is dependent upon end user perception of its usefulness (Figure 1). TAM defines usefulness as, ‘‘the degree to which a person believes that using a particular technology will enhance his/her performance’’ (58). This study evaluated physician perceptions about the use of patient self-report health information for preoperative cardiovascular risk assessment using a web-based tool. Physician acceptance and perceptions of usefulness in their daily clinical workflow was assessed along with data collection on end-user feedback from clinicians for discovering areas of improvement.

The objectives of the current study were to conduct a usefulness evaluation of the patient self-report tool and assess how well the prototype meets functional goals (features, format, and interface) and to determine end users’ perceptions of the facilitators and barriers to using the prototype at the point of care.

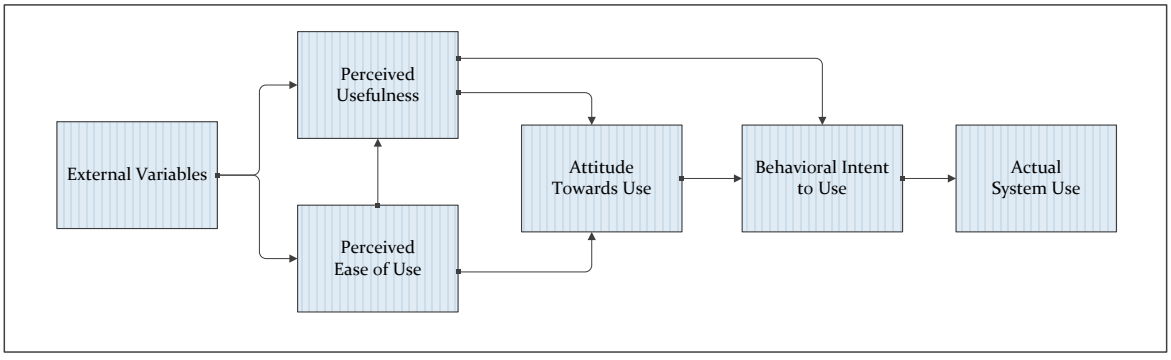

Figure 4.1 – Technology Acceptance Model

4.2 Methods

4.2.1 Study question

What are physician perceptions of the usefulness of a patient reported decision support tool for risk assessment and stratification during pre-operative evaluations for cardiovascular complications?

4.2.2 Study Design

To evaluate clinician perception of the usefulness of a proposed patient driven clinical decision support tool, we conducted a mixed methods evaluation of the clinicians working at the preoperative medicine clinic of the Minneapolis VA healthcare system. We performed a single center, cross-sectional study utilizing personal interviews and focus groups for exploratory and qualitative evaluation. Ten providers, comprised of primary care physicians and nurse practitioners, regularly perform pre-operative medical assessments at the study hospital. Eight out of the ten providers agreed to participate in this study. Table 1 describes some characteristics of the participating clinicians.

For the quantitative assessment, we developed a questionnaire survey to assess the psychometrics of provider perceptions of the usefulness of patient reported risk assessment information. Our main goal was to explore and understand provider perceptions of usefulness for a patient self-report decision support tool populated by information provided by patients, and to describe the barriers and facilitators of clinician utilization of such tools. The survey contained a total of 15 multiple-choice questions.

These questions were framed as closed ended and partially ordered to allow for accurate ranking or ordering of responses, and scored using a Likert scale (score range from 1-7).

Characteristic	N (%)
Male	5 (62.5%)
Age range	
20-30 Years	4 (50%)
31-40 Years	1 (12.5%)
41-50 Years	2 (25%)
51-60 Years	1 (12.5%)
Type of Provider	
Internal Medicine	7(87.5%)
Nurse Practitioner	1 (12.5%)
Years of Experience	
1-5 Years	5 (62.5%)
More than 5 years	3 (37.5%)

Table 4.1 - Characteristics of Participating Medical Providers

The institutional review boards at the Minneapolis VA Healthcare system and University of Minnesota reviewed the study and recommended exemption from formal review after reviewing the study design. The investigator (SM) contacted all clinical providers working at the Pre-operative Medicine Clinic for study interviews. The investigator conducted all interviews based on the semi-structured interview technique (59) utilizing a planned discussion outline drawn from a focused literature review. The interviews consisted of two broad sections. In the first section, the study questions evaluated baseline clinician perceptions of clinical decision support systems, and the merits and disadvantages of patient reported health information. The second part of the interview evaluated specific provider feedback after demonstrating the proposed patient self-report

decision support tool. Semi-structured interviews allowed the emergence of unanticipated, but relevant issues and attitudes associated with provider perceived usefulness of patient reported health information. Four of the eight participating providers were interviewed individually, and the other four attended a focus group session.

4.2.3 Quantitative Survey Development

The quantitative assessment of provider perceptions was performed after a demonstration of the tool and complete discussion of any related questions asked by the providers. Guided by literature on survey development and question design (52,60-62), a 15-point survey instrument to evaluate provider perceptions of usefulness and ease of use for the proposed patient self-report decision support tool was developed. This instrument was created by adapting questions from established survey instruments such as the Technology Acceptance Model (TAM) (63), TeleMedicine Perception Questionnaire (TMPQ) (64), and the Computer System Usability Questionnaire (CSUQ) (65). To explore provider perceptions further, we added four more questions developed by expert consensus, to the survey to better understand perceptions of patient acceptance and workflow. The authors established an intended referential and connotative meaning of each question to ensure that the respondents interpreted the question as intended. Criteria and recommendations for survey development and questionnaire appropriateness were also considered while designing the survey (61,62,66).

4.3 Data Analysis

Data from the surveys was analyzed using SAS (version 9.3) statistical package. Standardized Cronbach's alpha was calculated to evaluate the surveys' internal

consistency (67). Descriptive statistics were used to describe survey responses and respondent demographics. Nvivo 10 was used to organize the audio files, interview transcripts and summarize the thematic analysis.

4.3.1 Grounded Theory

Strauss et al. defined Grounded Theory as the methodology for developing theory that is grounded in data systematically gathered and analyzed (68). Grounded theory has been used for exploring social, technical, and organizational factors relevant to focused contexts. Grounded theory was used as a basis to code and summarize the thematic analysis, as it has been used extensively in health information technology studies to discover technology's impact for applications like computerized provider order entry (CPOE) and clinical decision support (69-72). One investigator (SM) iteratively performed the coding for the interview and focus group transcripts till thematic saturation was achieved. Another investigator (DSP), with advanced training and experience in informatics and qualitative research, independently recoded a sub-portion (20%) of the transcripts to ensure valid inter-rater reliability for the thematic coding. After discussing coding discrepancies and remaining non-overlaps, the mean agreement between the two coders was excellent (93%).

Results of the qualitative and quantitative data analysis were collectively considered to gain comprehensive and representative insights into provider perceptions and attitudes toward the use of patient driven clinical decision support tools.

4.4 Results

4.4.1 Qualitative Assessment

The qualitative analysis of the personal interview and focus group transcripts yielded 4 major themes: Provider *perceptions* of clinical decision support, *barriers* to effective utilization of decision support technologies, *attitudes* towards patient driven clinical decision support systems, and *gaps* in patient-provider communication..

Theme 1: Provider perceptions of clinical decision support

Interesting perspectives emerged from provider definitions of clinical decision support systems. Providers shared the belief and understanding that CDS systems provide pictorial and/or text-based information, alerts or reminders that helped them make timely and quantifiable clinical decisions.

However, we also noted attitudes associated with perceived fear of losing control of their workflow and inequity towards the benefits of CDSS. One physician said, "*I think it gives you a one liner at the bottom of your note, but beyond that I mean they are either in heart failure or they are not in heart failure....*". Another provider commented, "*It is something to help you with the decision but nothing really replaces, that's why it is a physician in the office doing a preop*".

Subtheme: Types of CDSS utilized by providers

To further explore the concept of provider definitions of CDSS we inquired on the types of CDS systems that they currently use or have used in the past. Clinician choices ranged from web based calculators like the *CHADS2 calculator* (73) and knowledge management tools like PubMed, Medline, and UptoDate. Interestingly, we also noted that

physicians associated non-technological encounters like reading books, going to library, discussions with colleagues and consults with other specialists with the concept of clinical decision support. As one physician said, "*Colleagues can be consulted for EKG and other consultations for decisions and other clinical dilemmas*." Guidelines, Order sets, Google, and the Physicians' Desk Reference (PDR) were some other entities described by providers when asked about the CDS systems they used.

Besides the wide variety of decision support options utilized by preoperative physicians, this theme also reinforces the understanding that a multitude of factors including age, clinical setting, individual factors (like gender), cultural background, experience, etc., affect individual perspectives and preferences for acceptance and use of technologies like CDSS (58,74,75).

Theme 2: Barriers to effective utilization of decision support technologies

When providing their opinion about the use and utility of decision support applications, the providers described barriers that potentially prevented their effective uptake and utilization

One physician said, "I always double check to make sure if guidelines have changed, (if) and they are on or not on the same page now", indicating lack of workflow integration as a potential barrier. Another provider seconded this by saying, "there are some difficulties there in getting the data from the patient into the EMR and it's particularly challenging for peripheral information as well". The statement, "It should look like the VA Computerized Patient Record System (CPRS). Should be easy and familiar in look and use the same format", is indicative of provider inertia to change

Subtheme: Technical expertise and technology literacy?

Statements like "*I don't like too many things to click and open*" and "*I don't use too many websites. I'm not very tech savvy*", suggest provider inertia due to insufficient technology literacy and Health IT training.

Subtheme: Provider needs for decision support technologies

"I *keep a copy of the important papers on guidelines that were published to make sure those are available, however sifting through 74 pages sometimes leaves a bit to be desired.*"

"*It is reassuring to know that if you go through the tools section. You have UptoDate available through CPRS… I probably don't use the tools all the time but I'm aware that they are there and so it is like a safety blanket*." These statements indicate provider need and appreciation for the availability of knowledge management and decision support tool at the point of care.

Theme 3: Attitudes towards patient driven clinical decision support systems

Providers favored and supported the premise of patient self-reported health information and the technologies that helped them achieve it.

As a start, physicians elicited trust in their patients for correctly reporting their medical histories. "*They know far more of their own history than what is in CPRS", "A lot of vets are more knowledgeable than what is in the chart*".

Subtheme: Improved efficiency through Patient driven decision support

Besides getting better history from patients, providers also favored patient driven tools because of their potential for making preoperative evaluation more time efficient. "*The biggest bottleneck is the time, you have a 30-minute appointment for a preop… some*

patients have everything under the sun" indicating that retrieving patient information before seeing the patient could save valuable time. Other providers agreed, and another physician added, "*if we have a more streamlined approach or change where the patient actually does this whole thing at home and comes in then I think our efficiency will improve"*.

Subtheme: Improved effectiveness through patient driven decision support

Clinicians also indicated that patient reported health information could potentially improve the effectiveness of preoperative assessment. One physician said, "*If there are issues of controversy on a particular element - did a patient have an Myocardial infarction or not…having the patient reported data to help clarify ambiguity, is helpful."*

Physicians also argued that the quality of historical information provided by patients could significantly improve through the use of patient driven clinical decision support tools. One provider said, "*In front of us they want to please us and they want to tell us what we want to hear… they might be more honest if they are not in the room being interrogated with the idea that they want to tell us the right answers."*

Subtheme: Reliable patient provided information

When questioned about the kinds of patient provided information that the providers considered reliable, the answers ranged from medical history, exercise tolerance, social history, smoking, alcohol and drug history, surgical history, cardiac procedures and stress testing. As one physician explained his common inquires to his patients, "*Do you have allergies?, what medications do you take?, what is your activity and can you be specific about the activity you do?, have you had surgeries?, did you do ok?, do you know*

anything about the outcome or complications like alcohol withdrawal or delirium or confusion or allergies or rashes a drug?…."

The providers believed that patients could be trusted to provide the correct information but were also cautious about the complete accuracy of the provided information, as elicited by a physicians' comment, "*I think patient reported information is accurate for what they say but whether it is true or not that you have to see*."

Theme 4: Gaps in patient communication

While all providers agreed that patients could play an important role in improving the completeness and overall efficiency of preoperative cardiovascular assessments, they also shared some concerns related to gaps in patient communication. *One physician said, "Vets have had an aortic valve replacement and they don't even report that"*. Another provider talked about patient expectations, alluding to a patient-provider communication gap by saying, *"I think it would be useful to know what the expectation of the patient is? If it is not consistent with scientific evidence…then it's good to correct that, so that they don't have any out of line expectations from the surgery*".

Feedback specific for the web patient self-report instrument

After demonstrating a web-based prototype of the proposed web based patient reporting tool, we gathered specific feedback from providers.

Positive feedback: Physicians received the tool well, as demonstrated by the following statements- *"It's great that even before you see the patient you can actually, you know get an idea about overall risk of the patient and then you go from there, I think it's great", "I think it is user friendly",* and *"I love it, I think it's really cool!"*

Constructive feedback: Physicians gave a number of suggestions to improve the web based system like – "*I would like to see everything in one page*", referring to the tool interface that required some scrolling over slightly more than one page. Another physician said, *"I would like to see smoking history and the patient perception of risk"*, signifying the need to see more patient reported data for effectively performing evaluations and indicating the desire to gauge patient self-perceptions of cardiovascular risk, to possibly address any differences in patient expectations. Providers also desired improved interoperability for the tool by commenting, *"It would be nice if this is tied into the EMR so it would show up automatically."*

4.4.2 Quantitative Assessment

We evaluated the quantitative assessment of tool usefulness through the provider usefulness survey instrument. We calculated Cronbach's alpha to determine the internal consistency of the provider usefulness survey instrument. We found that the instrument had excellent internal consistency, with a standardized Cronbach's alpha of 0.92.

Overall, the providers evaluated the instrument to be useful for their clinical activities related to preoperative cardiovascular risk assessment. The median for the average scores of all questions was 6.12 out a maximum possible 7 (Table – 4.2). We also calculated an *overall usefulness score* by obtaining the numerical total of all question scores generated by each physician respondent, with a minimum possible score of 120 (Score of 1 for each response x 15 questions x 8 providers) and a maximum possible score of 840 (Maximum score of 7 for each response x 15 questions x 8 providers). The overall usefulness score combined for all survey responses was 732 (out of 840) or 87%.

On average, all providers agreed that patient self-report tool would make it easier to perform preoperative cardiovascular evaluations, and help them accomplish the preoperative evaluation quickly and increase their productivity.

All providers, except one, agreed that using the patient self-report tool would enhance their productivity.

Overall, the physicians agreed that the tool was easy to use, a convenient form of collecting pertinent patient level information, and felt comfortable using it. On average, they also agreed that the tool's data collection preserved patient privacy, and collectively agreed that they would recommend this tool to their patients if it were implemented in their hospital.

4.5 Discussion

We explored physician perceptions about the usefulness of a patient self-report decision support tool for doing pre-operative cardiovascular examination, using a mixed methods evaluation. Overall, physicians at the VA Medical Center, Minneapolis found our prototype for patient driven health information retrieval tool useful. Providers expressed usefulness of decision support applications at the point of care, and agreed that the patient report tools have a potential to improve the completeness and overall efficiency of pre-operative evaluations. Zandbelt et al have reported that facilitating behavior by providers was positively associated with effective patient disclosure of information and active participation behavior (76)

However, while exploring provider perceptions about clinical decision support systems, we discovered a variety of barriers like provider inertia to change, lack of technology

literacy, and reliability of patient self-report information were perceived to prevent effective uptake and utilization of CDS technologies.

Our study results indicate that providers had strong perceptions of the usefulness of patient reported clinical decision support tools, and that patient driven decision support tools will facilitate efficiency and productivity while performing preoperative cardiovascular evaluations. Only one provider somewhat disagreed that using this tool would improve perioperative outcomes for their patients. We postulate that this attitude may be reflective of lack of subjective dependence on computer-based applications for performing preoperative evaluations.

Previous studies suggest that provider use of evidence-based guidelines can significantly improve patient perioperative outcomes (14). A large body of scientific literature suggests that patient self-reported health information is a valid resource of information and holds immense potential for improving the provision of healthcare (18,24,33,37,46,54,55).

There are a number of limitations to this study. The single site design and a small sample size could yield different results if generalized to different geographical and institutional settings. The authors have tried to supplant these deficiencies with addition of a detailed quantitative assessment by exploring social, technical, and organizational factors relevant to focused contexts of provider perceptions of usefulness for patient reported tools through qualitative interviews and focus groups. The authors also limited their scope to the assessment for perioperative cardiovascular complications, to minimize bias in provider perceptions of post-operative risk that may be driven by other risk factors and pathologies. Furthermore, actual provider uptake and use of technologies like CDS may

be different from and dependent on other factors, and may not be entirely correlated with provider perceptions of usefulness for such technologies.

Future studies should be focused on actual end-user adoption and use, and the impact of hospital wide implementation of patient reported decision support applications on quality of care and post-operative outcomes.

4.6 Conclusion

We tested perceptions of usefulness among primary care providers for a patient reported surgical risk information tool. We found that providers perceived patient-reported health information as significantly useful and view them as a valid resource of information for executing cardiovascular preoperative evaluations. Clinicians perceived the web based prototype of the patient driven clinical decision support tool as easy to use and useful for effectively completing preoperative cardiovascular risk assessments.

4.7 Conflicts of Interest

The authors declare that they have no conflicts of interest in this research study.

4.8 Human Subjects Protection

The study was performed in compliance with the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects. Prior to commencement of this study, all selected patient records were de-identified and stored using institutionally recommended data security protocols. This study was carried out

after receiving due approvals from the Institutional Review Boards at Minneapolis VA healthcare System and University of Minnesota.

Questions	**α**	***Provider Scoring***								$\bar{X}(std)$
Q1 Using the patient self report tool would enable me to accomplish preoperative cardiovascular risk evaluation quickly ¥	0.93	6	6	6	6	7	6	6	7	6.25(0.4)
Q2 Using the patient self-report tool would improve preoperative cardiovascular risk evaluation¥	0.91	5	6	6	6	7	6	6	6	6(0.53)
Q3 Using the patient self-report tool during my assessments would increase my productivity during preoperative cardiovascular risk evaluation¥	0.92	5	6	5	7	7	6	7	6	6.12(0.8)
Q4 Using a patient reported tool would enhance my effectiveness for preoperative cardiovascular risk evaluation ¥	0.92	4	6	6	6	7	3	7	4	5.37(1.5)
Q5 Using a patient reported tool would make it easier to perform preoperative cardiovascular risk evaluation ¥	0.91	5	7	7	7	7	6	7	6	6.5(0.75)
Q6 The patient reported tool is easy to use β	0.92	5	7	6	7	6	6	6	5	6(0.75)
Q7 Patient privacy seems protected during the use of the tool β	0.92	5	7	6	7	7	7	6	6	6.37(0.7)
Q8 Patient reported tool is a convenient form of collecting pertinent patient health information β	0.94	6	6	6	7	6	7	7	7	6.5(0.53)
Q9 The patient self-reported tool for cardiovascular risk evaluation will potentially mitigate the time management during preoperative evaluations ϕ	0.92	4	7	6	6	7	6	6	7	6.12(0.9)
Q10 The description and terminology used in the patient self-report tool would be easily understood by patients ϕ	0.93	6	7	6	6	7	4	6	5	5.87(0.9)
Q11 If implemented, at my hospital, I would recommend my patients to use this self-report tool for preoperative cardiovascular risk evaluation ϕ	0.91	5	7	6	7	7	6	6	6	6.25(0.7)
Q12 Using patient self-report risk evaluation would improve Perioperative outcomes ϕ	0.92	5	6	6	7	7	3	6	5	5.62(1.3)
Q13 Patient generated information is presented in an easy to understand manner σ	0.92	5	6	6	7	7	4	7	6	6(1)
Q14I felt comfortable using the preoperative cardiovascular risk evaluation σ	0.92	5	6	6	7	7	6	6	7	6.25(0.7)
Q15 It was easy to learn to use the preoperative cardiovascular risk evaluation σ	0.91	5	7	6	7	7	5	6	7	6.25(0.8)

Table 4.2 – Provider Survey Analysis

Key: α - Cronbach's Alpha for Survey with Question Deleted, $\bar{X}$- Mean Item Score, std – Standard Deviation; Likert Scale: 1 = Strongly disagree, 2 = Disagree, 3 = Somewhat Disagree, 4 = Neutral, 5 = Somewhat Agree, 6 = Agree, 7 = Strongly Agree; Question Adapted from - ¥ -TAM, β –TMPQ, ϕ – New, σ – CSUQ

Chapter 5

5.1 Conclusion

Since surgical care is a key cost and quality driver for the current health care system, the addition of low cost and patient friendly technologies are important and needed information management tools. The results from observations and analysis of these studies would help understand provider, patient experience and attitudes on the use of a decision support tool. These tools will be informed by latest evidence based best practices and guidelines to accurately predict preoperative risk of cardiovascular complications of non-cardiac surgery.

The first two studies described in chapters 2 & 3 describe how we laid a solid foundation for creating a patient self report decision support instrument and subsequently validated the instrument against gold standard provider assessment. These results have implications for use in surgical risk triaging to help reduce the risk of adverse patient outcomes, surgical cancellations, and to optimize clinical care management.

In the first study, we successfully created prediction rules to form the basis for a patient generated risk prediction tool for patient centric health care with timely stratification of preoperative risk. The results from this study provided key insights on the association between patient reported health information and expert clinician diagnosis of preoperative cardiovascular risk for patients undergoing non-cardiac surgery.

In the second study, we estimated the concordance between Revised Cardiac Risk Index (RCRI) scores generated by patient provided information and comprehensive chart

review and provider assessment and concluded that patient identified risk factors and the generated RCRI scores had near perfect agreement with gold standard clinician diagnosis. Upon examining the validity of patient reported health information, we concluded that the all five patient self-reported RCRI risk factors had a good and statistically significant overall accuracy, high specificity and negative predictive values compared to gold standard clinician evaluation. This confirmed our hypothesis that patient reported data is a valid resource for pre-operative risk assessment.

The third study helped us assessed how the prototype met functional goals (features, format, and interface), and what were end user' perceptions of the facilitators and barriers to using the prototype at the point of care. Information gathered from this study helped us further the application based on specific user feedback. This step was important to achieve optimal integration for finalized versions of the CDSS prototype. Clinician experiences and ideas for improvement of the current version were collected and will be used for further development of the application. Participant providers agreed that patient-driven information acquisition tools are clinically reliable and potentially viable information technologies to support clinical care coordination, cost reduction, patient self-engagement and following the accountable care paradigm.

The three studies shared a limitation of single center and moderate sample. In spite of this limitation, these studies provide vital insights into the use of patient driven tools for cardiac risk assessment and provide important data on viability of the approach which are likely extendable to other clinical sites and patient populations.

The NHLBI working group on Preoperative Medicine report has concluded that post–operative complications are costly and must be recognized as a national concern. The report concluded that attention and specialized testing should be targeted towards high-risk groups to reduce high costs of complications and surgery delay. The committee recommended risk-profiling patients and sought new avenues for reducing post-operative complications (77). In a collaborated report by the American Association of Hip & Knee Surgeons (AAHKS) and FORCE-TJR (Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement) concluded that addition of patient-reported preoperative risk factors significantly improved the 30-day complication and readmission rates for post joint replacements (78) Since, patient history is important component for determining cardiac or comorbid diseases that put patients at high surgical risk and has been established to be a valid information resource (18,24,33,37,46,54,55), patient driven tools like the one developed as part of this doctoral research cater to a crucial information need in pre-operative medicine.

The combined knowledge of from this thesis serves a novel attempt to acquire and validate patient reported information on symptoms, risk factors, surgical history, exercise capacity, and pre-existing conditions for the purpose of pre-operative cardiac risk evaluation. Findings from the three studies outlined in this manuscript should inform developments in the field of patient driven decision support. Other body systems and disciplines like pulmonary, neurological, hematology, mental evaluation and medication reconciliation, can be integrated to form comprehensive patient driven pre-operative assessment application in future. There is significant evidence that involving patients in decision-making may improve patients' satisfaction, well-being, lifestyle and health

outcomes (19,79-81) providing a fertile ground for future research work. These collective findings should inform future innovations in the design of patient driven technological applications using web based and mobile platforms to easily acquire and leverage patient self-reported health information and bolter patient–provider communication, and patient engagement and contribute to reduction in treatment costs.

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Appendix A

I.	Unstable coronary syndromes including unstable or severe angina or recent MI
II.	Decompensated heart failure including New York Heart Association (NYHA) functional class IV or worsening or new-onset heart failure (Appendix A)
III.	Significant arrhythmias including high-grade AV block, symptomatic ventricular arrhythmias, supra-ventricular arrhythmias with ventricular rate > 100 bpm at rest, symptomatic bradycardia, and newly recognized ventricular tachycardia.
IV.	Severe heart valve disease including severe aortic stenosis or symptomatic mitral stenosis.
V.	Recent percutaneous coronary intervention (PCI).
VI.	Aortic stenosis - Aortic stenosis (AS) is not included in most risk indices as a risk factor. The reason attributed for this is the rare incidence of AS. However moderate to severe AS has been to seen to be a significant risk factor for post-surgical outcomes.

Table A.1 - Pre-existing conditions that associated with high risk of post-operative complication (7)

Unstable coronary syndromes	Unstable or severe angina (CCS class III or IV) Recent Myocardial Infarction
Decompensated HF (NYHA functional class IV; worsening or new-onset HF)	
Significant arrhythmias	High-grade atrioventricular block Mobitz II atrioventricular block Third-degree atrioventricular heart block Symptomatic ventricular arrhythmias Supraventricular arrhythmias (including atrial fibrillation) with uncontrolled ventricular rate (HR greater than 100 bpm at rest) Symptomatic bradycardia Newly recognized ventricular tachycardia
Severe valvular disease	Severe aortic stenosis (mean pressure gradient greater than 40 mm Hg, aortic valve area less than 1.0 cm^2, or symptomatic) Symptomatic mitral stenosis (progressive dyspnea on exertion, exertional presyncope, or HF)

Table A.2 - Active Cardiac Conditions for Which the Patient Should Undergo Evaluation and Treatment Before Non-Cardiac Surgery (7)

Appendix A.3

Pre-Operative Self-Risk Assessment Questionnaire for Patients

What is this survey about?

This survey is to help your provider assess the risk of possible heart related complications that may result of your upcoming surgery. Please complete and return this form to your provider at the start of your pre-operative clinic visit.

Instructions

Please read the following questions carefully and enter your responses for all questions to the best of your knowledge.

1. Based on your current health status and knowledge of existing medical conditions, how would you rate your risk of a heart related complications (such as heart attack, heart failure etc.) during or as a result of surgery?

- ☐ Not at Risk
- ☐ Low Risk
- ☐ Moderate Risk
- ☐ High Risk
- ☐ Very High Risk

2. What is the most strenuous physical activity that you have been able to do in the last 3 months? **Check all that apply.)**

- ☐ Walk for exercise (Brisk pace- covering 1 mile in less than 20 minutes) **Or** Walk to/from work
- ☐ Rake lawn or weeding garden or shovel snow by hand
- ☐ Climb more than 1 flight of stairs or walk up a hill
- ☐ Ride a bicycle 3.5 mph or faster
- ☐ Sports activities like tennis, basketball, football, skiing, golf (carrying clubs)
- ☐ Sexual activity (Moderate to vigorous effort)
- ☐ Other (Please Specify) _____

3. For each of the following, please indicate if it has ever happened to you**:**

	YES	NO	NOT SURE
Do you ever have any pain or discomfort in your chest?	☐	☐	☐
Does walking at a normal pace on level ground give you chest pain?	☐	☐	☐
Does walking fast uphill give you chest pain?	☐	☐	☐
Have you ever been told by a physician that you have had a Heart Attack and/or suffer from Unstable Angina?	☐	☐	☐
Have you ever been told by a doctor that you have congestive heart failure (CHF)?	☐	☐	☐
Do you have leg swelling due to fluid retention?	☐	☐	☐
Have you ever been told by a physician that you have had a ministroke, or transient ischemic attack (TIA)?	☐	☐	☐
Have you ever had sudden painless weakness on one side of your body?	☐	☐	☐
Have you ever had sudden numbness or a dead feeling on one side of your body?	☐	☐	☐
Have you ever had sudden painless loss of vision in one or both eyes?	☐	☐	☐

Q3: Continued: For each of the following, please indicate if it has ever happened to you

	YES	NO	NOT SURE
Have you ever suddenly lost the ability to understand what other people are saying?	☐	☐	☐
Have you ever suddenly lost the ability to speak or write?	☐	☐	☐
Do you use insulin for treatment of diabetes?	☐	☐	☐
Have you ever been told by a physician about or seen your lab results showing blood creatinine level greater than 2 mg/dL?	☐	☐	☐
Have you ever been on dialysis?	☐	☐	☐
Have you ever been told by a physician about heart rhythm problems (like irregular or skipped beats) such as atrial fibrillation (Afib)?	☐	☐	☐

4. Have you ever undergone following procedures:	YES	NO	NOT SURE
	☐	☐	☐
Cardiac Stress test (treadmill test)?	☐	☐	☐
If Yes, enter year of last test |___|___|___|___|			
Heart bypass Surgery (CABG)	☐	☐	☐
Heart stent or angioplasty (PTCA) or balloon angioplasty	☐	☐	☐
	☐	☐	☐

5. Which surgical procedure you are going to have?

_____

_____

_____

_____

Please list any other medical conditions not covered in this questionnaire, and are important considerations for your upcoming surgery:

1. _____

2. _____

3. _____

4. _____

PLEASE GIVE THIS FORM TO YOUR PHYSICIAN AT THE START OF YOUR PRE-OPERATIVE ASSESSMENT.