THE ECOLOGY OF CLINICAL DECISION MAKING

THE ECOLOGY OF CLINICAL DECISION MAKING: PHYSICIANS' PERCEPTIONS OF FACTORS THAT INFLUENCE CLINICAL PRACTICE DECISIONS AND IMPLICATIONS FOR PROVIDING HIGH-VALUE CARE

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TITLE: The ecology of clinical decision-making: Physicians' perceptions of factors that influence clinical practice decisions and implications for providing high-value care

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LAY ABSTARCT

Despite the highest health-care expenditure in the world, patient health outcomes are suboptimal in the United States (US). Additionally, out-of-pocket patient costs are increasingly a cause of financial distress to American patients. Although Canada spends comparatively less than the US on healthcare, it is one of the top ten countries for healthcare spending as a proportion of the gross domestic product. In spite of this level of spending, patient outcomes in the US and Canada are worse when compared to many other economically developed countries that spend relatively less on healthcare. A substantial portion of healthcare spending is for services that do not improve patient outcomes while services proven to improve patient outcomes are underused. Utilizing sequential quantitative and qualitative studies this thesis is a purposeful attempt to identify and examine the factors that influence clinical decision making by physicians. The knowledge gained in this study may help inform the development and evaluation of strategies targeted at increasing adoption of evidence-based practices leading to improved health-outcomes at affordable costs.

ABSTRACT

Despite substantial healthcare costs, patient outcomes are suboptimal in the United States and Canada compared to other countries that spend proportionally less on healthcare. This has led to recognition of the need to improve healthcare value, utilization of tools including clinical practice guidelines and development of initiatives such as the Choosing Wisely Campaign to achieve this goal. In spite of the intuitive appeal of these interventions designed to increase physician awareness of evidence and empower patients to engage in shared decision-making, they have had limited success in changing practice and physician prescribing behaviours. Using a mixed-methods approach, this thesis represents a purposeful attempt to understand the failure of existing approaches through an examination of the factors that influence clinical decision making.

Specifically, the thesis integrates quantitative and qualitative methodologies to develop a deeper understanding of clinical decision-making. Consisting of a clinical vignette based survey, the quantitative study explores decision-making in four specific commonly encountered case contexts. After choosing the preferred management option, participants rated the influence of different factors on their decisions. Follow-up questions explored knowledge, attitudes and practices regarding incorporating cost considerations into decision-making. The results of the study were explored further in the qualitative component of the mixed study. The results indicate that clinical decisionmaking is influenced by an interrelated set of socioecological factors with evidence and clinical practice guidelines playing a secondary role. Because lack of knowledge is not a

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major factor in guideline discordant care, strategies to improve knowledge will have minimal effect in improving care. The qualitative study included an inquiry into the need for teaching and learning on the topic of cost and cost-effectiveness and sought input from physicians working in diverse settings on methods and topics that need to be included in medical education. The contributions of this thesis include a deeper understanding of the factors that influence clinical decision-making and suggestions for enhancing medical education.

Keywords: Clinical Decision-Making; High-Value Care; Overuse, Evidence-Based Medicine, Clinical Practice-Guidelines, Healthcare Costs, Medical Education

DEDICATION

I dedicate this thesis to my patients at the Veterans Affairs Health Care System in Western New York and Northern California. They have inspired me to be a better person, physician, and a researcher. Their selfless sacrifices enable us to live in a free society and pursue our dreams; they deserve the best veteran-centered healthcare we can provide.

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First and foremost, I would like to thank my supervisor and supervisory committee for their consistent support and encouragement throughout my studies at McMaster, this thesis would not have been possible without their guidance. I have been incredibly fortunate to be guided by these four unique, committed, passionate, knowledgeable and generous individuals. Their insightful comments and feedback improved my analytical and writing skills tremendously. I will forever be grateful to my dissertation supervisor, Dr. Susan Jack, who stepped in when I needed a helping hand, encouraged, cajoled and nurtured my passion for exploring clinical decision-making and guided me through my forays into qualitative research. Dr. Gordon Guyatt, who is a role model to so many of us, his kindness, inclusivity, keen intellect, and ability to identify the crux of a puzzle continue to inspire me to do and be better. Dr. Sandra Monteiro motivated me to continue on this journey with her unique outlook and passion for decision-science and her support of my education in designing and analyzing survey results. Dr. John You's astute observations of physician-patient interactions improved my understanding of the topic and enhanced this work substantially.

My family – My achievements belong to my family as much as they belong to me. I am because of them. Their support at every step has made it possible for me to reach the conclusion of my doctoral studies.

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DECLARATION OF ACADEMIC ACHIEVEMENT

This "sandwich" thesis consists of four manuscripts resulting from a mixed-methods study of US and Canadian physicians of factors that influence clinical decision making. At the time of writing (October 2018) two of the four individual manuscripts (chapters 2 and 3) have been published in peer reviewed journals, and the remaining two (chapters 4 and 5) have been submitted for publication.

The student (Veena Manja) is the primary author on all of these studies. Her contribution to this work include: developing the research questions, designing the studies, developing and writing the study protocol, performing the data collection, conducting the analyses, writing all manuscripts, and the incorporation of thesis committee, co-author and journal reviewer feedback into the manuscript revisions. All published work has been reproduced with permission.

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LIST OF ABBREVIATIONS

- ACC: American College of Cardiology
- AHA: American Heart Association
- ANOVA: Analysis of Variance
- AUC: Appropriate Use Criteria
- CA: California
- **CPG: Clinical Practice Guidelines**
- CBC: Complete Blood Count
- CT: Computerized Tomography
- CTA: Computerized Tomography Angiography
- CCS: Canadian Cardiovascular Society
- CME: Continuing Medical Education
- CABG: Coronary Artery Bypass Grafting
- CAD: Coronary Artery Disease
- CEA: Cost Effectiveness Analysis
- **CPK:** Creatinine Phosphokinase
- ECG: Electrocardiogram
- ED: Emergency Department
- EBM: Evidence Based Medicine
- FDA: Food and Drug Administration
- GDP: Gross Domestic Product
- HMO: Health Maintenance Organization
- HRS: Heart Rhythm Society
- ICD: Implantable Cardioverter Defibrillator
- IOM: Institute of Medicine

- LVEF: Left Ventricular Ejection Fraction
- LDL: Low Density Lipoprotein
- MI: Myocardial Infarction
- NICU: Neonatal Intensive Care Unit
- NYHA: New York Heart Association
- NIDDM: Non-Insulin Dependent Diabetes Mellitus
- OECD: Organization for Economic Cooperation and Development
- OOP: Out-of-Pocket
- PCI: Percutaneous Coronary Intervention
- QOL: Quality of Life
- **RVU:** Relative Value Unit
- SPECT: Single Photon Emission Computerized Tomography
- SONPM: Society of Neonatal Perinatal Medicine
- STEMI: ST Elevation Myocardial Infarction
- SCD: Sudden Cardiac Death
- URL: Uniform Resource Locator
- US: United States
- VF: Ventricular Fibrillation
- VT: Ventricular Tachycardia
- WCD: Wearable Cardioverter Defibrillator
- ZIP code: Zone Improvement Plan code

CHAPTER ONE

INTRODUCTION

Background

In the United States (US), health care expenditure is growing faster than the economy¹; according to the Centers for Medicaid and Medicaid Services projection, it will account for nearly 20% of the gross domestic product (GDP) by 2026.² Patients' out-of-pocket healthcare spending accounts for an increasing portion of this spending; in 2010, out-of-pocket patient expenditure accounted for 11.8% of total national health expenditure amounting to \$306.2 billion dollars³; people with employer-sponsored insurance accounted for over 80% of this spending. Patients' concerns over out-of-pocket spending were reflected in the results of a recent survey⁴: even though a majority of patients (62%) indicated that quality of care was the most important aspect of value, 28% of patients indicated that cost was most important.

Although Canadian spending on healthcare is significantly lower that the US, it ranks in the top 10 in healthcare spending as a percentage of the GDP among the Organization for Economic Cooperation and Development (OECD) countries.⁵ Canadian healthcare financing is very different compared to the US and patients' out-of-pocket spending is less frequent.⁶ In spite of this substantial expenditure on healthcare, when measured on the basis of outcome indicators, the performance of the American and Canadian health care systems is poor.¹

While there are several factors implicated as causes of rising healthcare costs including the aging of the population,⁷ adoption of new medical innovations and increasing use of expensive medical technology⁸; physicians' clinical decision-making is an important factor to consider. Physicians under-prescribe interventions proven to improve patient outcomes,⁹ while a substantial portion of health spending is for services that do not improve patient health outcomes.¹⁰ Unnecessary medical testing and treatment in the US¹¹ and Canada¹² are well documented and the literature on the extent of unnecessary testing and treatment (frequently referred in the literature as 'overuse') is increasing.^{13,14}

In response to these observations, several proposals¹⁵⁻¹⁷ have been put forth to limit this practice, including promoting 'high-value' care.¹⁸ The American College of Physicians defines 'high-value care' as healthcare that balances clinical benefit and harms with costs with a goal of improving patient outcomes while making better use of limited rsources.¹⁹ Although providing high-value care is of tremendous interest and much has been written on this topic by experts,^{20,21} professional societies¹⁹ and associations,²² designing and implementing strategies to increase high-value care as a strategy to limit overuse has proved challenging^{23,24} as illustrated using the example of the Choosing Wisely campaign.

This initiative was launched in 2012 by the American Board of Internal Medicine and Consumer Reports²² and has been adopted by several countries²⁵ including Canada.²⁶ The centerpiece of the campaign is a list of evidence-based recommendations published by each medical specialty society to avoid unnecessary tests, treatments or procedures. Within the Choosing Wisely initiative, strategies to achieve this goal include efforts to engage physicians and patients in shared decision making. More than 80 societies have joined the effort to date with over 600 published recommendations.²⁷

In spite of the enthusiasm and commitment by professional societies to the campaign, a measurable decrease in the delivery of unnecessary interventions has been difficult to achieve.²⁸ A retrospective analysis of claims data for members of Anthemaffiliated commercial health plans with 25 million members across the US found mixed (modest improvement and declines) results for seven low-value services included in the Choosing Wisely campaign.²⁹ Similarly, Welk and colleagues in their study using administrative data from Ontario, Canada, found no change over five years in three practice patterns featured in Choosing Wisely Canada Recommendations.³⁰ There is little evidence therefore that the Choosing Wisely Campaign has succeeded in achieving its goal of increasing high-value care. Proposed reasons for this deficiency include limited awareness of the campaign and its recommendations among frontline providers.³¹ Utilizing ineffective strategies to optimize the value of healthcare due to an incomplete understanding of the drivers of overuse have also been noted as a reason for limited results.^{28,32,33}

The overall objective of this thesis was to examine physician decision-making in specific contexts and to explore factors that limit high-value care. Our goal was to develop and publish a body of work elucidating the factors that influence clinical

decision-making by physicians in the US and Canada and thus contribute to our understanding of cost and value considerations in clinical decision-making. This includes considering how physicians use knowledge of evidence, costs, clinical practice guidelines (CPG) and other factors in their decisions. The results of this study can inform the design of strategies aimed at changing physician behavior to facilitate high-value care. Furthermore, based on responses to the survey expressing a need for improved teaching in medical education about costs and value in healthcare, I wanted to explore teaching and learning needs during medical education as perceived by practicing physicians to enable future physicians in providing patient-centered high-value care.

The remainder of the chapter will provide an overview of frameworks to understand drivers of overuse, efforts to improve physician knowledge of best available evidence to influence decision-making - specifically CPG, the complexity of clinical decision-making, the research design and methods used for this thesis, and the potential impact of this work on optimizing clinical decisions to provide high-value patientcentered care.

Frameworks to improve high-value care

Treatment decisions are typically made within the context of a patient-physician encounter in which the physician is the expert in the scientific knowledge about the disease and its treatment. The role of the physician is central to many models of medical decision-making that have emerged from a wide range of decision theories.³⁴ The models ascribe a range of physician influences in the decision-making process from a physician

controlled pattern in the paternalistic model to variable patient participation and control in models of shared-decision making.³⁴

The evidence-based medicine (EBM) framework^{35,36} focuses on improving evidence-based knowledge and is a component of strategies aimed at improving application of knowledge such as the knowledge-to-action frameworks.³⁷ Other published frameworks³⁸⁻⁴⁰ attempt to identify and understand the drivers of overuse. In 2017, Morgan and colleagues³⁹ used an iterative, expert-informed, evidence based process to develop a practical framework that conceptualizes the patient-clinician interaction as the nexus of clinical decision-making and of decisions regarding inappropriate interventions and overuse. This patient centered approach targets optimizing outcomes for patients in the weighting of clinically reasonable options. Domains include the culture of professional medicine, clinicians' attitudes and beliefs, the culture of healthcare consumption, patient factors and experiences and the practice environment. For most of the domains (and factors related to each of these domains), available evidence was low quality.

Clinical Practice Guidelines

Clinical Practice Guidelines⁴¹ (CPG) are statements intended to optimize patient care based on evidence of benefit and harms of an intervention . CPG are developed based on a systematic review of the literature including an assessment of evidence quality and are one strategy to promote evidence based care. They incorporate various factors

including the magnitude of benefits and harms, evidence quality,⁴³ patients' values and preferences and – increasingly – resource use and costs, summarized into recommendations.^{43,44} Clinical practice guidelines developed by the American College of Cardiology (ACC)⁴⁵ in collaboration with the American Heart Association (AHA) have been the primary source of guidance for practicing cardiologists in the US for over three decades.⁴⁵ In spite of the potential for improved patient outcomes with adherence to guideline recommendations,⁴⁶ implementation has remained suboptimal.⁴⁷⁻⁴⁹ Using guidelines as tools to improve evidence-based decision-making has met with limited success.^{47,50}

Cost-considerations are being explicitly incorporated in clinical practice guidelines by many medical societies.⁵¹ In 2014, the ACC decided to consider evidence on cost, value and cost effectiveness,⁵² when feasible, in the development of their CPGs. This practice is currently being implemented. The guidelines on evaluation and management of syncope published in 2017 include extensive information on cost and cost effectiveness.⁵³ However, a survey conducted by Ginsberg and colleagues⁵⁴ reflects variation in clinicians' knowledge and attitudes towards incorporating costs and costeffectiveness in clinical decision making as does a more recent study of oncologists published in 2016.⁵⁵ The impact of including costs in guidelines is uncertain and needs further study.

Clinical Decision-Making

Clinical decision making during a patient- physician encounter is complex and involves several inter-related steps. Even in the simplest of encounters, it involves clinical assessment to recognize and prioritize a patient's problems, formulate a differential diagnosis, order diagnostic tests if needed, interpret and integrate streams of information from the patient's history, physical exam, test results to make a diagnosis, formulate a treatment plan while considering patient's values and preferences and educate the patient about the benefits, side effects and alternatives to the chosen treatment option.

The psychology of clinical decision-making suggests that physicians (and patients) are not rational actors when making decisions.^{56,57} Research in behavioral economics has shown that real-world prescribing choices are heavily influenced by irrational biases⁵⁸ and under-appreciated influences.^{59,60} One example is the illusion of control that has been labelled 'therapeutic illusion'³² in the context of healthcare decisions. This is a form of confirmation bias leading to over-estimation of the benefits of medical interventions facilitating continued use of inappropriate tests and treatment.³² Commonly cited examples include the treatment of low back pain⁶¹ and the use of joint-lavage for relief of osteoarthritis knee pain despite evidence based recommendations against its use.⁶²

The Current Thesis: Rationale

The focused review of the literature presented above on the limited success of efforts to improve high-value care and the inadequate understanding of the factors that drive low-value clinical decisions provides the impetus for an in-depth examination of the factors that influence clinical decision-making by physicians in specific clinical contexts. Based on limited success of knowledge translation strategies, it is evident that improving knowledge about evidence, costs and value may not be sufficient to change physician prescribing behavior. To better understand the socio-cognitive factors that influence clinical decision-making, I conducted this sequential explanatory mixed-methods study.

Factors examined in this study include quality and practice elements that may influence clinical decisions. The Institute of Medicine (IOM)'s framework for quality of care⁶³ has been adopted by many organizations⁶⁴ and researchers⁶⁵ and was used to inform the survey design in this study. It organizes the determinants of quality into six domains: safety, effectiveness (evidence-based), patient centered care, timely, efficient (resource use and cost-considerations) and equitable. Timeliness and equity issues were not applicable to the vignettes included in this study. The influence of the remaining four domains (Safety, Effectiveness, Patient-centered and Efficient) was assessed. According to the definitions put forth by the IOM⁶³, the domain of safety refers to avoiding harm to patients from the care that is intended to help them. Effectiveness refers to providing services based on scientific knowledge to all who could benefit and refrain from providing services to those not likely to benefit (avoiding underuse and misuse respectively). Patient-centered care is providing care that is respectful of and responsive to individual patient preferences, needs and values and that patient values guide all

clinical decisions. Efficiency refers to cost and resource stewardship.⁶³ In addition to the four IOM domains, I included in my survey three additional factors from Morgan and colleagues' conceptual framework for overuse.³⁹ These include medicolegal considerations, physicians' prior experience and local practice. To support the decision to include these factors in the survey, the following paragraphs provide a brief background literature on the influence of these three factors in clinical decisions.

Medicolegal liability and the practice of defensive medicine^{66,67} has been implicated as a cause of overuse. An analysis based on a survey and the Medicare database by Reschovsky and colleagues⁶⁸ found an association between malpractice fears and higher spending per patient. Based on data on admissions to hospitals in Florida and linking them to malpractice history of the attending physician, Jena and colleagues⁶⁹ also found that after adjusting for patient characteristics, higher resource use by physicians was associated with fewer malpractice claims. Work from organizational and social psychology suggests that the hierarchical nature of the provider-patient relationship may lead physicians to prioritize their own outcomes over patient outcomes.⁷⁰ Medicolegal concerns may motivate physicians to choose management options that are 'defensive' and protect the provider against medical liability while not necessarily being useful to the patient.

The physician's clinical experience and expertise and other contextual factors in the practice setting also influence decisions. These include hospital protocols,⁷¹⁻⁷³ peer influences^{74,75} and local hospital practices⁷⁶ as well as physician prior experience.^{77,78} The importance of prior professional experience and the role of 'clinical intuition' was

explored in a recent qualitative study⁷⁷ that found that learning from their own and other colleagues' experiences contributed a major part of physicians' professional development and was integrated with evidence of effectiveness from clinical trials to decide on management options.

I chose to focus on cardiology based on my background and expertise as a cardiologist in clinical practice in the US and on significant costs of care and resource use in patients with cardiovascular diseases. Available literature documents significant overuse of testing and treatment in cardiology.⁷⁹⁻⁸¹ Due to the high prevalence of cardiovascular disease and high treatment costs, spending on cardiovascular diseases continues to increase⁸²; it constitutes 17% of overall national health expenditure.⁸³ Studies project increases in total direct cost of treating cardiovascular disease to \$818 billion with an additional \$276 billion in indirect costs due to lost productivity⁸³ by 2030. In Canada, management of cardiovascular diseases accounts for several billions of dollars in annual costs to the healthcare system.⁸⁴

In a parallel study that was (largely) separate from this thesis, I also elicited the perspectives of neonatologists on factors contributing to low-value care. In the US preterm births account for a quarter⁸⁵ of all pediatric healthcare costs and lead to several billion dollars in healthcare spending every year.^{86,87} There is an increasing focus in the neonatal literature on considering cost effectiveness^{88,89} in medical decision making. For the chapter in this thesis that reports on the topic of teaching and learning, I was able to include responses related to teaching and learning in interviews that were conducted with neonatologists.

Purpose Statement

The purpose of this mixed methods study was to examine and understand the factors that influence clinical decision-making in cardiology. I used an explanatory sequential mixed method design that involved collecting quantitative data first and then explaining the quantitative results with in-depth qualitative data. In the first, quantitative phase of the study, a clinical vignette-based survey consisting of four common cardiology scenarios addressed the influence of seven factors on clinical decision-making in diverse practice settings in the US and Canada. I tested the association of various physician characteristics (practice setting, years out of training and gender) with their responses. The second qualitative phase was conducted as a follow up to the survey results to help explain the results of the survey. In this qualitative study, I explored the influence of the factors on clinical decision-making including specific cost considerations. Use of these two complementary methods provided increased understanding of clinical decision-making and also accomplished data triangulation.⁹⁰

Using the two methods in sequence as described provided a comprehensive understanding of the process of decision-making. The influence of specific contextual factors described in the vignettes and the survey results was explored during the semistructured interviews. Neither method is sufficient to capture the relative influence of these factors across a diverse group of clinicians in different practice settings (addressed by the quantitative phase) *and* to provide an in-depth understanding of the reasons behind clinical decisions while considering costs, values and preferences (explored in the

qualitative phase). When used in combination, these methods provided a more complete understanding of clinical decision-making.

The Quantitative Phase – Clinical Vignette Based Survey

In the first phase of this study, to examine the influence of quality and contextual factors in decision making in the context of specific patient-clinician interactions, I designed clinical vignettes specifying a hypothetical patient with a specific medical condition. Each vignette contained realistic detail to simulate clinical conditions that clinicians encounter routinely. Clinical vignette based surveys have been used to measure practice variations⁹¹ and physician performance.⁹² The ability to manipulate specific aspects of the vignette can provide insight about the influence of different factors on behaviors and decisions that may be difficult to evaluate in real-life situations due to confounding sources of variability.⁹³

Although concerns about the 'artificiality' of vignettes and the validity^{94,95} of research findings using clinical vignettes have been raised in the literature, available evidence suggests that with well-constructed vignettes participants respond to hypothetical and real life situations in a similar manner.^{92,96} Several studies have found vignettes to be a valid, reliable, inexpensive and practical method for assessing clinical practice.^{91,97} One approach to exploring decision making by clinicians is to evaluate how they consider the evidence of clinical effectiveness and cost effectiveness and how they balance patient centered care with practice and resource constraints within a specific

context described in a clinical vignette. Limiting the context to specific populations may offer richer information regarding the influence of patient context.

I designed the survey including four clinical vignettes describing a specific patient presentation in each. The cases chosen represent common clinical scenarios with variation in practice and significant resource use including overuse in testing and treatment.^{80,81} After reviewing the vignette, participants were asked to choose from five management options. The response options included a choice consistent with current CPG recommendations. Once participants chose the management option, they were asked to rate the influence of seven factors (safety, effectiveness, patient-centered care, efficiency, local hospital-practice, medicolegal concerns, and prior experience) on their decision using a scale of 1 (unimportant) to 7 (critically important). Follow up questions explored the impact of CPG recommendations, cost considerations, and medicolegal issues.

The Qualitative Phase – Qualitative Descriptive Study

The results of the case-based surveys were further explored in the second phase of this mixed methods study. The conduct of the qualitative study was informed by the principles of qualitative description. In qualitative description⁹⁸⁻¹⁰⁰ the researcher stays close to the data and provides factual summaries of the participants' experiences and perceptions without much interpretation. This approach uses low-inference in its description and is grounded in the principles of naturalistic inquiry. Since this study seeks

to describe the factors that influence decision making, qualitative description is well suited for this purpose.

The results of the survey informed the interview guide for the semi-structured interviews. Based on a recent systematic review on the topic by Kallio and colleagues,¹⁰¹ the following recommended steps were followed in the development of the interview guide for the qualitative portion of this study:

Step 1 - Identifying the prerequisites for using the semi-structured interviews

Aim of this phase is to evaluate the appropriateness of the semi-structured interviews as a rigorous data collection method in relation to the selected research questions. The semi-structured interview is suitable to study topics related to individuals' perceptions and opinions and when exploring values and intentions. Based on our research questions relating to understanding the use of evidence, costs and values in clinical decision making, the semi-structured interview is the most appropriate method for data collection. It allows an understanding of the properties and dimensions of a concept being explored and for diverse perceptions to be expressed by clinicians with difference preferences and values and to explore the findings of the survey in depth.

Step 2 - Retrieving and using previous knowledge

The aim of this phase is to gain a comprehensive and adequate understanding of the existing knowledge on the topic. This can create a predetermined framework for the interview. A review of the literature identified current knowledge and gaps in our

understanding of clinical decision making that are summarized earlier in this chapter. Identification of topic areas that need further study led to the development of the specific clinical vignettes and follow up questions included in the survey. The responses on the survey, including the free-text comments to the questions form the basis of the interview guide.

<u>Step 3</u> - Formulating the semi-structured interview guide

The aim of this phase is to formulate the interview guide. The interview guide is a list of questions which directs the conversation during the interview. The quality of the interview guide not only guides the implementation of the interview but also the analysis of the collected data. Keeping the interview guide flexible and changing the order of questions based on the flow of the conversation leads to the richest possible data collection.

Analysis of the survey data informed the development of the questions to be included in the interview guide. The questions were designed to help explain the variation in the responses and to further explore some of the comments made by the survey respondents in response to the free text option. The wording of the research questions was carefully reviewed to ensure a neutral position and be open-ended. Follow up questions and prompts were prepared for use where needed to enhance the depth of understanding.

The questions were clearly worded, participant oriented, not leading and open ended to generate spontaneous in-depth and unique responses based on the participant's experiences. The interview guide consisted of two levels of questions – the main themes

and follow up questions. The main themes cover the main topics of the study and follow up questions were based on the responses to the main themes to capture details and aim to gain a deeper understanding of the phenomenon of clinical decision making during individual patient-physician interactions

While the wording of the questions encourages open ended responses allowing participants to fully express their viewpoints, one potential difficulty with open ended questions may be with coding data; it may be difficult to extract similar themes or codes from the interview transcripts compared to less open-ended responses. Analyzing the responses to accurately reflect the overall perspective of the responses through the coding process may be challenging. The benefit of this process, however, is that it has the potential to reduce interviewer and researcher biases.

<u>Step 4</u> - Pilot testing the interview guide

The aim of this phase is to confirm the relevance and coverage of the formulated preliminary guide and to identify the possible need to reformulate questions and to test its implementation. This was done in several ways including internal testing, expert assessment and field testing. I tested the interview guide internally, removed ambiguous language and inappropriate leading questions and interviewer bias. The relevance of the questions were discussed with cardiologists, wording and arrangement of questions were revised to allow for a logical flow of topics during the interview. The preliminary interview guide was tested with two study participants to determine if the questions were intelligible, ascertain the effectiveness of the questions and follow up questions to

improve the flow of the interview. This also enabled an assessment of the time that would be required to complete the interview.

<u>Step 5</u> - Presenting the complete semi-structured interview guide in the study paper. The final interview guide is included as an appendix to the final manuscript of the qualitative study.

Summary of Thesis chapters

Chapter 2 describes the mixed-methods study protocol¹⁰² and explains the rationale for using a mixed methods approach. The strength of using a mixed methods approach includes a comprehensive understanding of the phenomenon of clinical decision-making in specific contexts and exploring the influence of specific factors in those contexts. The study protocol has been published in the European Journal for Person Centered Healthcare. The full citation for this study is: Manja V, Monteiro S, Guyatt G, You J, Lakshminrusimha S, Jack S. Understanding the factors that influence clinical decision making – a sequential explanatory mixed methods study protocol. European Journal for Person Centered Healthcare 2018; 6-2:329-338. This protocol includes description of a survey of neonatologists that was carried out in parallel to the study of cardiologists and is not included in this thesis.

The methods and results of the clinical vignette based survey (the quantitative component) are presented Chapter 3.¹⁰³ The study identified specific contextual factors that influenced decisions in different case-scenarios. This study has been published in the European Journal for Person Centered Healthcare. The full citation for this study is:

Manja V, Guyatt G, Monteiro S, Jack S, Lakshminrusimha S, You J. Sources of practice variation in cardiology – The influence of clinical context, cost, physician perceptions, and practice considerations. European Journal for Person Centered Healthcare 2018; 6-3:492-504.

Chapter 4 reports the results of the qualitative descriptive study (the qualitative component) which explored the results of the survey using semi-structured interviews with twenty one cardiologists practicing in diverse settings in the US and Canada. This study found a significant influence of socioecological factors; the results were mapped to the ecological systems theory framework. The study results have been submitted to the journal Heart and are under review.

Chapter 5 reports on the teaching and learning needs on the topic of incorporating costs and value in medical decision-making during medical education identified by practicing physicians in cardiology and neonatology. In addition to content related to costs, participants identified a need to improve data-interpretation and literature review skills and communication skills to facilitate patient-centered high-value care. A manuscript describing this study has been submitted to the journal Advances in Health Sciences Education and is under review.

Chapter 6 summarizes and integrates the results of the quantitative and qualitative components of the mixed methods study, makes recommendations for clinical practice, policy and education, and identifies directions for future research in this field.

Importance

We live in a time of ever increasing technological sophistication and costs. While there have been tremendous advances in improving health outcomes, significant waste and unnecessary use of resources threaten to slow the progress towards universal affordable healthcare. A thorough understanding of the factors that influence clinical decision-making is essential to providing high-value care. This study is a step towards improving our knowledge of factors influencing clinical decisions and may assist with developing strategies to promote patient-centered, affordable high value care.

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CHAPTER TWO

The study protocol: **'Understanding the factors that influence clinical decisionmaking - A sequential explanatory mixed methods study protocol'** has been published in the European Journal for Person Centered Healthcare. Permission from the journal editors to include the published paper in this thesis and to post this work in the University repository and Archives Canada is included on the next page followed by a reproduction of the published paper.





26 January 2018

Dr. Veena Manja Department of Surgery 2221 Stockton Blvd. Sacramento CA 95817 USA

Dear Dr. Manja,

Article: Understanding the factors that influence clinical decision-making – A sequential explanatory mixed methods study protocol.

I am pleased to advise you that the signed License to Publish covers you to include your Article within your PhD Thesis.

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PROTOCOL

Understanding the factors that influence clinical decisionmaking - a sequential explanatory mixed methods study protocol

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Abstract

Background: Despite soaring healthcare costs, patient outcomes are suboptimal in the USA. Efforts to limit healthcare costs and improve quality of care have had limited success. An improved understanding of factors that influence clinical decision-making may provide insight into optimizing the quality and costs of care. The process of healthcare decision-making is contextual, complex and poorly understood. This study aims to explore the factors that influence clinical decision-making in the setting of limited evidence of effectiveness, limited or conflicting guidance, significant resource burden and variation in values and preferences.

Rationale for study design: This sequential explanatory mixed methods study includes a case-based survey (quantitative phase). The results of the survey will guide the sampling and questions for the semi-structured interviews (qualitative phase). The interviews will provide an in-depth explanation of the survey results. Combining the two methods provides complementary information and deeper understanding of the phenomenon of clinical decision-making.

Methods: The quantitative strand will consist of case-based surveys in the fields of neonatology and cardiology. Participants are asked to pick the best management choice for each question followed by a rating of the influence of different factors on a 7-point Likert scale. Follow-up questions explore knowledge and influence of evidence, guideline recommendations and costs on decision-making. Analysis of the survey results will inform sampling and the focus of qualitative interviews. The interviews will be analyzed using qualitative description.

Discussion: To our knowledge, this is the first study using a mixed methods approach including a case-based survey of physicians practicing in diverse settings to explore the factors that influence clinical decision-making. The results of this study may assist with strategies to implement high value care resulting in improved patient outcomes and limiting costs.

Keywords

Clinical practice guidelines, evidence-based healthcare, healthcare costs, medical decision-making, mixed methods study, patient-centered care, person-centered healthcare, values and preferences

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Introduction

Healthcare expenditure in the United States (US) is growing faster than the economy [1]. In spite of the huge expenditure, population health outcomes in this country are not as favourable as in Canada or many European nations that spend relatively less on healthcare [2]. This was underscored in a recent Commonwealth Fund report [2], that in spite of spending more than any other country on healthcare (17.7% of GDP, \$8,508 *per capita* in 2010) and having the highest proportion of specialist physicians, when measured on the basis of outcome indicators, the performance of the American healthcare system is lacking.

Cost considerations have traditionally not been a part of medical decision-making at the individual patient level in the US; on the contrary, many have argued that introducing cost into our discussions threatens to destroy what remains of the patient-physician relationship. Thus, physicians should consider only what is best for the individual patient [3]. Reasons for the opposition to cost-effectiveness analysis include mistrust of the underlying methods or the motives of the parties conducting the analysis, or the desire to deny or downplay the underlying problem of scarcity of resources in healthcare [4]. Indiscriminate use of resources, however, may benefit neither the patient nor Society.

In addition, due to limited health insurance coverage, escalating medical costs have a personal impact on many patients in the US. Based on a national random-sample survey of bankruptcy filers in the US in 2007 [5], 62.1% of all bankruptcies have a medical cause and most medical debtors were well educated and middle class; three quarters had some form of health insurance. The share of bankruptcies attributable to medical problems rose by 50% between 2001 and 2007 [5] and this trend has likely continued since. Many physicians now believe that considering costs not only serves equitable distribution of finite resources, but also the real interests of individual patients [6].

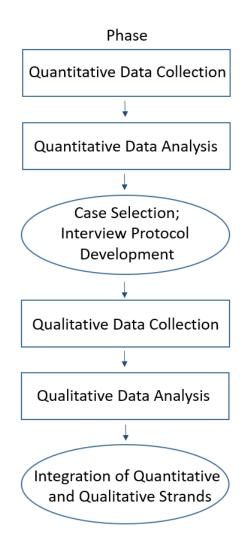
In many countries around the world including Canada, the United Kingdom, the European Union, Australia and New Zealand, cost-effectiveness analysis (CEA) is integral to the approval process for health technologies. The Canadian heathcare system for instance, has considered cost-effectiveness of management strategies since the early 1990s [7,8]. In the US, although cost considerations are included in evaluations of therapeutic equivalence by the Food and Drug Administration (FDA) [9], it does not consider cost and cost-effectiveness in its approval process. Until recently, cost-effectiveness of health technologies have not been routinely considered in clinical decision-making in the US. Due to escalating healthcare costs, there is an increasing focus in the literature on considering costs and cost-effectiveness [10,11] of diagnostic and therapeutic strategies in medical decisionmaking. Medical societies [12] and organizations [13] are publishing guidance on cost-effectiveness and appropriate use criteria for procedures and care pathways. Costs and cost-effectiveness of technologies are increasingly being included in clinical practice guidelines (CPG) [14]. A recent review, for example, found that approximately half of the largest physician specialty societies in the US indicate publicly that their methodological approach to clinical guideline development explicitly integrates cost considerations [15]. The impact of including costs in these guidance documents on clinical decision-making by providers is, however, unclear and knowledge and attitudes of medical providers on cost considerations is not well understood.

The American College of Cardiology (ACC) has published rigorously developed CPG for over three decades [16]. In 2014, due to rising healthcare costs, the ACC decided to consider evidence on cost, value and costeffectiveness [17], when feasible, in the development of their CPG. This practice is currently being implemented; for instance, the guidelines on evaluation and management of syncope published last year include extensive information on cost and cost-effectiveness [14]. For inclusion of evidence regarding cost and value to influence clinical decision-making, it must be understood by clinicians, patients and other stakeholders. However, practicing clinicians' knowledge of this topic and their ability to incorporate this information into clinical decision-making is unknown. Indeed, a survey conducted by Ginsberg and colleagues [18] reflects variation in clinicians' knowledge and attitudes towards incorporating costs and cost-effectiveness in clinical decision-making; this finding is persistent in a more recent study of oncologists published in 2016 [19]. As a result, the impact of including costs in these guidelines is uncertain.

In this study, cost is defined in absolute terms and refers to the financial cost of an action. Cost-effectiveness, on the other hand, refers to a form of economic analysis which considers relative costs and effects (outcomes) of two or more management strategies. Analyses are commonly conducted from a Societal or healthcare perspective and take into account long term costs and consequences [20]. The 'value' of a clinical option is contextual and variable based on patient scenarios [21,22]. There are many definitions of 'value'. In economics, value is determined by the output (health gain) relative to the input (unit costs) - in other words, improved quantity and quality of 'health' gained per 'unit of resource' used (resources may be represented in monetary terms or in other units). The extent of 'health gained' by an intervention is determined by the evidence for effectiveness of that technology. Although providing 'high-value' care is of tremendous interest and much has been written on this topic by professional societies [23] and associations [24], successfully designing and implementing strategies to decrease 'low-value' care has proved challenging [25]. In this study, value is considered based on the impact of the intervention on the patient from a patient-centered perspective.

Clinical decision-making is complex, encompassing decisions made by the clinician regarding a patient's diagnosis, prognosis and management plans and is influenced by many factors including the evidence, CPG, the clinician's experience, beliefs and patient history. An understanding of the cognitive processes involved and the factors that influence decisions on an individual level, remains elusive. One approach to exploring how clinicians make decisions - consider the evidence of clinical and costeffectiveness and how they balance patient-centered care with practice and resource constraints - is to explore these issues within a very specific context. A similar procedure was employed by Brandt-Vegas and colleagues [22]. In that study, participants (practicing physicians) were provided with case-based scenarios requiring management choices and asked to select the next step in management. Unfortunately, the results were limited to quantitative rankings of various factors and the case contexts were too broad, spanning a range of adult healthcare issues. The underlying reasons for participants' management choices were unexplored. Follow-up interviews with participants could provide an in-depth understanding of this process and explain variations in practice. The factors that influenced the decision may then be explored in follow-up

Figure 1 Visual Model for this sequential explanatory mixed method design phases and procedures



Procedure

- Cross-sectional Web-based Survey
- Neonatology N ≅ 350
- Cardiology N \cong 100
- Analysis of survey results using SPSS
- Frequencies, descriptive
- ANOVA / Multi level model
- Purposeful Sample based on survey results N=12 each in Neonatology and Cardiology
- Develop interview guide to explain survey findings
- Individual in-depth interviews lasting 30 to 60 minutes each.
- Nvivo data analysis platform
 Coding and thematic analysis
- Interpretation and explanation of quantitative and qualitative findings

questions to gain an understanding of the decision-making. Furthermore, limiting the context to specific populations, may offer richer information regarding the influence of patient context.

To understand the rationale for healthcare management choices made by healthcare providers, this mixed methods study adopts a sequential explanatory design. To our knowledge, this is the first study to explore this topic using a robust mixed methods approach. The sequential explanatory design is ideal because the interviews (qualitative phase) are tailored based on the results of the survey (quantitative phase) to explore the rationale for the healthcare decisions and gain an in-depth understanding of the process. Figure 1 is a depiction of the phases and process of this multistep project.

Rationale

This study is designed to enhance our understanding of the factors including costs, evidence and values that influence clinical decision-making regarding patient care

management. A series of clinical scenarios were designed to reflect available evidence and important resource considerations (including patients' out of pocket healthcare costs) to provide insight into determinants of the variations in practice patterns. This is the first time that such specific contexts have been explored to understand how management decisions are made by physicians. Understanding the variability of factors that influence decisions in these contexts may inform future efforts to design and implement strategies to limit 'low-value' care practice and to increase the provision of 'high-value' care options.

To capture the 'value' (improved quantity and quality of 'health' gained per 'unit of resource' used) of a clinical service, this study will consider factors that determine 'quality' of care provided. The Institute of Medicine (IOM)'s framework for quality of care is widely used [26] and organizes the determinants of quality into six domains. They are: safety, effectiveness, patient-centered care, timely, efficient and equitable [27]. Timely and equitable are not applicable to individual patient decisions in the case-based scenarios included in this study. This study will evaluate the influence of the domains of safety, effectiveness, patient-centered care and efficiency as well as additional practice elements that may impact clinical decisions including the clinician's prior clinical experience, local hospital practice and medico-legal concerns [28] on clinical decision-making. For consistency, the quality domains and practice elements included in this study will be referred to as 'factors' in this study protocol.

This study will focus on the clinical specialties of neonatology and cardiology, two areas with high resource utilization and costs. In the US, preterm or low birth weight infants account for half of infant hospitalization costs and a quarter of all pediatric costs [29]. In 2005, costs that result from prematurity accounted for over \$26 billion of all healthcare expenditures per year in the US alone [30,31]. Daily neonatal intensive care unit (NICU) costs exceed \$1000 to \$3500 per infant and it is common for costs to exceed \$1 million for a prolonged stay [30]. The cost of hospitalization, including re-admissions, is most dramatic for infants born at the threshold of viability (23-24 weeks) [32-34]. The cases chosen in neonatology represent areas of current clinical controversies with very limited evidence for effectiveness and limited guidance on best practice. The focus of the neonatology survey will be on decision-making in the setting of very limited evidence for effectiveness, high costs and weak or conflicting CPG recommendations.

Similarly, due to the high prevalence of cardiovascular disease and high treatment costs, spending on cardiovascular diseases continues to increase [35]. One study projected that in the US the total direct cost of treating cardiovascular disease will increase by 2030 to \$818 billion with an additional \$276 billion in indirect costs due to lost productivity [36]. The cases chosen in cardiology represent common clinical scenarios where a known disconnect between there is CPG recommendations and practice. These include non-invasive testing in the routine follow-up of patients with coronary artery disease (CAD) and in the evaluation of syncope. Other cases consider treatment for ventricular arrhythmias in the setting of CAD and the disposition of a patient presenting with chest pain. The IOM's publication on improving diagnosis inspired the case on management of chest pain [37]; this publication is accompanied by a video of case vignettes of missed diagnosis. One of these is the case of a patient presenting with chest pain [38] who is discharged after a negative evaluation in the emergency department only to return two weeks later with persistent symptoms requiring a heart procedure. From the information available, it is unclear if additional testing or observation during the initial presentation would have resulted in a different outcome, but the implication of the video is that it would have. In many instances, there is a tension between limiting (unnecessary) testing and treatment and satisfying the patient's concerns over their symptoms and the need to be 'thoroughly' evaluated.

Due to differences in cost considerations and different healthcare systems, the knowledge, attitudes and beliefs concerning costs and value considerations may differ in Canada and the US. Accordingly, this study will evaluate the influence of these factors in clinical decision-making by clinicians in different settings (academic, private, hospital-based) and in the US and Canada.

Study goals/objectives

To measure and explain the factors that influence decisionmaking by physicians in neonatology and cardiology.

Questions that will be addressed in this study

In the initial quantitative phase of the study, the research questions will focus on the relative importance of the seven factors in clinical decision-making determined by casebased surveys in neonatology and cardiology. In addition, the survey will gather information regarding knowledge and attitudes about costs, cost-effectiveness analyses and out of pocket patient healthcare expenses. In a second qualitative phase, in-depth interviews with distinct participant groups will explain the results of the survey. The overarching questions to be addressed by the surveys and explored in depth in the qualitative interviews are as set out in Box 1.

Box 1 The overarching questions to be addressed by the surveys and explored in the qualitative interviews

- 1a. How do neonatologists make clinical decisions in the setting of limited evidence of effectiveness, high resource use and limited or conflicting CPG recommendations?
- 1b. How do cardiologists make clinical decisions in the setting of limited evidence of effectiveness, high resource use while considering CPG recommendations?
- 2. What is the relative importance of the Institute of Medicine Quality Domains (Safety, Effectiveness, Patient Centered Care and Efficiency) and other practice elements (local hospital practice, prior clinical experience and medicolegal concerns) in healthcare decision-making by clinicians in neonatology and cardiology in the US and Canada?
- 3. How are clinicians considering cost, patients' out of pocket healthcare costs and cost-effectiveness in their decision-making?

Methods

Study Design

A sequential explanatory mixed method design will be used to obtain a breadth and depth of understanding of the topic. Figure 1 depicts the phases and processes involved in this mixed methods study protocol. A measurement of the relative influence of various factors in clinical decision-making by clinicians in diverse practice settings across the US will be obtained by administering a casebased survey to a national sample of neonatologists and cardiologists in the US and a more limited sample of neonatologists and cardiologists in Canada. The results of the survey will be analyzed and inform the next qualitative phase.

Mixed methods research takes advantage of the complementary nature of quantitative and qualitative study designs and results. In this sequential explanatory mixed methods study [39,40] the case-based survey will be followed by a qualitative descriptive study [41,42] (Figure 1). The statistical analysis of the results of the case-based survey (quantitative phase) will provide the foundation for decisions made in planning and conducting the semistructured interviews (qualitative phase) in order to delve into the reasons and rationale of the response patterns in the survey. 'Mixing' of the two components occurs twice in this study design; once at the point of qualitative data collection (the results of the quantitative study inform the sampling and interview guide used for the qualitative phase) and again during interpretation when the results of the interviews are used to explain the results of the survey.

Purpose Statement

This mixed method study will address factors that influence clinical decision-making in neonatology and cardiology. An explanatory sequential mixed method design involves collecting quantitative data first and then explaining the quantitative results with in-depth qualitative data. In the quantitative phase of the study, a case-based survey will address the influence of seven factors on clinical decision-making in diverse practice settings in the US and Canada. We will determine the association of various physician characteristics (practice setting, nationality, years out of training and gender) and their judgments of the relative importance of the seven factors. A second qualitative phase will provide insight into the results of the survey. In this qualitative study, we will explore the influence of these factors on clinical decisionmaking in depth and examine the consequences of considering these factors in shared decision-making with individual patients. Use of these two complementary methods will also accomplish data triangulation (compare and corroborate the data from the two methodologies) [39].

We will use the two methods because neither method is sufficient to capture the relative influence of factors described above in clinical decision-making across a diverse group of clinicians in different practice settings (addressed by the quantitative phase) *and* to provide an indepth understanding of the reasons behind clinical decision-making in the setting of limited evidence and while considering costs, values and preferences (the qualitative phase). When used in combination, these methods provide a more complete understanding of the phenomenon of clinical decision-making.

Phase 1: Case-based survey

After reviewing the patient case scenarios, participants will select the next step in management from options (3 or 4 options in the neonatal survey and 5 options in the cardiology survey) provided. The degree to which the factors influenced clinical decision-making will be measured on a 7-point Likert scale. Each question is followed by additional information about evidence, costs, or values to explore the knowledge and attitudes of these topics in the form of multiple choice or free text responses.

Objectives of the survey

1a. To assess how neonatologists make clinical decisions in the setting of limited evidence of effectiveness, high resource use and limited or conflicting CPG recommendations?

1b. To assess how cardiologists make clinical decisions in the setting of limited evidence of effectiveness, high resource use while considering CPG commendations?

2. To measure the relative influence of seven (safety, effectiveness, patient-centered care, efficacy, local hospital practice, medicolegal concerns and provider's prior experience) factors in clinical decision-making and to understand how decision-making varies based on the clinician characteristics of nationality (US *versus* Canadian), practice setting (private practice, academic practice and hospital-based practice), years out of training (<10 years, 11-20 years, >20 years) and gender.

3. To explore the knowledge and attitudes about costs, cost-effectiveness and value considerations in the setting of limited evidence for effectiveness of management options.

Sample

Neonatal Survey - To engage neonatologists from academia and the private sector, we will distribute the surveys by email to members of the Society of Neonatal Perinatal Medicine (SONPM) of the American Academy of Pediatrics. The email list served consists of approximately 3,600 neonatologists and we anticipate approximately 350 responses representing both academic and private sectors. A similar survey will be sent to Neonatology Division Chiefs in Canada requesting distribution of the survey to neonatologists in their divisions.

Cardiology survey - This will be distributed by email to the ACC's 'CardioSurve®' panel following completion of an ACC survey. CardioSurve is an invited panel of over 350 cardiologists practicing in diverse settings in the US who participate in monthly surveys administered by the ACC with approximately 150 responses expected to the ACC survey. It is anticipated that a smaller proportion will complete a second survey (the survey link will be presented at the end of the ACC survey), we anticipate 30 responses (20% of 150). We have approval by the American College of Cardiology to administer the cardiology survey to the CardioSurve® panel. The Canadian Cardiovascular Society has agreed to post the survey on their member page to engage Canadian Cardiologists. Cardiologists at the University at Buffalo in New York, US and at McMaster University in Canada will also be requested to complete the survey.

Data Collection

Development of the survey

Experienced clinicians and researchers in neonatology and cardiology developed the case descriptions reflecting common variations in clinical decision-making. The clinical appropriateness of the case scenarios were confirmed during pilot testing with a group of neonatologists and cardiologists, respectively and, the surveys were modified based on their feedback. Recommendations in current CPG were reviewed and informed formulation of response options. A second round of pilot testing was performed with a separate group of neonatologists and cardiologists to confirm the sensibility and applicability of the case scenarios, response options and factors included for rating.

Each set of possible clinical courses of action is followed by a list of the seven factors, each to be rated on a seven-point scale according to their importance in influencing the chosen course of management (from unimportant to critically important). In some cases, after the initial decision, existing evidence or recommendations are presented to ascertain if this knowledge changes the clinical decision. In others, follow-up questions related to the case on costs, cost-effectiveness, out of pocket patient's healthcare costs and patient's values are presented to measure and explore current knowledge, attitudes and understanding of these topics among neonatologists and cardiologists. Response options to these questions include multiple choice options or free text responses.

Conduct of the survey

The survey will be anonymous, administered by email or through the SONPM and the ACC/CCS and accessed through the URL (uniform resource locator) link in the email. The survey will be conducted and data collected using the SurveyMonkey® platform [43].

Statistical Analysis

Results will be analyzed in IBM SPSS statistics for windows [44]. We will present descriptive statistics to analyze the response to each question. The average importance of each factor across all scenarios will be ranked based on the mean and the differences between means tested in an analysis of variance. To accommodate the repeated measures within a respondent (one measure for each scenario), we will perform a multilevel model with level of importance of the factor as the dependent variable *and* survey respondent (nationality, practice setting and years out of training) entered as random effect and case scenario entered as a fixed effect.

Responses in the free text box will be analyzed using basic content analytic strategies. Data from both the survey responses and open text boxes will inform iterative modification of the interview guide for the qualitative interviews.

Phase 2: Descriptive Qualitative Study

Objectives

1. To describe the experience of neonatologists and cardiologists in considering evidence, costs, costeffectiveness in clinical decision-making in the setting of limited evidence and the changing healthcare landscape (increasing recommendations to consider costs, cost-effectiveness and provide 'high-value' care without having been formally trained to consider and incorporate these considerations into decision-making).

2. To explain the relative influence of various factors measured in the survey on clinical decision-making.

Research Questions

1. What is the clinicians' experience of considering information on evidence, costs and costeffectiveness in clinical decision-making in the setting of limited evidence of effectiveness? How have recent guideline recommendations to consider costs and provide high value care influenced shared decision-making?

2. How do the factors described in the survey influence decision-making?

Design

The conduct of the second phase of this sequential mixed methods study will be informed by the principles of qualitative description. Qualitative description [41,42] allows the researcher to stay close to the data and provide factual summaries of the participants' experiences and perceptions without much interpretation by the researcher. This approach is grounded in the principles of naturalistic inquiry and uses low-inference in its description [42].

Sampling

Survey participants who volunteer to participate in a 30 to 60 min 1:1 semi-structured interview will be considered for inclusion in the qualitative strand of the study.

A purposeful sample of physicians who participate in the survey will be chosen using the method described by Ivankova and colleagues [45] who developed a systematic process to identify a typical respondent from different groups. Based on the responses to the relative importance of the seven factors on the survey, we will calculate the summed mean scores and their respective group means for all participants in neonatology and in cardiology in each of the four practice settings (US academic practice, US private practice, US hospital-based practice and Canadian practice). Due to limited ability to contact Canadian clinicians in a systematic way, we anticipate a limited number of Canadian participants in the study. In case we can recruit Canadian neonatologists from different practice settings, we will separate the Canadian clinicians based on practice setting and increase the number of participants accordingly (Canadian academic and Canadian private practice).

To choose prototypical participants of the respective groups, we will use standard error of the mean to establish lower and upper boundaries for the scores clustered around each group mean. Using the cross-tabulation procedure in SPSS, we will identify participants from each group with mean scores within one standard error of the mean. Within the four practice settings we will compare participants based on demographic variables of years out of training (<10, 10-20, >20) and gender.

Using maximum variation sampling we will select 3 participants from each practice setting which allow us to preserve multiple perspectives based on practice setting and demographics. In total, we anticipate 12 participants each in neonatology and cardiology (3 in each of the 4 practice settings) for a total of 24 participants in the qualitative phase of the study.

Although we anticipate many survey responses based on previous experience of surveys administered by the neonatal/cardiology specialty societies in the US, due to busy clinical schedules, it is possible that only a small number of survey respondents volunteer to participate in interviews. In case of limited survey respondents volunteering to participate in the qualitative phase of the study, if we are not able to obtain data saturation due to limited number of participants in each practice setting and demographic, we will recruit additional participants who match the demographic and practice setting but who did not participate in the survey.

Data Collection

The interviews will begin with a brief explanation and introduction to the study. After obtaining verbal consent, participants will be asked to reflect on the findings of the survey to help interpret and explain the findings. Participants will be invited to complete a single one-onone in-depth semi-structured interview and encouraged to speak in rich detail about their experience of considering costs, cost-effectiveness and values in clinical decisionmaking, will be invited to participate in the study. In qualitative interviews, this method of data collection allows for the exploration of participants' perceptions and beliefs. The purpose of the interview will be to explore the clinician's knowledge, attitudes and beliefs about incorporating information of costs, cost-effectiveness and values into clinical decision-making. A second goal of the interview will be to explain the survey findings and gain an understanding of the most influential factors that influenced decision-making. Each interview will be approximately between 30 - 60 minutes in length. Permission to digitally record each interview will be requested. Demographic information including practice setting, years out of training and gender will be recorded followed by the interview.

Data management

The interviews will be transcribed *verbatim*, identifying information removed and data will be stored in a password protected electronic device (password protected desktop computer). NVivo11 [46] qualitative software will be used to store, file, manage the data and the platform on which coding will occur.

Data Analysis

The general principles of conventional content analysis [47] will be used to identify the themes expressed by clinicians and to guide the coding and synthesis of the transcript data. All interview transcripts will be read in their entirety followed by coding and analysis. A broadbased coding will be used to create a collection of experiences and accounts followed by regrouping the data according to themes. A codebook with definitions for each code will be inductively developed and applied to all transcripts. Using a primarily inductive approach, open codes will be developed based on the words and concepts within the text. In the next stage, codes will be collapsed into categories followed by identification of major themes using a process of constant comparison. Theoretical memos will be kept by the first author to capture developing ideas and personal thoughts about the study and inform the analysis and results.

Overall rigor and trustworthiness of the data will be enhanced by the application of strategies to address credibility, dependability and confirmability [48]. The analysis and results will be reviewed with experts in the field of clinical decision-making.

Data Integration of the two strands

Linking of data between the two strands will occur at different levels. The results of the quantitative phase will inform the sampling and interview questions for the qualitative phase. Data will also be integrated at the end of the analysis of both the phases by cross tabulating the results. These results will be analyzed to consider similarities and differences and develop a broader and deeper understanding of the topic.

Discussion

The results of the study will provide a rich understanding of the clinical decision-making process providing insights into improving clinical practice at the individual clinician and policy levels. Based on the results of the survey and the interviews, strategies to support clinicians in providing high value care and in incorporating costs and values in decision-making can be designed and implemented.

Using a mixed methods study design is an added strength of this study protocol. Results of previous surveybased studies do not provide insight into the reasoning and rationale for decisions made in healthcare. In addition to reporting on the choice of management strategy adopted by physicians, combining the methods will provide a rich description of the underlying cognitive process that resulted in the choice. This added insight may be a crucial element to improve adoption of 'high value care'.

Limitations

This survey only explores clinicians in the two specialties of neonatology and cardiology and other specialties with increasing healthcare costs such as oncology are not included in this survey. This is a limitation. However, including neonatologists and cardiologists is a reasonable start since these specialties contribute to high healthcare costs and have published guidance on considering costs and cost-effectiveness to provide high-value care. The case-based surveys are time and effort intensive to administer and another limitation may be limited sample size if we are not able to recruit many participants. We are exploring only 5 cases in neonatology and 4 in cardiology. These are a representative sample and the results of this study may not be generalizable across other scenarios and clinical specialties.

Conclusion

Despite significant strides in our understanding of the epidemiology and pathophysiology of disease and increased awareness and appreciation of evidence-based medicine, factors influencing clinician's decisions for diagnosis and care of the individual patient remain poorly understood. This timely mixed methods study will explore these factors, deepen our understanding of the process of decision-making at the individual patient level and provide a basis to develop strategies to improve patient care.

Conflicts of Interest

The authors declare no conflicts of interest.

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CHAPTER THREE

The results of the cardiology case-based survey titled: **'Sources of practice variations in cardiology - The influence of clinical context, cost, physicians' perceptions and practice considerations'** have been published in the European Journal for Person Centered Healthcare. Permission from the journal editors to include the published paper in this thesis and to post this work in the University repository and Archives Canada is included on the next page followed by a reproduction of the published paper.



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AM/aw 28 September 2018

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Dear Dr. Manja

Sources of practice variations in cardiology - The influence of clinical context, cost, physicians' perceptions and practice considerations

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ARTICLE

Sources of practice variations in cardiology - The influence of clinical context, cost, physicians' perceptions and practice considerations

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Abstract

Background: Practice variation is common and may represent variation in values and preferences in the setting of limited evidence regarding optimal care or indicate deficiencies in care.

Methods: We administered a case-based survey to cardiologists in the United States and Canada. Participants selected their preferred management option and then rated the influence of 7 factors (safety, effectiveness, patient-centered care, efficiency, local hospital practice, medicolegal concerns and prior experience) on their decision using a scale of 1 (unimportant) to 7 (critically important). Follow-up questions explored knowledge and attitudes on healthcare costs. The relationship between management choice and perceived influence of each factor was examined using repeated measures ANOVA. Free text comments were analyzed using basic content analysis.

Results: One hundred and six cardiologists completed the survey. Respondents rated safety (5.8), effectiveness (5.7) and patient-centered care (5.7) as important determinants irrespective of their management choice. Cardiologists frequently (range 19%-87%) chose options not recommended by clinical practice guidelines (CPG), with individual cardiologists sometimes choosing guideline-suggested options and sometimes not. Differences in ratings of factors between those who chose guideline-suggested options and those who did not varied based on the case. Respondents considered cost to be important in decision-making; however, they did not feel well informed and, consequently, seldom discussed this with patients.

Conclusion: Cardiologists rate evidence-based practice as an important factor influencing their decision-making whether or not they make CPG-concordant choices. Sources of practice variation include case-context, local hospital practice and medicolegal concerns. Implementation strategies to improve high value patient-centered care should consider physicians' perceptions of effectiveness of the management options. Successful strategies to improve patient-centered care will require engagement from physicians, particularly to understand how best to support their ability to counsel and involve patients when choosing treatment options and considering cost in these decisions. A deeper understanding of practice variation and its implications will require use of qualitative methods.

Keywords

Cardiology, clinical context, clinical decision-making, clinical practice guidelines, evidence-based medicine, healthcare costs, high value care, management options, patient-centered care, person-centered healthcare, practice variations

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Introduction

Variation in utilization of health services has been extensively documented [1] and identified as a marker of disparity in quality and efficiency of healthcare systems [2]. Variations in diagnostic and therapeutic procedures are well documented in cardiology [3,4]. Shah and colleagues analyzed a national registry in the United States (US) and found a range of 17% to 73% for stress testing in the first 12 months after percutaneous coronary revascularization in different hospitals with no difference in mortality or acute myocardial infarctions [5]. Similarly, an analysis of the US Medicare database revealed substantial variation in intensity of outpatient cardiology care unassociated with hospitalizations or mortality [6].

Although a lack of high-quality evidence to guide practice and differences in patients' values and preferences explain some of the observed variation, diversity in physicians' practice styles is an important cause [7,8]. In a study of primary care physicians in Norway, Grytten and colleagues found that 'physician-specific' effects [9] (*versus* patient-specific effects) explained the majority of the variation of expenditure for laboratory tests, consultations and procedures with other studies reporting similar results [10]. However, relatively few studies have elicited physicians' input to understand the sources of practice variation [11].

Despite the resultant uncertainty in understanding of sources of variation, efforts to improve the quality and efficiency of care have increasingly targeted physicians [12]. For instance, current policy initiatives to improve the value of care, such as the Choosing Wisely® [13] campaign, target education and knowledge translation strategies to increase appropriate use of medical technologies but fail to consider factors that may influence physician's judgement during decision-making.

Designing and implementing strategies to provide high value care have proved challenging [14,15] and the efforts to date have had a minimal impact or even a contrarian effect on physicians' practice patterns [16,17]. An improved understanding of factors that motivate physicians' decisions is necessary for the design of successful implementation strategies.

Therefore, to understand the sources of practice variation in cardiology, we conducted a survey of cardiologists using clinical vignettes. To evaluate potential differences due to contextual factors, we recruited clinicians in different settings (academic, private, hospital-based) in the US and Canada.

Methods

The Institutional review board at the University at Buffalo, Buffalo, New York, USA and the Hamilton Integrated Research Ethics Board at McMaster University, Hamilton, Ontario, Canada approved the study. We briefly summarize our study methods here; the protocol, with further details, was published in the preceding issue of this *Journal* [18].

Objectives

The objectives of the survey were to measure cardiologists' ratings of the influence of 7 factors (safety, effectiveness, patient-centered care, efficacy, local hospital practice, medicolegal concerns and the provider's prior experience) on decision-making and to explore cardiologists' perceptions and attitudes on costs of care.

Survey Development

Since clinicians strive to provide high quality care [19], we designed this study to explore the influence of different domains of quality on clinical decision-making. To capture the elements of quality of care, many organizations [20] and researchers [21] have adopted the Institute of Medicine's framework for quality of care [22]. This framework organizes the determinants of quality into 6 domains: safety, effectiveness, patient-centered care, timeliness, efficiency and equity. The domains of timeliness and equity were not applicable to the clinical vignettes presented in this study. We included the remaining 4 domains (referred to as 'factors' in this study) and 3 additional factors, based on the literature, that may also influence clinical decisions: local hospital practice [23] medicolegal concerns [24] and provider's prior experience [25,26]. To limit differences in interpretation, effectiveness was labelled as 'evidence-based' and efficiency as 'cost-considerations' on the survey. Respondents rated the influence of each factor on their decisions using a scale of 1 (unimportant) to 7 (critically important).

Several studies have found vignettes to be a valid, reliable, inexpensive and practical method for assessing medical decision-making and clinical practice variation [27,28]. For this study, experienced clinicians and researchers in cardiology developed 4 case descriptions to reflect scenarios commonly encountered in clinical practice. Each vignette included 5 response options including some consistent with current clinical practice guideline (CPG) recommendations and others reflecting practice variations. Participants were asked to choose one response followed by a rating of the importance of the 7 factors that might have influenced their decision. Followup questions asked respondents about their attitudes on cost and value concerns related to the vignettes and included free text response options. Pilot testing with a group of 5 cardiologists confirmed the clinical sensibility of the vignettes and the survey was modified based on their feedback. To confirm the applicability of the vignettes, response options and the factors included for rating, a separate group of 4 cardiologists participated in a second round of pilot testing that led to a refinement of the language. A brief description of the cases follows (Box 1). Details of the vignettes, response options and follow-up questions with references to relevant American College of

Table 1 Case descriptions, response options and follow-up questions with brief summary of pertinent guideline recommendations (in boxes following the case description)

Case Scenario	Management Choices	Follow-up questions
Case 1. A 77 year old man comes for a routine follow-up visit. He	1. Perform pharmacologic stress test with	The patient has a high deductible insurance and asks your input on
follows up regularly with his primary care provider who diagnosed	moccardial nerfusion imaging to evaluate for silent	his 'out of pocket' expenses for the recommended testing and
him with new onset non-insulin dependent diabetes mellitus 4	ischemia given risk factors and new onset NIDDM	treatment.
months ago. He has a history of hypertension, diabetes mellitus.	2. Perform a Holter monitor to ensure adequate	1. In vour practice, how often do patients inquire about their 'out of
atrial fibrillation and nerinheral vascular disease. He is status nost	ventricular rate control of atrial fibrillation	mocket' expenses for the care voli recommend? Please choose one
coronary artery bypass grafting 3 years ago. He does not complain	3. Perform an echocardiogram to evaluate left	ontion - <1%. 1-5%. 5-20%. 20-50% and >50%
of any new symptoms: however, his physical activity is limited due	ventricular ejection fraction	2. Do von feel well informed to answer these questions? Please
to arthritis in his back and knees. His medications include aspirin	4. Obtain a fasting linid profile and basic metabolic	choose one ontion - Yes or No
81 mo daily warfarin atorvastatin 40 mo daily metonrolol	nanel	3 Should nation's out of nocket costs he considered in the nationt-
succinate 50 mg daily lisinonril 10 mg daily and metformin 1000	5 No further testing necessary follow the patient in	nhvsician's chared decision-making discussion? Please choose one
me turice o day. On abuiled around to me duity and moustain 1000	o more	prijer Ver on Me
Ing twice a tay. On physical exam, he weighs 22/ pounds, brood	a yean.	$\frac{001001}{0} - 165.01100$
pressure is 12///4 mmrig, puise is 8/ beats per minute and		
saturations are 94% on room air. Physical exam is otherwise		
unchanged from previous visit. An ECG performed in the office		
reveals atrial fibrillation with non-specific ST-T abnormalities,		
unchanged from previous. Your next step in management of this		
patient is: [a-c].		
The recommendations on follow-un stress testing in	vmntomatic natients with history of prior revasculariza	assuntomatic patients with history of prior revascularization vary between suidelines [h d e1 from reference 2 [h] - Class Ua-
Exercise moscardial perfusion SPECT at 3 to 5 years after revealed arither PCI or CARG) in selected hish-risk assumonatic nations (1 evel of Evidence R) refer to the 2003 (4)	arization (either PCI or CABG) in selected high-risk as	mntomatic nations (Level of Evidence: R) refer to the 2002 [f]
indre des wijdense wieder to the 1007 for white white a close Uk westmander in the second data for the first westmannen in a contribution of tests of the first westmannen in the second data in the westmannen for the second data in the second second data in the second	an marker of the second and a states that the second attempts that the	are are incufficient data to instity recommending a northerdar
$\frac{1}{r}$	$\frac{1}{1}$	$-\pi$
frequency of testing. The tevel of recommendations seems to have changed without adaitional evidence. Choesterol guidetines- The secondary prevention and risk reduction guidetines (gl	ngea without adaitional eviaence. Cholesterol guiaetine	\underline{s} - The secondary prevention and risk reduction guidelines [g]
emphasize treatment with statins including achieving a low density hipoprotein (LDL) target, whereas the 2013 guideline on treatment of blood cholesterol recommends high dose statin but	poprotem (LDL) target, whereas the 2013 guideline on	reatment of blood cholesterol recommends high dose statin but
moves away from a target LDL [c] recommendation. Lipid guidelines published by other professional societies also have varying recommendations.	published by other professional societies also have var	ving recommendations.
Case 2. A 70 year old man presents with complaints of chest	1. Perform catheter ablation of the VT	One driver of healthcare costs are the rapid technological advances
tightness, palpitations and light-headedness. He briefly passed out	2. Initiate amiodarone and reassess LVEF in 90	in expensive diagnosis and treatment options.
on the way to the emergency department. An ECG reveals	days	1. Should the costs of these technologies be considered in decision-
ventricular tachycardia (VT) at a rate of 160 beats per minute and a	3. Implant implantable cardioverter-defibrillator	making at the individual patient level? Please choose one option –
blood messure of 80/50 mmHo Cardioversion restores sinus	(ICD) hefore hosnital discharce	Yes No Only consider nation?'s out of nocket costs Not sure
rhuthm tests reveal a tronomin of 1.0 m/dl Coronary and orreachy	A Implant ICD only if V/T is inducible by	2 Chaild over affactiveness analyses he considered in individual
111) III) IESIS IEVEAI A UOPUIIII OL 1.2 IIZ/UL. COLOIIALY AUGUSTAPILY		
reveals three vessel disease with left ventricular ejection fraction	electrophysiologic study	patient decision-making? <u>Please choose one option</u> Yes, No, Unly if
(LVEF) of 35 to 40%. Echocardiogram confirms the LVEF, he	5. Use the wearable cardioverter-defibrillator upon	pattent is liable for portion of the costs, Not sure
undergoes coronary artery bypass grafting. Which option would	discharge followed by LVEF reassessment in 40	3. On a scale from 1-5 (1 being not familiar at all and 5 being
you recommend next? [h,i]	days to determine need for an ICD.	extremely familiar), how familiar are you with methodology,
		benefits and downsides of cost-effectiveness analysis?
In the scenario presented in case-2, determination of therapy for VT varies based on the cardiologist's determination of the source of troponin elevation. If the cardiologist determines the 'low-	aries based on the cardiologist's determination of the s	ource of troponin elevation. If the cardiologist determines the 'low-
level' troponin elevation to be secondary to hemodynamic stress from VT induced myocardial supply-demand mismatch, this patient would have a class-I indication for an implantable	VT induced myocardial supply-demand mismatch, this	oatient would have a class-I indication for an implantable
cardioverter defibrillator (ICD) based on the 2012 update [j] of the ACC/AHA/HRS 2008 Guidelines [k] for Device-Based Therapy of Cardiac Rhythm Abnormalities (page e-37 and e-43).	ACC/AHA/HRS 2008 Guidelines [k] for Device-Based 7	herapy of Cardiac Rhythm Abnormalities (page e-37 and e-43),
however, if the cardiologist determines the low-level troponin elevation to be a primary myocardial infarction then the same guideline makes a class-I recommendation to reassess LVEF 40 days	on to be a primary myocardial infarction then the same	quideline makes a class-I recommendation to reassess LVEF 40 days
after revascularization before making a determination of an ICD implantation. The guidelines do not provide further input on troponin level that qualifies as a 'low-level' elevation to distinguish	lantation. The guidelines do not provide further input or	troponin level that qualifies as a 'low-level' elevation to distinguish
between the two class-I guideline recommendations. During pilot testing of this clinical vignette, practicing cardiologists had concured that the level of troponin elevation presented was	ing of this clinical vignette, practicing cardiologists hac	concured that the level of troponin elevation presented was
consistent with troponin elevation due to myocardial supply-demand mismatch. Clarification between considerations and recommendations for primary and secondary prevention of VT in the	mismatch. Clarification between considerations and re-	ommendations for primary and secondary prevention of VT in the
guidelines may impact decision making in this scenario.		
2012 guideline-Page e37 [] 'Patients with coronary artery disease who present with sustained monomorphic VT or VF and low-level elevations of cardiac biomarkers of myocyte injury/necrosis	ho present with sustained monomorphic VT or VF and l	ow-level elevations of cardiac biomarkers of myocyte injury/necrosis
should be treated similarly to patients who have sustained VT and no	documented rise in biomarkers. Prolonged episodes of	no documented rise in biomarkers. Prolonged episodes of sustained monomorphic VT or VF may be associated with a rise in
cardiac troponin and CPK levels due to myocardial metabolic demands that exceed supply in patients with coronary artery disease. Evaluation for ischemia should be undertaken in such	ds that exceed supply in patients with coronary artery d	isease. Evaluation for ischemia should be undertaken in such

 patients. However, when sustained VT or VF is accompanied by modest elevations of cardiac enzymes, it should not be assumed that a new MI was the cause of the sustained VT. Without other clinical data to support the occurrence of a new MI, it is reasonable to consider that such patients are at risk for recurrent sustained VT or VF. With these considerations in mind, these patients should be treated for this arrhythmia in the same manner as patients without biomarker release accompanying VT'. Recommendations on page e-43 - Class I - ICD therapy is indicated in patients with LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than or equal to 30%, and are in NYHA functional Class I. (Level of Evidence: B) Class I - ICD therapy is indicated in patients with LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than or equal to 30%, and are in NYHA functional Class I. (Level of Evidence: A) 2017 VT/SCD guidelines [i] - Page 73, Figure 5 - In patients with ischemic heart disease and sustained monomorphic VT, coronary revascularization alone is an ineffective therapy to prevent recurrent VT. 	st elevations of cardiac enzymes, it should not be assume o consider that such patients are at risk for recurrent sus without biomarker release accompanying VT'. ease and spontaneous sustained VT, whether hemodynam e to prior MI who are at least 40 days post-MI, have an L hemic heart disease and sustained monomorphic VT, cor	lest elevations of cardiac enzymes, it should not be assumed that a new MI was the cause of the sustained VT. Without other to consider that such patients are at risk for recurrent sustained VT or VF. With these considerations in mind, these patients without biomarker release accompanying VT'. Same and spontaneous sustained VT, whether hemodynamically stable or unstable. (Level of Evidence: B) sease and spontaneous sustained VT, whether hemodynamically stable or unstable. (Level of Evidence: B) to prior MI who are at least 40 days post-MI, have an LVEF less than or equal to 30%, and are in NYHA functional Class I. chemic heart disease and sustained monomorphic VT, coronary revascularization alone is an ineffective therapy to prevent
Case 3: A 42 year old woman presents to the emergency department with syncope and fall. She has experienced two other episodes of syncope over the past 2 months. They have occurred when she was standing and she has noticed a brief period of dizziness before these episodes. She does not have any other medical problems and does not take any medications. There is no history of similar complaints in anyone else in her family. On exam, her BP is 118/78 mmHg, she is not orthostatic, heart rate is 72 beats per minute. Physical exam is otherwise unremarkable. An ECG performed in the ED in normal. Which of the following do you recommended next? [1]	 Echocardiogram to evaluate for structural heart disease CT of the head Carotid Doppler imaging Comprehensive metabolic panel Referral for tilt table testing 	 The recently published ACC/AHA guidelines for the evaluation and management of syncope summarize available evidence of costs and cost-effectiveness of different management strategies [1] How often do you discuss cost and cost-effectiveness of further testing and treatment with patients during decision-making? <u>Please choose 1 option –</u> Never/Infrequently/Frequently/Frequently/Very Frequently How often are patients open to the idea of discussing and considering costs and cost-effectiveness during shared decision-making? <u>Please choose 1 option –</u> Never/Infrequently/Somewhat Frequently/Frequently/Very Frequently How often are patients open to the idea of discussing and considering costs and cost-effectiveness during shared decision-making? <u>Please choose 1 option –</u> Never/Infrequently/Very Have you consulted the 2017 ACC/AHA guidelines on the evaluation and management of syncope guidelines for patient management decision? <u>Choose 1 option Yes or No</u>
to s s - I s - I , phr. , phr. e un anc anc anc anc anc	ubstantial healthcare costs [m]. The response options wer II: No Benefit B-NR Routine cardiac imaging is not useful ysical examination, or ECG. Although some investigators I with syncope who lack clear signs or symptoms of cardiov common; a "screening" echocardiogram is of low utility. trasonography, and electroencephalography, contributed t ther retrospective series of 128 inpatients with syncope, it the evaluation of syncope."	e based on the ACC/AHA Syncope guideline [I] recommendations. in the evaluation of patients with syncope unless cardiac etiology is have advocated for cardiac imaging - particularly transthoracic ascular disease, clinical evidence does not support such practice. In 1 evaluation of 2,106 inpatients with syncope, a battery of testing, o the diagnosis or management in <5% of cases and helped was found that echocardiograms in patients with no clinical additional information for arriving at a diagnosis (37%). Finally,
Case 4. A 66 year old woman with hypertension presents to the emergency department (ED) with sharp retrosternal chest pain unrelated to exertion and worse with coughing. She is recovering from an upper respiratory tract infection and has noticed the chest pain during the past 3-4 days. Her vital signs are within normal limits and physical exam is remarkable for a component of the chest pain reproducible by local pressure. An ECG reveals non-specific ST-T changes and troponin is less than the lower limits of normal. The ED nhysician wants to admit the nation for observation	 Discharge the patient from the ED if a second troponin value drawn 4 hours after the first one is negative with follow-up with primary care provider the next day. Recommend the patient be admitted and ask the chief resident and nursing supervisor to review patients on telemetry and nurse staffing in order to make room for this patient Recuest an echocardiosram in the ED with plans 	As you discuss the treatment plan with the patient and her husband, you find out that her husband was discharged from a local ED 6 months ago after being evaluated for chest pain and had a massive heart attack a week later. He ended up with a weak heart and has NYHA class II heart failure symptoms in spite of optimal therapy. The patent and her husband are very worried about something similar happening to her which is driving their apprehension of the patient being discharged before a complete cardiac evaluation.
and further testing due to a HEART score of 4 (2 points for age >65 years, 1 for non-specific ECG changes and 1 for hypertension). You see the patient in consultation upon the request of the chief resident because there is only one telemetry bed available and a patient with an MI is being transferred for coronary angiography from another hospital. You recommend -	to discrete the patient if there are no wall motion abnormalities 4. Ask the ED attending to observe the patient in the ER overnight and schedule stress testing the next morning. 5. Call other hospitals to see if the patient can be transferred for coronary CT angiography to rule out	 In your practice, how often do you percieve an inherent conflict between limiting unnecessary testing and avoiding medical errors due to missed diagnoses? Please choose one option: Never/Infrequently/Somewhat Frequently/Frequently/Very Frequently In your practice, how often do you percieve practice restrictions (imposed by insurance or hospital policy) limiting your ability to

significant CAD (your hospital does not perform order appropriate testing or treatment options for your patients? coronary CTA). Please choose one option: Never/Infrequently/Somewhat Frequently/Frequently/Very Frequently
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Cardiologists/American Heart Association (ACC/AHA) guidelines is included in Table 1.

Box 1 A brief description of the cases

Case 1: Non-invasive testing in routine follow-up of an asymptomatic patient with history of coronary artery disease (CAD) - Empirical evidence for use of non-invasive testing to improve patient outcomes is limited and recommendations in ACC/AHA guidelines addressing this topic vary.

Case 2: Management of sustained monomorphic ventricular tachycardia (VT) in the setting of CAD and low-level troponin elevation. Different class-I guideline recommendations [29] may apply based on the cardiologist's interpretation of the significance of the troponin elevation.

Case 3: Evaluation of a patient with uncomplicated syncope -Diagnostic evaluation of syncope in clinical practice is extensive and often unrevealing, leading to substantial healthcare costs [30].

Case 4: Disposition of a patient presenting to the emergency department (ED) with chest pain explores decision-making in an anxious patient with non-cardiac chest pain who requests further evaluation.

Sample

This survey was posted by the ACC's through CardioSurve® and by the Canadian Cardiovascular Society (CCS). CardioSurve® represents an invited panel of cardiologists practicing in diverse settings in the US who participate in monthly surveys administered by the ACC. A link to this case-based survey was made available to the panel following completion of the September 2017 ACC survey (they could access this survey only after completing the scheduled ACC survey for September). To engage Canadian cardiologists, CCS posted the survey on their member page in November 2017. We also distributed the survey to cardiologists at the University at Buffalo, New York, US and McMaster University in Hamilton, Canada, through posting on academic department websites and personal requests.

Conduct of the survey

The survey was anonymous, administered *via* email or through the ACC/CCS and accessed through the uniform resource locator (URL) link. The survey was conducted and data collected using a web-based platform (SurveyMonkey, San Mateo, CA) [31].

Statistical Analysis

Results were analyzed in IBM SPSS statistics for Windows [32]. The ratings of the 7 factors were first compared across cases using repeated measures ANOVA, then compared using 2 within subjects factors of case (4 cases) and factor (7 factors). To understand how each of the 7 factors may have influenced choosing the ACC/AHA guideline recommendation, the ratings of each factor were submitted to a repeated measures ANOVA with factor

ratings as a within subjects variable (7 factors) and treatment option as a between subjects factor [33]. We used descriptive statistics to examine the distribution of responses to each question (percent selecting ACC/AHA guideline recommended management option compared to others). The frequency of each type of response based on demographic characteristics was analyzed using χ^2 tests. To determine if individual participants consistently selected the guideline recommended option, agreement across cases was measured using the Kuder Richardson 20 test for internal consistency. Responses in the free text box were analyzed using basic content analytic strategies [34,35].

Results

Demographics

A total of 106 cardiologists completed the survey. An overall survey response rate could not be calculated since the survey posting included websites with an open invitation (unknown denominator). Twenty percent of cardiologists who responded to the September 2017 CardioSurve® survey participated in our study. The average time taken to complete the survey was 11 minutes. Forty-three percent of cardiologists practiced in an academic setting, 35% in private practice and 22% in hospital-based practice. Almost half (47%) were < 10 years in practice, 28% were in practice for 10-20 years and 25% for > 20 years. Seventy-eight percent of participants were male and 18% were Canadian.

Management choices

Overall, respondents selected a non-CPG recommended option more frequently than the CPG-recommended option in the first 3 case scenarios (58% in case 1, 87% in case 2, 70% in case 3 and 19% in case 4). Across the 4 cases, respondents manifested high variability regarding whether they chose CPG or the non-CPG recommended option (sometimes they did, sometimes not; internal consistency measured by Kuder Richardson 20 was < 0.1). (See Box 2).

Relationship between factor ratings and decisions

There was a main effect of the factors (average factor ratings varied using the data from all 4 cases) [(F(6,612) = 55.38), p < 0.001]: overall, the influence of safety (5.8), effectiveness (5.7) and patient-centered care (5.7) were rated highest, followed by a provider's prior experience (5) and efficiency (4.9). Medicolegal concerns were somewhat important (4); local hospital practice was rated the lowest (3.5). Figure 1 is a graphical representation of the overall ratings of the 7 factors using the data from all 4 cases.

There was a main effect of case on rating of factors $(F_{18,1890} = 8.61, p < .0001)$ and an interaction between case and factor [(F(18,1836) = 8.35), p < 0.001]. The main effect

Box 2 Selection of management options by the respondents

<u>Case 1</u>. The patient described in the scenario is being appropriately followed and treated by his primary care provider, is using a high-potency statin and blood pressure is at recommended goal. 42% of respondents chose not to pursue further testing which best aligns with ACC/AHA guideline recommendations; 28% chose a fasting lipid profile plus basic metabolic panel and 30% chose some form of further cardiac testing. A higher proportion of academic physicians (49%) chose the option of no further testing compared to other practice settings (34%) (p=0.03).

<u>*Case 2.*</u> The second scenario described a patient with CAD who presents with an episode of sustained VT and low-level troponin elevation that may be secondary to supply-demand mismatch (type 2 myocardial-infarction) [36] in the setting of prolonged VT with hypotension. The guideline recommended management choice (secondary-prevention) is implantation of an internal cardioverter defibrillator (ICD) [37]; however, only 13% of participants chose this option. The majority (60%) chose to use the wearable cardioverter-defibrillator upon discharge followed by reassessment of left ventricular ejection fraction in 40 days to determine need for ICD (Guideline recommended choice for VT in the setting of a type 1 myocardial-infarction). The remaining 27% chose amiodarone or an electrophysiologic study directed management strategy. A higher proportion of cardiologists in academic practice (27%) chose the guideline-recommended option compared to other practice settings (4%) (p = 0.026).

<u>Case 3.</u> The third scenario involved uncomplicated syncope in an otherwise healthy 42-year-old woman. The ACC/AHA CPG make a conditional recommendation to refer the patient for tilt table testing [38] and 30% chose this option. The ACC/AHA guidelines recommend against echocardiograms in patients without suspicion of structural heart disease based on history, physical exam and ECG (patient in the clinical vignette) [38]. Nevertheless, 55% chose to perform an echocardiogram. The remaining 15% chose head computed tomography, carotid Dopplers or a comprehensive metabolic panel. There was no significant association of choice with demographic characteristics.

Case 4. In the fourth scenario, a patient with a non-cardiac chest pain presentation with a negative work up in the ED requests admission and further evaluation due to concern over a missed diagnosis. Most (81%) participants chose to discharge the patient; 19% chose either further testing or prolonged observation in the hospital. There was no association of choice with demographic characteristics.

Figure 1 Overall rating of factors for the 4 cases

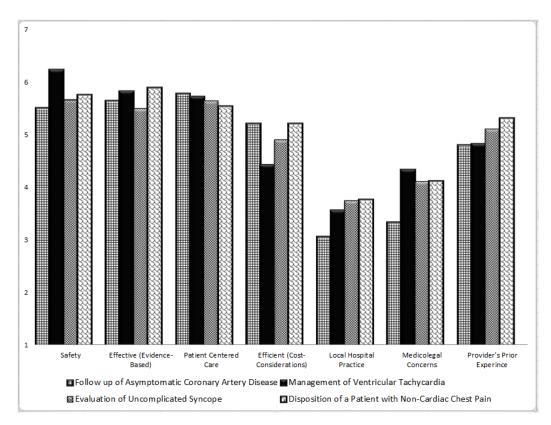
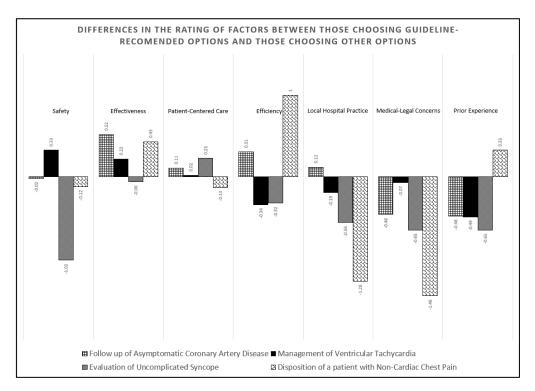


Figure 2 Difference in ratings of the influence of the 7 factors between cardiologists who chose a guideline suggested option (positive if rated higher) and those who chose a different option (negative if rated higher)



indicates that average factor ratings varied by case; the interaction indicates that the pattern of factor ratings differed for each case. For the case of a patient with sustained VT, safety and medicolegal concerns were rated of greater importance and efficiency (cost) was rated as being of lesser importance compared to other cases. In reference to case 3, cardiologists who chose to perform an echocardiogram (not guideline-recommended) rated safety and medicolegal concerns higher than cardiologists who chose to perform tilt table testing (guideline-suggested). In case 4, cardiologists who chose to discharge the patient rated local hospital practice (3.5) and medicolegal concerns (3.8) lower and efficiency higher (5.4) than physicians who chose other options.

When we examined the difference in ratings between cardiologists who chose a guideline recommended option compared to cardiologists who chose other options, we found variation in the difference in ratings between factors (Figure 2). There was a greater than 1 point difference in the ratings between cases for safety, efficiency, local hospital practice and medicolegal concerns suggesting a context specific influence of these factors. Medicolegal concerns were rated higher by cardiologists choosing nonguideline recommended options in all 4 cases.

Follow-up Questions

Although a majority of physicians (91%; n=96) stated that out-of-pocket healthcare costs should be considered in patient-physician shared decision-making discussions, most (60%, n=62) did not feel well informed to address these issues with patients. Over two-thirds of physicians indicated that costs (69%, n=73) and cost-effectiveness (72%, n=76) of therapies should be considered in individual patient decision-making; nevertheless, most (62%, n=66) did not include these topics (infrequently or never) in discussion with patients. Follow-up questions to the vignette on non-cardiac chest pain asked if the participants experienced a conflict between limiting unnecessary testing and avoiding errors due to a missed diagnosis; 81% (n=86) said they felt this conflict at least somewhat frequently.

Written comments

Participants provided 61 comments reflecting on a range of issues presented in these cases. Table 2 summarizes the qualitative synthesis of the comments to the free text response options. Comments revealed that cardiologists are well aware of cost concerns. More than a third of comments on out-of-pocket patient costs related to its impact on patient compliance to prescribed therapies (or investigations) due to an inability to pay and the need to include this topic in discussion and shared decisionmaking. However, due to a combination of factors including patient and peer expectations, medicolegal concerns, limited time to discuss the nuances of the value of treatment options before making a recommendation, they do not routinely incorporate costs into decisionmaking and feel conflicted about the treatment decisions they make. A frequently expressed concern was the opaque nature of pricing and the inability to easily understand overall costs and out-of-pocket costs for the individual patient. Cardiologists also commented on the influence of

Table 2 Synthesis of cardiologists' comments

	Торіс	Select Quotes
	Consider costs	'If physicians don't assist in "bending the cost of care" downward the government will do it for us.
Cost and Cost Effectiveness	Responsibility to the patient, do not consider	'The primary responsibility of a physician is to do the best for their individual patient'. 'The provider is 100% responsible to the patient. If this country decides to ration healthcare, then I have
	costs	no control, but while I do, I will use every tool to assure best QOL, and longevity'.
	Obtaining information	'Really knowing what true costs are, is not a simple task, as many factors that a typical physician would
	on costs.	be unlikely to be familiar with contribute to cost'.
	Incorporating costs in decision-making	'It is unclear to me how one can incorporate cost effectiveness analysis into INDIVIDUAL care management when there is an established standard of care in the field that indicates a treatment pathway'.
	Teaching / Learning	'Need to increase awareness and improve training re cost effectiveness during residency and fellowship'.
	Out of pocket costs &	'Out of pocket expenses realistically will dictate compliance w. prescribed meds. and treatment plans'
patien Deter Pocka patien	patient Compliance	'These are frequently uncommunicated concerns which may dictate patient behavior and compliance'.
	Determining Out of	'In our current chaotic "system" it is very difficult to determine what those out of pocket expenses will
	Pocket costs for each	be'.
	patient	'Out of pocket expenses are important but information are not easy to obtain'
2 <u>5</u>	Shared Decision	'I always inform patients that if they cannot afford a medication or test to NOT pick up the medication or
Out of	Making – discuss costs	schedule the test and call me/the office.' 'Knowing out of pocket expense would not change necessary
	with patients Costs as a tool to	tests, however, it would allow for dialogue and formation of a payment plan if needed'. Probably having people bear a greater share of the costs of healthcare may prevent them from demanding
	change behaviour	tests; however, would also discourage the ones who we feel really need it.
s		'Patients perceive that a physician has not done anything for them when no tests are performed. They
Patient and Societal Factors	Patient and Peer Expectations, Medicolegal Concerns	commonly perceive as "the doctor does not care enough". The referring physician also has expectations that tests will be performed so they can give answers to their patient. Vasovagal syncope may be the most common cause. However, in my experience I have come across cases where that was the only cardiac symptom related to a patient having critical coronary artery disease needing coronary artery bypass grafting surgery. Patients may pass out from syndromes such as long QT and have sudden death. Unless it is one or two isolated episodes, if there was no cardiac work-up done, it becomes very difficult to defend oneself in court. The cost of my life getting disrupted with a law suit trumps the costs of doing an echo, carotid and event monitor or loop recorder. Thus, I would not factor cost effectiveness here' 'I feel that the primary conflict is with other providers, mostly outside of cardiology, who are fearful of missed diagnoses, and seem oblivious to the cost of false positives and overtreating and overtreatment'.
	Insurance companies policy is reasonable	'Insurance rules are usually based on Professional Guidelines and are reasonable, even though annoying. If physicians knew the costs of tests, they might change their ordering profile'.
Insurance and Contextual Factors	The problems with insurance company pre- authorizations and other restrictions.	'In private practice often times one must request "prior authorization" in order to proceed as per your clinical judgement, which comes from someone at the insurer with check list who really does not understand the clinical situation. This person may even be a physician but if he/she is an obstetrician who does not understand cardiology, for example, I have experienced totally inappropriate decision-making. The most glaring example was a patient presenting at night with a STEMI confirmed by emergency cardiac cath with atypical symptoms about whom my office was informed by the local insurance company on the following day that this procedure was going to be denied professional and hospital payment because the patient did not fit their criteria for the admission and cath/Percutaneous Coronary Intervention!'.
	Contextual Factor -US	'I am at the Veterans Affairs Hospital, where the issue of cost to patients is much less of an issue compared to private practice'.
	Canadian Context	'Such challenges are infrequent'.

patient perceptions and peer expectations on their decision to perform more tests. Cardiologists from Canada and those working in the Veterans Affairs Hospitals in the US noted less pressure to consider costs in their practice settings.

Discussion

In this survey of cardiologists practicing in diverse practice settings in the US and Canada, clinicians varied in their management decisions and often made management choices that are inconsistent with CPG recommendations. Individual clinicians sometimes chose the guideline recommended option, but sometimes did not: the internal consistency for choosing guideline recommendations was very low. Overall, whether cardiologists selected a CPG- recommended or non-CPG recommended option, they rated safety, evidence-based care and patient-centered care as of similar high importance in influencing their decision. Our study suggests contextual case-specific sources of variation including, different perceptions of options that increase safety, cost-considerations, local hospital practice and medicolegal concerns.

Response to follow-up questions regarding costs indicate an increasing awareness and inclination to consider costs in decision-making; however, due to limited knowledge and support, cardiologists are unable to incorporate costs in their decisions. A recent survey of 5031 patients and 687 physicians [39] in the US, suggests that physicians and patients may prioritize value differently; although a majority of patients (62%) and physicians (88%) indicated that quality of care was the most important aspect of value, 28% of patients indicated that cost was most important compared to 5% of

physicians. When patients were asked to choose five statements that best reflected their value, the top value statement chosen by 45% of patients was affordable outof-pocket healthcare costs; fewer (32%) chose the statement on improvement of their health. In our survey the majority of cardiologists felt they were not wellinformed to discuss out-of-pocket costs with patients. Analysis of free text comments in our study illustrates this conflict. Physicians and, according to the literature, perhaps patients, are divided in their opinion on their role in considering costs. Similarly, other studies have found variation in physicians' beliefs on incorporating costs [40] and diverse attitudes and beliefs about cost considerations in decision-making may contribute to practice variation.

Due to increasing healthcare costs [41,42] and suboptimal patient outcomes [43], there is currently an emphasis on developing and implementing strategies to improve health outcomes while limiting costs [44] promoting 'value' in healthcare. Until recently, the ACC/AHA guidelines did not consider cost in guideline development; however, in an effort to promote cost consideration in decision-making, recent guidelines are including information on costs and cost-effectiveness [45]. The ACC/AHA Syncope guidelines [38] included extensive cost and cost-effectiveness information. In the context of considering costs, the limited diagnostic yield of the echocardiogram in patients with no clinical suspicion of structural heart disease resulted in a class-III recommendation (specifically not recommended). However, this was the most frequent option chosen by cardiologists in our study. In their written comments, cardiologists emphasized the role of patient perceptions and peer expectations on their decisions to recommend tests irrespective of the added value of the test. These findings are similar to those of a recent qualitative study of cardiologists exploring clinician's decision-making on the use of echocardiograms. Fonseca and colleagues [46] found that a number of personal (training and medical experience, management of uncertainty) and systemic factors (accessibility, costs, hospital protocols) influenced the decision to order an echocardiogram and lead to nonadherence to guideline recommendations. Unfortunately, strategies to implement high-value care do not often account for these influences.

Cardiologists who opted to pursue further testing instead of discharging the patient with non-cardiac chest pain (case 4) rated medicolegal concerns higher than cardiologists who chose to discharge the patient. This may reflect 'defensive medicine' secondary to previous personal experiences with medicolegal issues or differences in regional malpractice legislation leading to practice variation. Farmer and colleagues [47] reported an association between medical liability reform and the approach to CAD management in states in the US that adopted damage caps. They found that physicians who face lower malpractice risk tolerate greater uncertainty leading to fewer invasive cardiac procedures. Similarly, in a pointof-care survey of disposition of a patient with chest pain conducted in an emergency care context, Brooker and colleagues [48] found that medicolegal concerns and

concerns of missing a diagnosis substantially increased admissions.

The novel insight that physicians largely rate the same factors as most important in their decision-making irrespective of their choice of treatment has implications for future efforts to promote high-value care. Clinicians' self-perception of practicing evidence-based medicine appears to be unrelated to their adherence to evidencebased guidelines. Similarly, cardiologists choosing very different management options all believed their choice provided optimal safe and patient-centered care. This remains the case even when cardiologists chose options with very little or no evidence of benefit such as performing echocardiograms in patients presenting with syncope with no suspicion for structural heart disease. If, as our results suggest, physicians believe they are practicing evidence-based care irrespective of their management choices, they are either unaware of the best evidence, or their interpretation of the evidence differs substantially. Elucidating this key difference would be important in informing strategies to encourage high value care.

Our study has several strengths, including assessing decision-making in very specific patient contexts, quantitative rating of factors that influence decisionmaking, exploring attitudes about costs and participation by cardiologists in diverse settings. Analysis of free text responses provided additional insight into drivers of decision-making. There are some limitations. Due to its limited sample size, our result must be viewed as preliminary. The response rate of 20% for Cardiosurve® participants, although low, is similar to the response rate in recent studies, reflecting the decline in response rates of both the general public (from 21% in 2006 to 9% in 2016) [49] and physicians who have response rates even lower than the general public [50]. Studies in the literature using clinical vignettes have included similar numbers [51] or fewer clinicians [52]. The results of this study may not be representative of practicing cardiologists due to the potential for respondent bias and may not be generalizable across other scenarios and other clinical specialties. Additionally, the ratings of the seven domains may have reflected socially desirable responses. Future work may be able to clarify these issues.

Conclusion

Cardiologists rate evidence-based practice (effectiveness) as a similarly important factor influencing their decisionmaking whether or not they make CPG-concordant choices. Sources of practice variation include context, costconsiderations, local hospital practice and medicolegal concerns. Our findings suggest that implementation strategies to improve adoption of CPG recommendations should consider physicians' perceptions of the effectiveness of the management choices they make. Successful strategies to improve patient- and personcentered care will require engagement from physicians, particularly to understand how best to support their ability to counsel and involve patients when choosing treatment options and considering cost in these decisions. A deeper understanding of practice variation and its implication for developing strategies to facilitate high value care will require use of qualitative methods.

Acknowledgements and Conflicts of Interest

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CHAPTER FOUR

The Ecology of Clinical Decision-Making: Cardiologists' Perceptions of Factors Influencing Clinical Practice Decisions

Abstract

<u>Background</u>: Healthcare costs are increasing in the Unites-States and Canada and a substantial portion of health spending is devoted to services that do not improve health outcomes. Efforts to reduce waste by adopting evidence-based clinical practice guideline recommendations have had limited success. We sought insight into improving health system efficiency through understanding cardiologists' perceptions of factors that influence clinical decision-making.

<u>Methods</u>: In this descriptive qualitative study, we conducted in-depth interviews with 18 American and 3 Canadian cardiologists. We used conventional content analysis including inductive and deductive approaches for data analysis and mapped findings to the ecological systems framework.

<u>Results:</u> Physician reported that major determinants of practice included interpersonal interactions with peers, patients and administrators; financial incentives; and system factors. Patients' insurance status represented an important consideration for some cardiologists. Other major influences included time constraints, fear of litigation (less prominent in Canada), a sense that their obligation was never to miss any underlying pathology, and patient demands. The need to bring income into their health system influenced American cardiologists' practice; personal income implications influenced

Canadian cardiologists' practice. Cardiologists reported that knowledge limitations and logistical challenges limit their ability to assist patients with cost-considerations. All these considerations were more influential than guidelines; some cardiologists expressed a high level of skepticism regarding guidelines.

<u>Conclusions</u>: Clinical decision-making by cardiologists is shaped by individual, interpersonal, organizational, environmental, financial and sociopolitical influences and only to a limited extent by guideline recommendations. Successful strategies to achieve efficient, evidence-based care will require addressing socioecological influences on decision-making.

Key words: clinical decision-making; over-testing; high-value care; evidence-based medicine; clinical practice guidelines

Introduction

Despite spending more than any other country on healthcare (17.9% of GDP; \$10,348 per capita in 2016),¹ the performance of the American health care system is comparatively poor.² Services that do not improve patient health outcomes are responsible for a substantial portion of healthcare spending, ³ while interventions proven to improve patient outcomes are underused.⁴ Given similar clinical information and circumstances, different physicians treating the same patient make very different decisions related to

testing and treatment.⁵ This type of variation in health services utilization is common in cardiology,⁶ and when there is a clear, optimal, evidence-based course of action, practice variation will be associated with disparities in quality and efficiency of care.⁷ Similar trends are reported in Canada.⁸

Strategies to improve quality and efficiency of healthcare have targeted physicians with educational interventions, audit and feedback, and use of software at the point of request, all with limited effect.⁹ Evidence-based clinical practice guidelines (CPGs) are intended to assist physicians in decision-making by appraising and summarizing available research evidence and producing evidence-based recommendations for prevention, diagnosis and treatment of diseases.¹⁰ Adoption of CPG-recommendations by cardiologists however is suboptimal.¹¹

Studies have identified 'physician-specific' effects as an important cause of variation in healthcare expenditures related to physician ordering of laboratory tests, procedures and consultations.¹² Nevertheless, much of the literature addressing variation in care is based on statistical analyses of large databases,⁶ seldom exploring detailed physician input to determine causes for variation.¹³ A deeper insight into the factors that influence decision-making, including physician access and use of evidence, understanding of related costs, application of CPG-recommendations and interactions that shape physicians' decision-making may provide key information for the development of more successful strategies to improve healthcare quality. We therefore conducted a sequential explanatory mixed-methods study to identify and understand the factors affecting cardiologists' decisions.

Methods

The Institutional Review Board at the University at Buffalo, Buffalo, New York, USA and the Hamilton Integrated Research Ethics Board at McMaster University, Hamilton, Ontario, Canada approved the study.

<u>Study Design</u>: This sequential explanatory mixed-methods study¹⁴ included two phases. In the first quantitative phase, a survey of 106 cardiologists evaluated extent of concordance with CPG recommendations and measured the rating of factors on decisionmaking¹⁵ and found that cardiologists rated the influence of evidence-based practice high in their decision-making even when they chose non-evidence-based, guideline-discordant management options. This qualitative phase delves into the reasons for the discordance between the perceptions of following evidence-based practice while opting for nonevidence-based management options.

The principles of qualitative description informed all methodological decisions related to sampling, data collection and analysis. Qualitative description¹⁶ allows the researcher to stay close to the data, provide factual summaries of the participants' experiences and perceptions, uses low-inference in its description and is grounded in the principles of naturalistic inquiry.

<u>Sampling</u>: We chose a purposeful maximum variation sample of cardiologists who participated in the quantitative phase. Based on published literature addressing optimal sample size in studies using qualitative interviews¹⁷, our goal was to interview 12 to 21^{14}

cardiologists in order to include diversity with respect to cardiologists' background and practice settings.¹⁸

<u>Data Collection</u>: Cardiologists participated in face-to-face or telephone semi-structured interviews conducted by the principle investigator (VM) between October 2017 and April 2018. Each interview lasted between 30 and 60 minutes and was digitally recorded. Based on the results of the survey, VM created an initial draft of the interview guide that was revised based on the input of the authors and further refined to improve clarity and flow of questions based on experience using the guide in the first two interviews. Supplementary table-1 presents the final version of the interview-guide.

Data Analysis: The principles of conventional content analysis¹⁹ guided the analytic process. We audio recorded the interviews, transcribed them verbatim, removed identifying information, and stored data in a password protected desktop computer. Data management and coding was performed by VM using Microsoft-Excel and Microsoft-Word. VM read the interview transcripts in their entirety several times to get familiar with the data. The senior author with over 20 years' experience in qualitative research coded 10% of the interviews, reviewed samples of coded interviews and supervised the analytic process. Using a broad-based coding process to create a collection of experiences and accounts we regrouped the data according to themes. Initially a primarily inductive approach led to development of open codes based on the words and concepts within the text which were collapsed into categories followed by identification of major themes. Analysis of the first four interviews revealed a pattern of interconnected individual, interpresonal and organizational factors that influenced decision-making aligning with

the ecological systems theory that specifies nested environmental systems; results were mapped to the social-ecological systems theory framework.^{20 21} Although originally developed to explain child development, investigators have used the theory in studies assessing a variety of social influences on decision-making.^{21 22} This process provided an opportunity for theoretical triangulation.

Results

Of the 25 cardiologists we approached, 21 agreed to participate; twelve interviews occurred face-to-face, and nine by telephone. The participating cardiologists worked in diverse practice settings in either the US (n=18) or Canada (n=3). Table-1 presents the participant demographic characteristics.

Table-1 Demographic Characteristics of participating cardiologists

		Number
Practice-	Academic	14
setting	Private	7
Sex	Male	16
	Female	5
Years in	< 20	10
Practice	>20	11

Overview of results

Participating cardiologists explained that in an ideal world, they would make decisions based on a combination of their knowledge of the pathophysiology of disease, evidence, CPG-recommendations, their prior personal clinical experiences and patients' values and preferences. However, in the real world, practice restrictions and community norms were identified as important and their decisions were sometimes influenced by what care the patient could afford. Cardiologists balanced the scientific evidence with patient and peer expectations and organizational, environmental and societal norms and constraints. Figure-1 depicts the various factors and their inter-related nature that influence decision-making and Table-2 presents results of the analysis mapped to the socio-ecological framework.²⁰

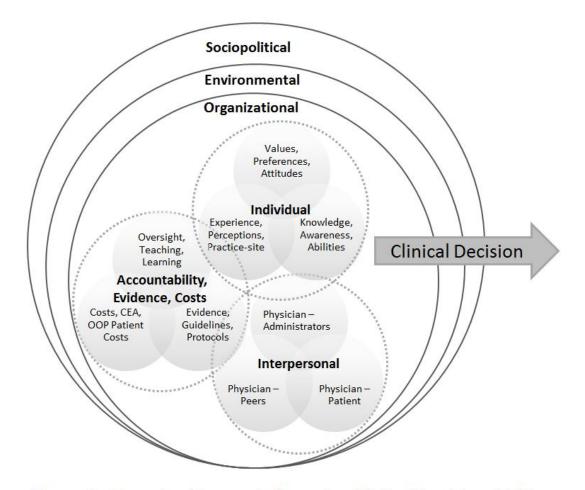


Figure-1: Domains/Factors Influencing Clinical Decision-Making

Figure-1: Domains and Factors Influencing Clinical Decision-Making

Abbreviations: CEA: Cost Effectiveness Analysis; OOP: Out-of-pocket

Table-2: Factors influencing decision making mapped to the socio-ecological framework.

	Categories	Explanation and Examples
	Attitudes, Values,	Preferences
	Values and Preferences	 Variable preference to use decision rules before ordering imaging tests (example - using the Wells or Geneva score before deciding if an imaging study is needed to diagnose pulmonary embolism versus going straight to imaging) Values based on patient demographics (offering intra-cardiac devices for primary prevention to all versus selectively based on age and comorbidities)
	Comfort with uncertainty	 Perceived responsibility not to miss anything, leading to increased testing to increase certainty Perception that cardiologists are constantly dealing with life and death situations and need to perform tests not to miss a potentially serious outcome (example -compared to dermatology)
	Patient advocacy	• Composing the history such that the symptoms sound more concerning than in physician's assessment to meet insurance preauthorization criteria
	Adaptability	• Ability to learn new rules, change practice and adapt to rapidly changing practice settings, reimbursement rules and regulations
	Knowledge, Awareness, Abilities	
	Physical exam	• Decreasing confidence in physical exam findings leads to increased testing
	Literature review skills	• Limited understanding of literature and ability to review further limits capacity for an evidence based plan
	Abilities	• Ability to apply knowledge to a patient care context (knowing versus doing)
	Time constraints	• Less time to talk to patients, easier to get a test than to discuss symptoms
ten		ptions, Practice routines
rosysi	Past lawsuit	• Increased apprehension resulting in practicing defensive medicine
Individual (Microsystem)	Follow all/most conditional CPG - recommendations	 Feel compelled to consider conditional (class-II) recommendations due to fear of lawsuit in-case of negative outcome. Overuse of tests without improving patient outcomes.
Indi	Routines; fill testing schedule	 Patients routinely get an echo before every cardiology appointment.

		• Need to do more tests to make payments on testing equipment.	
	Peer		
	Community norms	• Peer pressure to conform to prevalent community practice which may result in increased testing (yearly stress tests after PCI)	
	Expectations and needs of collaboration	 Referring provider expects some testing if they refer patients to specialist. Perform tests to satisfy collaborating physicians in other specialties. 	
	Issues of trust and power imbalance	 Lack of trust in primary care provider to test and treat effectively leading to increased/duplicate testing Treating based on preference of the senior-physicians in the practice 	
	Patient		
tem)	Expectations	• Patients expect tests to be performed, especially if they have insurance (return on investment)	
esosys	Satisfaction, reassurance	• Reassure patients, perform testing upon request; Need to keep patient in practice	
Interpersonal (Mesosystem)	Ability to pay (out of pocket costs)	• Patients with high deductible insurance consider costs of testing in decisions. Drug costs	
rso	Administrator		
Interpe	Practice managers and division chiefs may suggest increased testing to increase revenue (or decrease testing if DRG/bundled payments). Influenced by the manager or chief's values.		
	Evidence, CPG, AUC		
	Trust in EBM and CPG recommendations	 Mistrust of relevant evidence, mistrust of the CPG-panel members (conflicts of interest, perception of panelists as academic purists without experience treating patients in a busy practice) 	
Organizational (Exosystem)	Number and complexity of the guidelines	• Numerous guidelines on a topic with varying, sometimes discordant recommendations. Too long, too detailed (miss the forest for the trees), even executive summaries are complex.	
	Limited AUC Adoption	• Concerns with appropriateness of AUC (wishy-washy, too watered down). Most based on expert opinion, not evidence	
EX	Practice Environment		
al (Private-Practice	• Fee for service, increased revenue with increased testing	
oni	Academic	Productivity based bonuses, RVU-expectations	
zati	Hospital practice	• Efforts to decrease length of stay, decrease tests and consults	
ganiz	Number of procedures	• Need to meet minimum number of procedures to maintain proficiency in interpretation for accreditation	
•			

	Cast a survey size of		
	Cost comparison	• Hospitals provide feedback to cardiologists about their costs	
	with peers	compared to their peers to modify prescription behavior.	
	Teaching/Learning, Oversight		
	Impact of trainees	• Need to stay current if participating in a teaching program.	
	Lack of checks	• Inadequate quality controls for physicians in practices; no	
	and balances	consistent mechanisms to assess quality of care provided. Recertification and CME requirements insufficient to ensure high-quality practice.	
	Costs, Insurance (
	Insurance	Cardiologists practice within the confines of insurance industry	
	company rules and restrictions	rules. Sometimes rules applied inappropriately due to overlapping clinical scenarios and indications for testing and	
		treatment.	
Less testing with HMO patients,			
	Restrictions	Preauthorization, formulary restrictions, co-pays, deductible	
	Selective referrals	• Insurance encourage referrals to specialists who provide care at lower cost (ability to drill down costs attributable to individual provider)	
I	Medicolegal conce		
Environmental and Sociopolitical (Macrosystem)	Varies locally and legislation varies in different states in the USA, physician speci Interviewees eluded to change in ordering behavior based on medicolegal concern		
ob	 Pharmaceutical and Device companies 		
0Ci	Marketing	• Aggressive push to prescribe for off-label indications	
and S	Patient incentives	• Pharmaceutical companies cover patient copays, provide coupons etc.	
n) tal	Divergent views on best approach to affordable healthcare		
Environmental (Macrosystem)	Based on sociopolitical views, state supported insurance programs (Medicaid) vary		
Ino Ino	across states.		
vir.	Varied and divergent views on what constitutes best practices, on what is wrong with the		
M ²	current system and potential solutions to improve health care quality and efficiency		
	(noted during inter	views). Personal political views may influence practice pattern.	

Abbreviations: EBM – evidence based medicine; CPG – clinical practice guidelines;

AUC - appropriate use criteria; PCI - percutaneous coronary Intervention; RVU -

relative value unit (a measure to calculate productivity); CME - continuing medical

education; HMO - health maintenance organization

A brief description of interactions between the different domains and systems with illustrative quotes is presented under the following subheadings:

- 1. Practice expectations and patient preferences
- 2. Peer expectations and appropriate-use-criteria (AUC)
- Handling uncertainty, medicolegal concerns and skepticism regarding CPGrecommendations
- 4. Cost considerations
- 5. Canadian context

Additional select quotes supporting the themes are presented in Table-3

Practice Expectations and Patient Preferences:

Cardiologists described experiencing conflicts of interest that influence decision-making. In addition to the explicit conflict with fee-for-service reimbursement, ordering tests and procedures influences perceived clinical productivity, bonuses and maintenance of procedure volumes. Cardiologists noted pressure from managers and service chiefs in private and academic practice to increase tests and revenue; stating, for instance "*When we tried to limit echo referrals here, we actually got word from our chief, 'don't do that, echo is one of the major income generating sections of cardiology.*" Patients perceive testing as representative of good healthcare and it is easier to order an echocardiogram or a stress test than to have a detailed discussion regarding the benign nature of patient symptoms. As noted by a cardiologist in private practice, patients are satisfied with more testing, "*The patients feel everything has been checked and everything is fine*". A cardiologist mentioned that if the patient's symptoms did not meet insurance preauthorization criteria, he sometimes modifies his note:

You end up kind of stretching the truth, or composing your history such that the symptoms sound maybe more concerning than maybe you think they are, just so he qualifies for getting a stress test with nuclear imaging.

Peer Expectations and Appropriate Use Criteria (AUC):

There was general agreement among cardiologists that the AUC as a tool to limit unnecessary testing are not useful in clinical practice because of the broad categorization, lack of evidentiary support for the AUC recommendations and lack of 'buy-in' by practicing cardiologists. One cardiologist commented, "*But when you look at the AUC*, *there is very little that falls in a black and white category of absolutely yes and absolutely no, they are really wishy washy especially the imaging ones*." Respondents identified peer-expectations, the need to collaborate and community norms as strong drivers of clinical decisions, often overriding the AUC. One cardiologist noted, "*The primary care provider sends the patients to you for certain things, [so] there is an expectation [of tests] and they look for the results*." Another commenting on the influence of practice norms and expectations noted:

I try to follow AUC, and I have been criticized for being too conservative and not sending enough people to the [catheterization] lab. And sometimes it is difficult to ignore the peer pressure which may then drive decisions, especially for junior faculty. And the [more] junior they are the more likely they are to be, in my estimate, more aggressive than indicated by the criteria or by the patient.

Handling Uncertainty, Medicolegal Concerns and Skepticism Regarding CPG-Recommendations

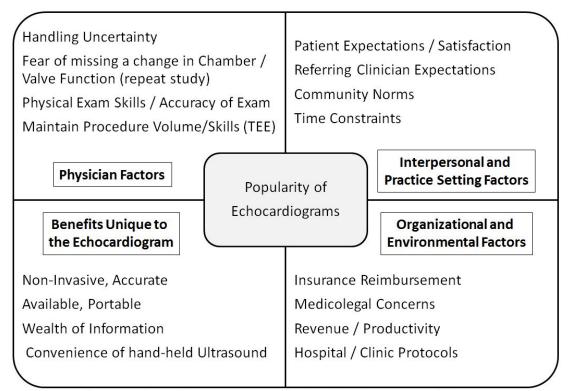
Cardiologists varied in their level of comfort with uncertainty; some preferred limited testing noting, "*Often patients will accept that [reassurance] and you don't need to look further.*" However, most were driven by a need for certainty, especially in a litigious environment. A common rationale used was the perception that cardiologists need to perform more tests because they are dealing with life and death situations. Cardiologists often quoted CPG-recommendations as justification for their clinical decisions when they aligned with their practice, but found them lacking when their practice diverged from CPG-recommendations. One common response was that the CPGs are written by clinical researchers out of touch with needs of busy clinical practice, summarized thus by a cardiologist:

Guidelines are often developed by academic guys who are more purists in terms of the data and do not see many patients, there is a disconnect between the purely academic people and those who have the responsibility to treat people. I think when you have the responsibility not to miss anything - that is where you get the divergence from the guidelines.

Another concern with the guidelines was that they were unwieldy, one cardiologist noting, "All the guidelines are so voluminous that they become almost irrelevant. They try to dig into the minutia so much that they lose the forest for the trees".

The determinants of the use of echocardiogram when not supported by evidence-based guideline-recommendations provide an insight into the factors that influence decisions leading to overuse of medical technologies and are summarized in figure-2.

Figure-2: Physicians' reasons for performing echocardiogram when not supported by evidence-based clinical practice guidelines.



Reasons For Performing Echocardiograms Not Supported By Clinical Practice Guideline Recommendations

Abbreviations: TEE: Transesophageal Echocardiogram

<u>Cost considerations:</u> When asked about the influence of cost on their decision-making, cardiologists acknowledged ignorance about the costs of testing, the charges to the patient and noted an inability to acquire information on costs. Respondents perceived an

urgent need to consider costs at a societal level, but also expressed a reluctance to consider cost when making clinical decisions for an individual patient. One academic cardiologist commented, "I think as a society we need to consider cost-effectiveness because we just cannot afford to keep paying for every latest and greatest therapy that has some marginal benefit." However, he went on to say:

I think that the way I take care of the patient is not necessarily the way I want society to take care of everybody. I am my patient's advocate and if I think they should have something that even though is not the standard of care, I feel obligated to do that.

Others modified the treatment plan based on the patient's insurance and ability to pay;

one cardiologist commented on her colleague's practice of prescribing less effective

cheaper options to patients with limited coverage:

She puts the patient on amiodarone [instead of a defibrillator], she sits down and talks to them so the patient is aware of the trade-offs. It just kills me to decide to treat different patients differently based on their insurance and affordability.

Many cardiologists expressed frustration with their inability provide patient's with

information on out-of-pocket patients' costs. One academic cardiologist stated:

I have a patient who wants to pay cash for a test, how much does it cost? My own organization will beat around the bush; say, 'we can't tell you, it all depends,' blah blah...... This is ridiculous. I mean the rest of the world it is very clear, I hire a plumber, he says it is \$50 an hour or it's a weekend it is \$67 an hour. Okay I know that, then why in medicine we've made this a game of cat and mouse, I have no idea. Why should a CT scan cost different based on your insurance, based on your ZIP Code? This is the conspiracy theory of medicine!

Some cardiologists highlighted another recent development related to cost: to improve efficiency and encourage cost-consciousness among physicians, hospitals and insurance companies collect and share physician-level cost data and sometimes use it in their referral decisions.

<u>The Canadian context</u>: Despite fundamental differences in healthcare financing between Canada and the US, many similarities were noted in practice patterns by cardiologists in the two systems. These included the influence of patient expectations and cardiologists' preferences for testing to decrease uncertainty. Canadians did not experience pressure by division chiefs to increase revenue but were influenced by both patient expectations and financial incentives. We found some perceived differences between the two countries due to differences in funding mechanisms and medicolegal concerns which are less pressing in the Canadian setting leading to a perception of decreased need for practicing "defensive-medicine."

Domains	Select Quotes
Practice	- 'We are all driven by RVUs [relative-value-units – a measure to
expectations	calculate clinical-productivity]'.
	- 'The more normal echocardiograms you can read, the faster you
	can get done. The ones that are inappropriate actually don't take
	much time.'
	- 'There is definitely a need to fill the cath [cardiac catheterization]
	laboratory, fill the time, do those procedures, looking like we are
	doing procedures, so there is a pressure to do that sometimes.'
Patient	- 'In private practice, people tend to be kind of demanding, [saying
preferences and	things such as] 'I passed out and you are not doing any tests?' or 'I
expectations	have an infection and you will not give antibiotics?'. They expect a
	return on investment if they have insurance.'
Using tests as	-'I have to say that if patients are asking for something, I will explain

Table-3: Select quotes supporting the main categories and themes

therapeutic interventions to allay patients' anxietywhy it is, or is not, needed and what my rationale is, you know if a patient is requesting their echo more frequently, or a stress test that they may not need, they are physically very active, it is a grey area, it is not a test that is going to hurt the patient, the risk of the test is low, their insurance covers it, the patient is feeling uncomfortable without that information, so the test almost becomes a therapeutic test [intervention].'Peer expectations- 'The social component of trying to collaborate and cooperate with other consultant services [infectious-disease] sometimes outweighs the absolute clinical indications.'Protocols driving increased testing- 'The EDs [emergency departments] have a flow chart – if the D- dimer is positive, they order a CT [computerized-tomography] angiogram, if the troponin is negative they get a stress test, if the troponin is positive, they get a cardiology consult and expect a [cardiac] catheterization.'Handling uncertainty. Perception that misdiagnosing cardiac problems may have major consequences- 'The risk of missing something is so strong and you have relatively benign tests, although echocardiograms are not cheap, you know they are non-invasive, you are going to be more liberal in doing them' - 'If I feel like there is a lot of uncertainty in my decision and there is not enough data, then I want to be more certain, you know particularly in our world which is life or deaths; if you make the umer choise are inverted for in a bia word'.	interventions to	
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		not enough data, then I want to be more certain, you know
	consequences	particularly in our world which is life or deaths; if you make the
wrong choice, patients suffer in a big way.	1	wrong choice, patients suffer in a big way.'
Issues with -' I find the European guidelines to be far easier to comprehend than	Issues with	
Guidelines the ACC [American College of Cardiology] guidelines. I know they	Guidelines	
want to be complete, but they are so overwhelming. Even the		
executive summaries are really complex.'		
Reasons for -'I know that it almost is never revealing if the physical exam is	Reasons for	
performing <i>normal; on the other hand, the echo is a benign test, most people's</i>		
echocardiograms insurance covers it. Patients are incredibly reassured by an echo, a		ů
when not <i>lot of times we get an echo because the patient is very concerned</i>	Ū	
indicated based even when it is purely a vasovagal episode. It is like everybody else		
on guidelines. <i>responded; it is a ridiculous response in a way, but most people get</i>		
an echo.'	0	
Insurance -'What we do around here at least my experience with the life-vest	Insurance	
company rules [wearable cardioverter defibrillator], and I think Medicare is the big		
influencing driver for this because they are very particular what they will		•
	0	· · · · · · ·
	treatment	\uparrow remining whether that to my electron two of the contemption \downarrow to the two electron transmissions and the transmission \downarrow
	treatment decisions	90 days after CABG here before they would even consider a device."

Opaque nature of	- 'For patients that do not have perfect insurance, they will get hit
Insurance	with charges, and there is no transparency. Essentially no
mourance	transparency in terms of what they will get billed, and they may get
	told one thing and billed another. '
Cost	- 'Maybe 20-30% of my patients want to know about the cost to
considerations	
considerations	them. It also depends on what insurance or what income category they belong to.'
	- 'Even if they have insurance, if they have a high deductible, they
	may have to pay for most of the cost of the test out of pocket.'
physician cost	- 'Individual providers get a report every quarter showing their cost
profiling	of care and how they compare to their peers, where were the
	opportunities for saving, for example, for some people it may be
	length of stay, for others, it may be pharmacy utilization and for
	those who do procedures or surgeries, what is their costs compared
	to their peers; it changes behavior dramatically.'
	- 'The primary care providers are often graded on their cost of care
	for their patients, so when they refer somebody to a cardiologist who
	is going to do all these fancy tests versus the other one who only
	orders them when they are necessary, then of course there is a
	different cost of care and now you are going to favour the one who is
	not running around doing tests. I do think there have to be some
	economic drivers to force people to do the right thing.'
The Canadian	-'I think there is also in many cases a personal financial bias that is
Context	exemplified by their chronic stable coronary patients, where many
	people who run a private practice have echo machines, have nuclear
	imaging in their office and there is self-interest in ordering these
	tests because they generate a lot of income. And patients, funny
	enough, don't seem to dislike a modest amount of excessive testing.
	<i>They think they are getting better care even though they may not be.</i> '
	- 'We have had similar issues with lower socio-economic areas in
	Canada. So, if you go to Etobicoke, where there is a large population
	of poor, similar to inner cities in the US, hypertension is rampant,
	dyslipidemia is rampant, and people cannot afford their
	medications.'

Discussion

Our results illustrate the complexity and layers of factors that influence clinical decisionmaking by cardiologists in the US. Physician behavior leading to unnecessary testing is driven by the need to fulfill practice expectations (productivity, costs, and procedure volumes), time constraints, financial incentives (both personal and system), financial barriers (patients' limited insurance and ability to pay), medicolegal concerns, peer pressure, and patient expectations. Cardiologists do consider evidence of effectiveness and CPG-recommendations in decision-making, but in many instances they play a secondary role. When cardiologists do not follow CPG-recommendations it is generally not due to lack of knowledge but because of competing influences. Although American patients are increasingly requesting information on costs, the inability to assist with cost information was a source of frustration for cardiologists who expressed an urgent need to improve cost transparency in healthcare.

American cardiologists, but not their Canadian counterparts, noted the practice of gathering and reporting physician specific cost data to provide feedback to individual physicians by hospitals and third-party payers in an effort to encourage costconsciousness. Respondents noted this practice to be an increasing and evolving influence on decision-making with potentially important impact on clinical practice and that they were caught between competing pressures to do more and initiatives to do less.

Strengths of our study include its use of the prior quantitative study to inform the current study,¹⁵ the varying perspectives of the team in creating and modifying the survey, and the modifications that followed initial results. Recruitment of cardiologists practicing in diverse settings and differing in age and sex enhance the transferability of our findings. Double review of a set of interview transcripts for the qualitative component ensured identification and labelling of key constructs. The application of strategies to address

credibility including methodological coherence, investigator credibility and triangulation further enhance the overall rigor and trustworthiness of the data. Including only three Canadian cardiologists is a limitation of our study; interviews with more Canadian cardiologists would have added to the understanding of similarities and differences between the two settings.

Our findings mirror those of others. In a recently published qualitative study addressing the determinants of appropriate use of echocardiography, Fonseca and colleagues²³ found that physician factors including training, medical experience, handling uncertainty and perception of peer and patient expectations influenced echocardiogram use. Similarly, Hisham and colleagues²⁴ found that despite having positive attitudes about evidence and CPGs, doctors' practice was often not evidence-based due to barriers including heavy workload and workplace culture.

Our results provide credence to critiques of the industrialization and profit focus of American health care. ²⁵ Financial incentives and the pressure to meet productivity goals drive over-utilization of unnecessary testing and treatment, limit time with the patient, and move the focus toward technical testing. This phenomenon is not limited to cardiology; evidence for variation in care attributable to differences in reimbursement mechanisms and supplier-induced demand exist for many specialties within healthcare including surgery,²⁶ nephrology,²⁷ neonatology ²⁸ and obstetrics.²⁹ Published studies include diverse health settings in several countries ^{28 30} and are not limited to the US, suggesting that financial incentives lead to similar practice patterns by physicians with different backgrounds in diverse settings. Our results make evident the unintended

consequences of current regulations, practices and policy. Peer, patient and community expectations play a major role in guideline-divergent decision-making. This finding may explain the limited success of approaches to increase the value of care by focusing on strategies to improve physician's knowledge.

Our findings have practice, research and policy implications for addressing medical waste. As long as financial and productivity incentives persist they will continue to drive increased testing. It will be extremely difficult to change behavior without fundamentally changing the practice environment and incentives. The influence of the interaction of the contextual factors identified in this study within the current complex healthcare environment needs further research. Increasing use of qualitative studies including focused ethnography may be helpful in this regard. Methods to encourage patient-centered, efficient and evidence-based care need further study before implementation.

Conclusions

Clinical decision-making by cardiologists is shaped by individual, interpersonal, organizational, environmental and sociopolitical influences and to a limited extent by CPG-recommendations. Our results suggest that the marginal success of current initiatives to optimize the efficiency and value of healthcare results from their ignoring the most powerful factors that influence clinical decisions. To develop successful interventions that result in positive, fundamental changes in practice will require a sophisticated understanding of the drivers of overuse in the social and ecological context.

Changes in reimbursement structure and greater transparency in healthcare financing is

essential to achieving efficient, evidence-based patient-centered care.

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Cardiology Qualitative Study - Interview Guide
After obtaining verbal consent and permission for recording the interview, a brief explanation of the background of the study was provided followed by a review of the four cases included in the survey (the survey and the interview guide were provided to the participants in advance of the interview):
 interview): Following your review of the case, can you please tell me what your clinical decision would be? Now, can you verbally walk me through your process of decision making and identify the factors that you took under consideration to come to this decision? (prompts – factors included in the survey)
2. What sources do you review for information on effectiveness of management strategies? Evidence changes, how do you keep up with current evidence? Do you routinely consider and consult clinical practice guidelines? (<i>prompts – reasons for guideline preference; if</i> <i>they use knowledge aggregators ask for reason</i>)
3. In considering 'patient centered care' and patient values, patients may request comprehensive treatment and testing but the treatment and testing may be expensive with limited evidence of effectivenesshow do you deal with such a request?
4. Under what conditions do you engage in shared decision making with patients and approach them prior to making a treatment decision? If you have had these conversations with patients, please describe the process or information shared? What are typically patients' responses to these discussions?
 5. Considering teaching and learning about these topics, a. Are these determinants of decisions (evidence, methods to assess the quality of the evidence, costs, patient's values/preferences, other factors that influence decisions) adequately/appropriately covered in medical school and graduate medical education? b. Should teaching about these determinants of decisions be modified in any way? c. What would be a good model to incorporate these topics during medical education?
6. (For cardiologists practicing in the US only) How has the evolving change in reimbursement in the US changed your practice over the past 5 years? What would you recommend to graduating physicians to be better prepared to work effectively in this system?
7. How familiar are you with costs of testing and treatment that you prescribe to your patients? Is there a mechanism for you to find the costs of care? Do you ever look to find the costs of care? If you look, where do you look?
8. Do you consider costs, cost effectiveness or out-of-pocket patient's costs in providing advice to the patient for recommendations for testing or treatment? If yes, is it a consideration in most clinical encounters or only in some? Please explain.
9. If the patient asks about costs, do you feel knowledgeable, informed and prepared to address this topic with patients at the patient's request?
10. Is there anything about the influence of evidence, costs and values on clinical decision making that we have not discussed that you would like to add?
Thank you for your time and thoughtful consideration of these topics.

Appendix-1 Cardiology Qualitative Study - Interview Guide

CHAPTER FIVE

Incorporating Content Related to Value and Cost-Considerations in Clinical Decision-Making: Enhancements to Medical Education

Abstract

<u>Purpose:</u> Although incorporating cost-considerations during healthcare decision-making is increasingly important to American patients and physicians, content related to these constructs is not routinely included in medical education. As a result, physicians are ill-equipped to consider costs. This study sought input from practicing physicians on perceived deficiencies in current teaching and recommendations on necessary content in medical teaching about healthcare costs.

<u>Methods</u>: The authors conducted a qualitative descriptive study using semi-structured interviews utilizing a purposeful maximum variation sample of cardiologists and neonatologists practicing in diverse settings. They analyzed interviews using conventional content analysis.

<u>Results:</u> 18 cardiologists and 17 neonatologists participated in this study. Respondents perceived that current teaching does not impart sufficient knowledge of value and cost considerations to achieve patient-centered, high-value decision-making. They identified the following priority areas for education related to healthcare costs: the business of medicine and information about out-of-pocket patient costs, training in health research interpretation skills to critically appraise evidence, and communication skills to engage patients as partners in shared decision-making. Participants recommended a variety of teaching methods, including didactic sessions on core topics, role modeling and case studies.

<u>Conclusions:</u> American physicians perceive learning needs related to the incorporation of costs into clinical decision-making that can inform curriculum development initiatives in this field. Physicians perceive knowledge of these topics and skills to be crucial to achieving patient-centered high-value care. Concomitant health system reforms supporting the needs of the patient at its center are essential to enable physicians to focus on a patient-centered approach to healthcare delivery.

<u>Key words:</u> teaching value-based care; clinical decision-making; high-value care; patientphysician interaction; healthcare costs

Introduction

Health care expenditure in the United States (US) continues to increase faster than the economy.¹ Despite spending more than any other country on healthcare (17.9% of GDP; \$10,348 per capita in 2016),² the American health care system underperforms on several indicators.³ Furthermore, in 2010, out-of-pocket healthcare expenditure in the US accounted for 11.8% of total national health expenditure amounting to \$306.2 billion⁴; people with employer-sponsored insurance accounted for over 80% of out-of-pocket spending. Based on a US national random sample of bankruptcy filers in 2007, out-of-pocket spending accounts for a growing number of medical bankruptcies⁵; most medical debtors were middle-class and had health insurance. A report published by the Kaiser Family Foundation⁶ found that, in 2013, Medicare beneficiaries' average out-of-pocket

healthcare spending was 41% of average per capita social security income, with significant projected increases by 2030.

Out-of-pocket healthcare costs not only result in patient financial distress, but may also affect patients' health and wellbeing.⁷ Patients' concerns over out-of-pocket spending were reflected in the results of a recent survey exploring value in healthcare of 5031 patients and 687 physicians⁸ in the US. Although a majority of patients (62%) and physicians (88%) indicated that quality of care was the most important aspect of value, 28% of patients indicated that cost was most important compared to 5% of physicians. More patients valued affordable out-of-pocket costs (45%) than improvement in their health (32%). Shrime and colleagues tested how Americans value trade-offs between health and bankruptcy in a discrete-choice experiment of 2359 members of the US population.⁹ Nearly one in ten participants chose trading in all health to maintain financial protection⁹ underscoring the need for including cost information in patient-centered medical decision-making. Although the majority of American patients and physicians consider discussing costs important when making decisions, these discussions occur infrequently.¹⁰

Knowledge of costs and value of healthcare interventions is essential not only for providing high-value patient-centered care but also for a successful physician practice. Hospitals and health care systems are increasingly evaluating physician performance^{11,12} including physician cost profiling^{13,14} to make patient referral and physician employment decisions. Insurers are increasingly implementing value-based reimbursement.¹⁵ A primary focus on decreasing healthcare costs has the potential to harm patients,¹⁶

highlighting the need to balance patient safety with cost-effective practice thereby improving the value of healthcare interventions.

The 'value' of an intervention is contextual, varies based on patient, clinician and practice considerations. One definition of value adopted from economics¹⁷ considers the output (health gain) relative to the input (unit costs) - in other words, improved quantity and quality of 'health' gained per 'unit of resource' used. Cost-considerations at the individual patient level have traditionally not been a part of medical decision-making and have not been included in medical education in the US. Despite an increased focus on cost in the medical education literature¹⁸⁻²⁰ and increasing explicit integration of costs in clinical practice guidelines from the largest physician specialty societies in the US,¹⁸ there has been little notable change in practice. Currently, most undergraduate and graduate medical education curricula do not include methods to consider costs in clinical decision-making.²¹ A recent survey of senior residents in internal medicine in the US found deficiencies in knowledge about costs.²²

In the current study, we considered that practicing physicians in two different specialty settings may have valuable insights on topics and methods that will improve teaching on costs during medical training. We therefore sought input from cardiologists and neonatologists, two sub-specialties with high healthcare costs including patient/parent financial hardship,²³⁻²⁶ practicing in diverse settings in the US. Objectives of this study were to explore physician perspectives on content and methods for teaching and learning on value and cost-considerations in medical decision-making during medical education.

Methods

Study Design: The Institutional Review Board at the University at Buffalo, Buffalo, New York, USA and the Hamilton Integrated Research Ethics Board at McMaster University, Hamilton, Ontario, Canada approved the study. The findings in this paper are drawn from the qualitative component of a sequential explanatory mixed-methods study designed to understand the factors that influence clinical decision-making by cardiologists and neonatologists.²⁷ The quantitative phase consisted of case-based surveys with follow-up questions on cost and cost-effectiveness. Analysis of comments provided by survey participants indicated a lack of adequate teaching on the topic of cost-considerations. The qualitative component consisted of a qualitative descriptive study using semi-structured interviews.²⁷ In response to the findings from our analysis of the open-ended comments from the physician survey, we included questions on teaching on cost-considerations in the interview guide. Qualitative description allows the researcher to stay close to the data and provide factual summaries of the participants' views and opinions with minimal interpretation by the researchers.^{28,29} This approach is grounded in the principles of naturalistic inquiry and uses low-inference in its description.²⁹

<u>Sampling</u>: We chose a purposeful maximum variation sample of cardiologists and neonatologists representing a range of demographics (sex, years in practice) and practice settings (academic and private). Based on published literature on optimal sample size in studies using qualitative interviews,³⁰ our goal was to interview 12-21²⁷ cardiologists and 12-21 neonatologists to achieve conceptual depth in our understanding.³¹

<u>Data Collection</u>: Cardiologists and neonatologists participated in face-to-face or telephone semi-structured interviews between October 2017 and May 2018. Each interview lasted between 30 and 60 minutes and was digitally recorded. A specific objective of these interviews was to explore current strengths and challenges in teaching and learning on the topic of value and cost-considerations and to elicit input on methods to improve knowledge and skills related to this topic among medical learners.

Data Analysis: We audio recorded the interviews, which were then transcribed verbatim, anonymized and stored in a password protected desktop computer. The first author (VM) read the interview transcripts in their entirety several times to get familiar with the data. Microsoft-Excel and Microsoft-Word were used for data management. Following the principles of conventional content analysis³² and using a broad-based inductive coding process we created a collection of experiences and recommendations followed by regrouping of the data according to themes. VM kept theoretical memos to capture developing ideas about the study and regularly reviewed findings with the senior author (SJ) with over 20 years' experience in qualitative research. SJ analysed 10% of the interviews, guided the analytic process and was intimately involved with all aspects of the study.

Results

18 were cardiologists and 17 neonatologists participated in this study (from 9 different states and Washington DC), Table-1 presents their demographic characteristics.

Table-1: Demographics of participating physicians

		Number
Practice-	Academic	26 (74%)
setting	Private	9 (26%)
Sex	Male	24 (69%)
	Female	11 (31%)
Years in	< 20	16 (46%)
Practice	>20	19 (54%)

One foreign-trained neonatologist with limited knowledge of the US medical education system did not wish to comment on teaching in the US; one cardiologist and two other neonatologists considered current teaching efforts related to value and cost considerations to be satisfactory. The remaining participants identified inadequacies of current curricula and provided input on opportunities to improve teaching on value and cost-considerations in medical education. The need for physicians to be knowledgeable in these topics was identified as important not only to optimize individual patient healthcare decisions but also to engage in local and national healthcare policy discussions.

Physicians noted that although medical knowledge was most important, it was not sufficient to provide a humanistic, patient-centered approach to healthcare. In addition to knowledge of healthcare costs, a solid foundation in evidence appraisal skills and the ability to communicate effectively was considered necessary in making patient-centered healthcare decisions.

We identified a set of inter-related factors that our participants felt influenced their ability to manage costs and discuss costs with their patients. Since cost-effectiveness of an intervention is inherently linked to its clinical effectiveness, physicians noted that costs cannot be assessed in isolation and have to be considered in the context of clinical effectiveness. Themes identified in this study are explained using the following section headings:

- 1. Deficiencies in current teaching
 - a. Classroom teaching (knowledge-content)
 - b. Teaching during rounds/patient encounters (knowledge-application)
- 2. Learning needs (Table-2).
 - a. Essential skills to provide high-value patient-centered care
 - i. Communication skills to facilitate shared decision-making
 - ii. Data-interpretation skills to critically appraise relevant evidence including cost-effectiveness analysis
 - b. Different aspects of healthcare costs
 - i. Business of medicine
 - ii. Out-of-pocket patient healthcare costs
- 3. Suggested teaching and learning strategies (Table-3)

1. Deficiencies in Current Teaching

Physicians noted that curricular content and bedside teaching in medical education have generally not kept up with the rapidly evolving healthcare landscape in the US. They identified several deficiencies including: lack of knowledge on this topic among educators, a need for ongoing professional development to be competent in the topic area, difficulty obtaining information on costs, time constraints with competing demands on time in medical school and during patient-encounters and a struggle to change established practice-patterns of unnecessary testing. Physicians understood cost/affordability as a barrier to patient adherence, with one cardiologist noting:

I think it's important for trainees to understand that cost is a critical consideration to the patient and when surveys are done, that is one of the big reasons for why patients don't follow-up with medications and testing.

Physicians noted that there was recognition of the need to include these topics, however, a lag in implementation exists as suggested in the comment, "*There is lot of lip-service paid to it.*" Furthermore, efforts to improve knowledge of topics are not tied to their application in practice, as noted by a neonatologist:

I don't think many of my mentors would bring up cost-effectiveness during rounds in their decision-making. I don't know if it is due to time limitations or a lack of understanding of the topic, it may be a little bit of both. Personally even though I remember having had lectures about evidence-based medicine, it is not something necessarily I incorporate in rounds.

Participants suggested that incorporating cost-consideration in medical decision-making is an advanced skill ³³ requiring time to reflect on the patient's presentation, the performance characteristics of testing and treatment, patient's values, their socio-economic status and insurance. Critical thinking was regarded as essential to considering the risk/benefit of and alternatives to an intervention and make decisions based on the value of that intervention in a particular patient. They observed that the excessive need for documentation in the electronic medical record limits time for critical thinking. If trainees are distracted by having to complete documentation, they may not have the time to synthesize the best option for that patient. One cardiologist put it thus:

They just keep clicking on the computer. Teaching is down the drain, I don't know what we are teaching the residents. They do the daily notes, discharge summaries, all documentation; they have no time to think. Reimbursement should not be linked to documentation, we spend very little time with patients, majority of time goes into documentation, and it is frustrating. People get used to these routines and protocols, you try to tell them that this is not right, they don't get it. It becomes routine and habit and then you stop questioning.

Complexity and opacity of healthcare costs as a barrier to teaching was stressed by most

physicians, many suggesting that increasing cost transparency was essential; a

cardiologist in private practice noting:

In my medical education we did spend some time discussing costs although I don't know if it goes far enough because there are so many levels and layers of cost. I think there is intended lack of transparency on multiple layers of cost because it is not in the interest of the people that are making the money, and then the cost appears ridiculous. It is just an example of when profit has an opportunity to be a motivating factor; it will be, because it is human nature, I mean it just feels slimy to me. There may be recognition among trainees but there is certainly is not a good transparency across the society as a whole. I don't know what the solution is but there can never be too much awareness of that.

Another academic cardiologist commented,

We have chaos. Other than teaching about the Walmart \$4 plan and how to find that, I find it difficult. I'm not sure how to teach people cost effectiveness, because I can't. My hospital won't give me a list of how much it would cost to order an x-ray, so how do I teach that?

Deficiencies were identified both in classroom teaching content and in teaching of

application of knowledge during patient encounters on rounds.

Classroom teaching: Participants identified deficiencies not only on topics related to cost

but also evidence interpretation and communication skills. Clinicians felt knowledge of

these topics essential to providing optimal care. Participants noted that teaching on some components of evidence-based medicine is included to a variable extent in the curriculum; within that context, they observed was little to no content on costs and resource use and how these influence decision-making. Physicians gained knowledge necessary to effectively use the medical literature, including cost issues, by getting additional degrees, by joining hospital committees or participating in cost analyses. A neonatologist in an academic setting said:

It is not really something I learnt in school, I had to invest a lot of time. I got a Masters in Public Health; it is almost like you personally have to seek out avenues to learn this.

<u>Teaching on rounds</u>: Observing clinical experts role-model the diagnosis and treatment of patients is a cornerstone of medical training. Participants identified a lack of rolemodeling of cost-considerations by clinical-faculty as a barrier to effective learning. Lack of time and logistical challenges in determining cost to the patient resulted in a reluctance to discuss costs with patients. One of the participating cardiologists, working in academic practice, further explained:

We don't have a lot of time to look for each patient, what is their co-pay, is this out-of-pocket costs for them; we just say, this is the standard of care for heart failure with reduced ejection fraction. You need to be on these five medicines and here are the prescriptions. Often patients don't bring it up to us that they can only afford this much. We have a difficult time looking at cost-effectiveness and patient's out-of-pocket costs and are not teaching that very well.

Approaches to medical practice are emulated by trainees even when they are without a sound rationale, leading to unnecessary, frequent and repeated testing with little value,

one cardiologist commenting, 'Stress test and the echocardiograms are horrendous how much they are ordered. We need to teach how to resist the urge to order an echo; does the patient really need it?' And another stating:

The students that I see and the residents that I see, they have this automatic list of tests for a diagnosis. People don't understand that if you order a myocardial perfusion study, it is \$4,000 and if the patient does not have insurance, their wages can be garnished to pay for the bill, for a test that may or may not be necessary.

2. Learning Needs

Physicians discussed various factors that clinicians need consider when assessing value of an intervention. Participants perceived that cost and value considerations are not simple constructs and incorporating value in decision-making requires additional expertise including communication and data interpretation skills.

<u>Communication skills</u>: Participants perceived the dynamics of the patient-physician interaction including the power imbalance as an important consideration in making patient-centered decisions. Among the participants, it was a common experience within their physician-client interactions, that patients and families often "hold back" and are hesitant to engage as an equal partner in discussions and decisions ultimately impacting their health. Unless physicians initiate the discussion, patients may hesitate to discuss issues of affordability. The clinicians perceived it crucial to acknowledge these problems and include teaching communication strategies to engage patients in shared decisionmaking. Physicians suggested that communication was similar to any procedure; trainees

have to deliberately practice to improve this essential skill. A cardiologist with >20 years'

experience in a hospital-based practice said:

In thinking of neonatology and cardiology one of the motivations for patients and family is 'this is it!' It is such a high priority that they will sacrifice everything without questioning the physician, and so we have a vulnerable population of patients who perceive that their heart or their child is more important than anything else in the world. As providers, we are invested with more power then we really know. And I don't think we are taught- I know we are not taught to really understand our ability to influence other people's lives. We don't appreciate it!

She went on to suggest the following to understand 'value' from a patient's perspective:

Experience living like most of the patients on a fixed budget, paying cash to understand the implication of our prescriptions. I think it's very important to figure out in medical school how to make sense of the chaos we live in and the best way to do so is to have everyone live without a credit card for a month. If you live only with cash, the psychological experience is that of much of our country who live paycheck to paycheck, they pay cash for everything. We are in a changing society, a privileged society; everybody has credit cards and I think it contributes to our disconnect from what things cost. I think it would be an interesting exercise to do as a learning experience because then when you start prescribing things, the experience of money is a different experience.

Many physicians stressed the need for certainty by the physician and the patient as a driver of often unnecessary testing and that efforts to decrease overuse need to consider physicians' and the patients' perception and level of comfort with uncertainty. They suggested that knowledge and effective communication of the risks, benefits and often low yield of additional testing may help patients and physicians accept a level of uncertainty.

Data interpretation skills: In considering the value of an intervention, physicians discussed the central significance of the magnitude of health benefit from an intervention and the quality of evidence in addition to costs, and patients' values. An understanding of basic statistics and factors that determine confidence in the estimate of treatment effect was regarded as fundamental to judging the value of an intervention and knowledgeably discussing this with patients during shared decision-making. Physicians acknowledged that an expectation of in-depth understanding of the nuances of critical appraisal would be unrealistic for practicing physicians; however, a healthy skepticism of the published literature, basic knowledge of clinical trial design and the ability to incorporate the confidence in the effect estimates into clinical decisions were deemed necessary. Participants mentioned recognizing the differences in value of primary versus secondary prevention strategies and absolute versus relative risk reduction as examples. One cardiologist explained the pitfalls of insufficient knowledge of methods to assess the quality of the evidence and magnitude of effect using an example of trial results discussed during a journal club:

We need to teach students some skepticism; they need to know basic statistics. They should know the difference between absolute and relative risk reduction. I attended the journal club discussing the [X] trial. I thought the trial results were unimpressive. But the lay press was gushing about it. The benefit in the composite endpoint was due to non-fatal MI with a 15% relative-risk reduction. This trial was paid for by the drug company. We need to teach them that just because it is [published] in the New England Journal of Medicine, it is not necessarily right.

Increasingly, cost-effectiveness analyses (CEA) of healthcare interventions are becoming drivers of healthcare reimbursement decisions and determinants of clinical practice

guidelines. Participants considered knowledge of the framework and components of

CEA and tradeoffs when considering individual versus societal implications of

management decisions as important. As one cardiologist stated:

Teaching them the framework within which that occurs and how something is evaluated, how relative therapies should be evaluated, not just from the outcomes standpoint but also the cost standpoint at the individual and societal level. It is important for medical students to understand the basic concepts and especially and for sure at the residency level it should be absolutely mandatory for them to understand it.

He went on to acknowledge the difficulties with including this in the curriculum:

The challenge is going to be how do you get the information to them - because it is such a changing dynamic, it is not like teaching physical exam skills which has not changed in a thousand years. Costs, cost considerations, and cost effectiveness are constantly fluctuating.

<u>Cost Considerations:</u> In addition to the overall economic impact of escalating health care costs, physician cost-profiling and rapidly rising patients' OOP costs were identified as compelling reasons to advocate improved teaching on the topic. Physicians are increasingly evaluated based on the cost and quality of the care they provide without having received training on methods to meet these standards. A cardiologist noted the evolving implications of physician cost profiling stressing the need to include teaching on

costs:

In medicine, because the decisions that individual physicians make have such a bearing on the cost, I think we *have* to teach our fellows how it has the potential to impact their professional careers over a lifespan. Most hospitals are looking at costs. The individual physicians will be told what their cost per case, what is the cost of their pharmacy utilization, how many consults they have called; the database will actually drill it down to the level of the individual physician. Health

systems are making decisions within their own physician groups of directing care in the direction of physicians who are lower costs and higher quality compared to those who may be high quality but high costs.

<u>Business of Medicine:</u> Physicians perceived teaching about the business of medicine as essential and currently lacking. Knowledge of coding and billing, different aspects of healthcare costs and insurance were deemed necessary for a successful practice. Physicians commented that they received little guidance during training but were expected to be well versed in these topics the moment they became attending physicians. One cardiologist stated:

When you get into practice, there is nothing you learned about the business of medicine. Some background about billing and coding, tax structure, how to relate to the insurance companies, I think that part would be more valuable than physical

exam skills, more practical.

Other comments stressed the need to understand day-to-day costs involved in a medical practice and the methods used in physician cost and quality profiling by hospitals and third party payers.

<u>Out-Of-Pocket Patient Costs</u>: Physicians noted the adverse patient consequences of a lack of knowledge of costs and the impact of prescribing without considering out-of-pocket patient costs. Patients on a limited income are sometimes forced to make tough choices between paying for healthcare and paying for other basic needs. Reviewing the potential out-of-pocket costs with the patient empowers them to make informed compromises, discuss alternatives or refuse treatment that they cannot afford. A cardiologist noted: Rather than just ordering a battery of tests, trainees need to be taught to talk about costs to patients; I didn't know during my training that it cost the patient between \$5000 to \$10,000 to get a LifeVest for 90 days, it was a substantial amount for a retired patient on a fixed limited income and he refused.

Table-2: Topics and skills that need to be included in medical teaching about healthcare

costs and value

Cost Considerations	 Business of medicine Billing, coding, practice costs 				
	• Costs of tests/treatment				
	Cost/outcomes profiling				
	Patients' out-of-pocket costs				
Interpretation Skills	Knowledge of basic statistics				
	Clinical trial design				
	• Interpretation of study results				
	Cost-effectiveness analysis				
Communication Skills	Dynamics of patient-physician interaction				
	• Patient's values and preferences				
	Acceptance of uncertainty				
	Discussing costs/value during patient				
	encounters				

3. Suggestions for teaching and learning strategies

Participants suggested that an introduction to cost and value concepts in medical school followed by increased depth of learning in graduate medical education as necessary and felt that overcoming time constraints by redesigning existing coursework was essential to achieve this goal. Table-3 lists suggestions on methods to incorporate teaching on cost and values to gain proficiency in this topic offered by participants. The suggested methods fell into three broad categories: role modeling, case studies, and didactic teaching (Table 3).

They suggested that role modeling patient-centered high-value care, including

discussions with patients or with learners about the need for and costs of testing and

treatment options would be an important educational strategy. One cardiologist stated:

I spend a lot of time talking about cost-effectiveness, over-testing and appropriateness on rounds. Because I think it is a huge problems and one of the major drivers of costs that we can control. We can't really control the cause of diabetes, but we can control the work up.

Another noted:

We teach fellows that not every chest pain needs a stress test and not every abnormal stress test requires an angiogram. You know, unnecessary procedures can have complications. We are probably not talking directly about costs, but that is cost to the patient.

A neonatologist suggested that integrating the cost and value information during

everyday patient-care discussions during rounds would be ideal to consistently consider

these aspects of care, saying:

When you are a resident making these decisions, no one tells you, 'a CBC costs this much and do you really want to order this? But now that I am on the other end, I feel that it would have been helpful to know. I mean there are just so many factors that go into decision-making. In medical school you are so afraid, you think, I will order this lab but you are never really thinking, 'is this something that will make a difference for the baby based on evidence-based medicine or is this cost-effective treatment. I think it would be nice if those conversations are weaved in at least with big decisions. Students should see attendings struggling with these decisions, exposing the students to the fact that it is a very complex decision making process, where you have to take into account the family's preference, other goals of care, costs, and likelihood of effectiveness of therapy and safety concerns.

Others suggested workshops addressing these topics including role playing as patients

and physicians.

Participants also suggested that case studies and conferences exploring the cost and value of healthcare decisions made on specific patients would be an effective educational strategy. Several suggestions included specific feedback during case conferences or a separate exercise of analyzing the itemized charges for a patient's hospitalization to understand the implications of physician orders. One cardiologist commented on an exercise in which she had participated:

As a group we sat down with a hospital bill for one of our patients whom we had discharged. That is a very tangible way to teach it as you talk about how to get from a chief complaint to an answer; you physically go through the bill. And that might be another mechanism of making it real.

Finally, participants recommended didactic teaching formats, such as coursework and

large group learning sessions (e.g. grand rounds), to teach cost of care, cost-effectiveness

analysis, coding and billing and the business of medicine.

Table-3: Physician suggested strategies to teach cost and value to medical learners

Exte	nt of	teachi	ng	on th	ese	top	ics a	t th	e m	edic	cal sch	nool	level v	versus	Grad	uate
Med	ical E	ducat	ion													
3.6.1		4			-		1.1	1	•			0.1	4.4	01	•	1

Medical students should understand the basic concepts of healthcare financing and costeffectiveness, it should be mandatory for residents and fellows to know the cost and value of care they provide.

Advocacy to achieve healthcare cost transparency Not knowing the costs was perceived as a barrier to effective patientcare and teaching. Transparency in costs felt to be essential to delivering optimal care Teach the teachers

Need to improve knowledge of the topic among teachers to effectively teach current medical learners

Role	Teaching during discussions with patients
modeling	Discuss affordability of testing and treatment recommendations with patients
HVPCC	as a model for trainees to follow. Examples include asking about copays,
	deductibles and other out-of-pocket costs.
	Teaching during patient-care rounds (most effective if costs and value
	weaved into discussions)

	Discuss futility of repeat and frequent testing, over-testing and
	appropriateness of suggested interventions and alternatives on rounds.
	Question need for daily labs, X-rays, other tests.
	Discuss costs and cost-effectiveness, of tests and treatment options with
	trainees during rounds. Some electronic medical record systems display costs
	of some testing and treatments (lab and pharmacy costs for example)
	Workshops and role modeling exercises
	Recommended to improve communication with patients, debrief, diffuse
	difficult patient interactions
	Display costs of tests and treatment options on order sets
	Display costs (or charges) of imaging and lab tests, pharmacy and other
	treatment options in the ordering menu and encourage a discussion about cost
	and relative value implications
Case	Include costs in case conferences
Studies	During case conferences in addition to presenting and discussing the
	sequence of events of patient presentation, various investigation and
	treatment decisions, include costs at each step. If available include what the
	patient was billed and what the out-of-pocket costs were. Discuss the cost
	effective literature on the topic and compare and contrast the cost-
	effectiveness for the individual patient versus a population.
	Discuss cost to the system but also the cost to the patients and the
	implications of affordability on compliance with case studies
	Include in the section on Ethics and 'ethics' conferences
	Include patient healthcare costs as a component of ethics curriculum and if
	departments have ethics case conferences, introduce costs as a component of
	ethical tensions
	Feedback on costs of care rendered
	Include cost implications of management decisions. Suggested formats
	include review of a case that a team of trainees (students, residents/fellows)
	had treated and discharged with added cost information. Effectiveness and
	cost effectiveness can be discussed at each step and specific feedback
	provided. This would incorporate the sensitive and specificity, the predictive
	values and other properties of tests and treatment that are routinely
	incorporated into cost effectiveness evaluations.
Didactic	Teaching cost implications and cost-effectiveness
Teaching	Teaching the framework within which cost-effectiveness is evaluated,
	including outcomes and costs at the individual and societal level. Discuss
	merits and challenges of including cost effectiveness analysis in decision-
	making
	Teach the basics of critical appraisal of the literature and statistics needed to
	judge validity of claims made by the conclusions of journal articles. Discuss
	potential conflicts of interests. Include these concepts in journal club
	discussions, during rounds and other opportunities.

Grand rounds and co	nferences					
Include grand rounds as	Include grand rounds and trainee conferences on these topics at regular intervals					
intervals						
Teaching the business	Teaching the business of medicine					
Optional 1 or 2 semester	r Include topics related to basic understanding of					
course on the business	of insurance policies, physician reimbursement,					
medicine	patient costs and other related topics. Topics					
	related to billing and coding and how they impact					
	reimbursement. How to operate a small business					
	if trainees wish to consider private practice.					
Awareness of evolving	Understand hospitals' and insurance providers'					
impact of physician cos	t practices of calculating costs of care provided by					
and quality profiling	a physician and how these calculations influence					
	reimbursement and referral patterns etc.					

Discussion

In this qualitative study of American cardiologists and neonatologists, we have summarized the educational concerns, challenges and recommendations for physicians with respect to their ability to provide optimal care. This study revealed a network of factors that influence provision of high-value care; in addition to teaching content on healthcare costs, clinicians placed a strong emphasis on the need to improve data interpretation skills to critically appraise the evidence, and communication skills in shared decision making.

Strengths of our study include a diversity of opinion from physicians in private practice and academics in two fields, methodological rigor including methodological coherence and double review of a set of interview transcripts. Limitations include participation by physicians in only two subspecialties, including physicians in other specialties and including administrators may have led to a more comprehensive understanding of learning needs on this topic.

Although a growing movement including the American Board of Internal Medicine's Choosing Wisely Campaign³⁴ and the American College of Physicians' high value initiative,³⁵ advocates considering cost-consciousness in health care delivery, few studies have elicited practicing physician input on how the field develops and prepares practitioners to meet this goal. In 2016, a statement on teaching high value care was published based on expert consensus of academic leaders from seven medical schools in the US.²¹ They recommended faculty development in high-value care principles, and implications for instructional design to include strategies and tools to assess high-value care.

Our study contributes to the field by adding evidence of similar need from frontline physicians. Similar to our findings, the consensus report stresses on teaching communication skills, the basics of evidence-based medicine and an increased awareness and consideration of costs of care. The authors also identified the need for an awareness and acceptance of uncertainty and faculty development. Due to inclusion of frontline physicians, our study adds practical issues not discussed in previous studies, including the perceived need for training in the business of medicine and knowledge needed to practice in an environment of physician cost and quality profiling. In contrast to 'leveraging technology' to provide optimal care, our study reports on the potential negative impact of excessive documentation requirements and time spent by trainees in front of a computer screen completing required tasks on trainees' ability to adequately asses patient problems,

in turn resulting in blindly following protocols and excessive testing. In addition to redesigning the curriculum, an urgent need to limit trainees' crushing documentation responsibilities was also identified in our study.

Physicians emphasized the need to develop basic literature review skills to be able to assess the quality of the evidence in making treatment decisions. Efforts to consider costs must be balanced with an ability to evaluate the value of an intervention to the individual patient.³⁶ A recent consensus statement based on a systematic review and Delphi survey recommended core competencies in entry-level evidence-based practice teaching and includes the basic knowledge content proposed by our participants.³⁷ Efforts to increase the focus on understanding and applying evidence with frequent practical application during patient decision-making may improve integration of evidence-based practice in delivery of optimal care.

Another key finding of our study was participants' perception of the need to appreciate the dynamics of the patient-physician interaction and develop effective communication skills. Much has been written on the topic of the influence of power and knowledge imbalance between patients and physician in meaningful shared decision making. Berry and colleagues³⁸ suggest that clinicians must be sensitive to the power-imbalance inherent in the patient-physician relationship and consider how this makes authentic patient involvement in shared decision-making impossible. They suggest that physicians have the power to change this dynamic by recognizing the patient's perceptions. Instead of viewing this relationship as imbalanced, Koeck³⁹ emphasizes the need to appreciate the patient-physician encounter as a co-creative process involving two experts with

different skills but at the same level of hierarchy. Including this perspective of patient as equal partner during medical training is necessary to develop an appreciation of patient values and preference consideration in decision-making.

Many physicians emphasized the need to educate trainees in the business of medicine. Documentation, analysis, and reporting of individual physician practice patterns and associated costs is increasing,⁴⁰ and increasingly used for reimbursement, referral and staffing decisions. Value-based reimbursement will continue⁴⁴ and evolve⁴⁵; physicians have to get familiar with these concepts. In this environment, knowledge of the impact of clinical decisions on costs and outcomes is integral to a successful physician practice. Other authors have reported a perceived need for teaching on billing and coding,^{41,42} with suggested solutions including focused educational offerings on the topic and full time business educators.⁴² Our findings further support the need for including coursework and additional teaching on the business of medicine. In 2011, providing cost-conscious care and stewardship of resources was added as a seventh core competency of medical education⁴³; medical schools and educators have, however, been slow to effectively integrate teaching on costs into curricula. One of the barriers identified in our study was the lack of adequate knowledge of costs among current teachers who need support in gaining competence in this field. Although medical knowledge is only one of seven core competencies in US graduate medical education,^{43,46} bioscientific knowledge⁴⁷ has traditionally dominated medical teaching, it is time to include substantial teaching in additional topics including costs and value considerations.

At the same time, health system and health financing reforms are urgently needed to simplify payment schemes and to effectively balance physicians' needs to learn about the business of medicine with the (arguably more important) need to learn how to care for patients. Critiques of the current system note the extent to which financial issues are driving the system at the expense of caring and kind practice,⁴⁸ and the need to achieve minimally disruptive medicine.⁴⁹ Further focus on cost issues, in particular spending time and energy on the business of medicine, could have destructive consequences of exacerbating the shift away from a focus on the patient and the patient's needs.

Conclusions

We have identified learning needs for physicians related to the incorporation of costs into clinical decision making which can inform curriculum development and modifications to clinical teaching in this field. The logistics and financing of healthcare delivery are rapidly evolving with consequences for physicians and patients necessitating simultaneous development of medical teaching to support high-value patient-centered care. Concomitant health system reforms supporting the needs of the patient at its center are essential to enable physicians to focus on a patient-centered approach to healthcare delivery.

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CHAPTER 6

DISCUSSION

In recent years, there have been tremendous advances in the medical sciences^{1,2} with resulting significant improvements in morbidity and life expectancy including in cardiology and neonatology. In the field of cardiolovascular medicine, such advances have occurred at multiple levels³; with a focus on health promotion,⁴ pharmacologic, therapeutic and technological advances including cardiac imaging, devices and genomics.⁵ In neonatology, improvement in perinatal management have led to improved outcomes for preterm and term neonates needing neonatal support.⁶⁻⁸ In parallel and to a considerable extent consequent on the technical advances in medicine, healthcare costs globally have increased,^{9,10} including in the US¹¹ and Canada.¹² In spite of this level of spending, measured patient health outcomes are suboptimal¹³ and significant gaps in implementation and utilization of proven therapies remain.¹⁴⁻¹⁶ This has resulted in an examination of the value of healthcare and the recognition for a need to reduce waste and provide evidence informed high-value care.¹⁷

Clinical decision-making is a complex process. A growing body of research in psychology has provided evidence that people are frequently irrational when making decisions.^{18,19} Despite this, efforts to optimize health care decision-making is based on a 'rational-actor' supposition of human behavior. One hypothesis for the lack of effectiveness of these initiatives is that factors unrelated to the target of these interventions may be influencing physicians' clinical decisions.

Thus, physicians' lack of knowledge of evidence may not be the main reason for non-adherence to evidence-based recommendations. A comprehensive understanding of the drivers of clinical decision-making is essential to design tools and strategies to increase high-value care. The preceeding chapters in this thesis present the results from a mixed methods study that was conducted to identify and describe factors that physicians perceive influence medical decision-making in cardiology. In parallel to the study with cardiologists, I was conducting a similar study with neonatologists (not a part of this thesis) and during interviews relating to decision-making in neonatology, was able to also seek input from neonatologists related to how to integrate this content into medical education. The triangulated findings from these two unique data sources are presented in Chapter-5.

The preceeding chapters (Chapters 3,4, and 5) fill a gap in the existing medical literature relating to cost and value considerations in clinical decision-making by physicians in the US and Canada. Each of the included manuscripts derived from the multi-phase mixed methods study (protocol outlined in Chapter 1 and explained in detail in Chapter 2) addresses a limitation of the existing literature and provides empirically based recommendations for advancing the understanding of the intensely contextual nature of decision-making. My aspiration in designing and executing this study is that the results will ultimately be useful to inform future development of tools and strategies to implement high-value care. This chapter summarizes the primary results of each of the studies, discusses the broader strengths and limitations of the present body of work and provides recommendations for education, practice, policy and future inquiry. An

improved understanding of the different factors at individual, organizational and societal levels that interact to influence decision-making will provide us with a deeper conceptual understanding of the problem at hand and inform the development of contextually specific medical curricula and practice innovations that may ultimately lead to the acheivement of high-value care.

This mixed-methods study explored the variable influence of inter-related factors on decision-making. Mixed methods research approaches employ rigorous quantitative methods to measure the magnitude and frequency of outcomes and qualitative methods to explore the meaning and understanding of related constructs.²⁰ It is well suited to answer research questions that need a real-life contextual understanding of socio-cultural influences. The two methods are complementary and offer unique insights into the research topic. Neither method alone is sufficient to provide a comprehensive understanding of clinical decision-making.

Specific to this thesis, the use of distinct commonly encountered clinical scenarios in the quantitative component (clinical-vignette based survey) allowed us to examine the influence of varying contextual factors on clinical decisions. In addition to the linkage for sampling, the two phases of the mixed methods study were connected by using the analytical results of the survey to inform the data collection during the interviews. Development of the interview guide, explicitly informed by the results of the quantitiative study, allowed for an in-depth understanding of the physicians' rationales for choosing one option over the other on the survey. In addition, the following section merges the data from the quantitative and qualitative studies. One of the goals of a

sequential explanatory mixed methods study is to integrate findings from the quantitative and qualitative components to create a higher level, more comprehensive interpretation of the findings.

Integration of quantitative and qualitative findings

The quantitative component of this study included four common clinical secenarios in clinical cardiology. The clinical vignettes specify a hypothetical patient with realistic detail to simulate clinical conditions routinely encountered in clinical practice. The four cases include: 1) routine follow up of a patient with stable coronary artery disease, 2) treatment of unprovoked sustained ventricular tachycardia, 3) evaluation of uncomplicated syncope and; 4) disposition of a patient with non-cardiac chest pain.

After reviewing the case description, participants chose from five management options. The management options included statements that summarized practice recommendations derived from published clinical practice guidelines (CPGs) as well as statements that reflect common medical decisions/actions seen in practice but not recommended by guidelines. After choosing a management option, the participants rated the influence of seven factors in their decision-making. These factors included safety, effectiveness (evidence-based), patient-centered care, efficiency (cost and resource considerations), local hospital practice, medicolegal concerns and physicians' prior experiences. Each case included follow-up questions regarding cost and value considerations.

Following the analysis of the survey, the second phase of the mixed methods study was conducted through the completion of a qualitative descriptive study. In this component, a purposeful sample of 21 cardiologists from the original sample each participated in a single semi-structured, in-depth interview. The interview guide was developed based on the responses to the case-based surveys including topics discussed by participants in the free text comments in the survey. With respect to increasing our understanding of the gaps and needs in medical education with respect to this topic (findings summarized in Chapter 5), interviews were also conducted with 17 American neonatologists. This allowed for the triangulation of data from two unique data sources (cardiologists and neonatologists), which increases the credibility and transferability of the findings to the more general field of medical education.

The following section presents an integration of the results of the quantitative and qualitative studies. Table-1 presents the quantitative and qualitative findings for each clinical vignette. The quantitative study findings (Chapter-3) column presents the management options chosen and if they were concordant or discordant with evidence-based CPGs. The qualitative study findings column summarizes the findings of the qualitative descriptive study (Chapter-4) that explains the rationale for the choices made in the quantitative study. The last column in the table provides additional comments regarding rating of factors and other relevant findings from the two studies.

Using specific commonly encountered case-vignettes allowed us to examine how variation in contextual factors leads to variation in clinical decisions. The four cases in the survey were purposefully chosen to represent common scenarios in which clinical

practice may diverge from evidence-based guidelines. Table-1 provides a summary of

findings including the quantitative and qualitative components of the study and

demonstrates the complementary value of combining these research methods.

Table-1: Mixed-methods display demonstrating complementary findings between the

quantitative and qualitative studies for the four case-vignettes

Cases	Quantitative Study Findings	Qualitative Study Findings (Reasons for guideline-discordant	Additional Comments
		decisions)	
Case-1. Routine follow up of stable CAD	42% chose no further testing – CPG-concordant. Significantly more academic cardiologists chose the CPG concordant option	Cardiologists who chose a discordant response (e.g. to do further testing) rationalized decision as: -Belief that further testing would assure "keeping" the patient on their roster -Lack of patient's or cardiologist's trust in primary provider's care. -Patient expectation of testing -Receipt of (by individual or organization) financial incentives to perform more tests	 Local practices and medicolegal concerns rated as the least important factors on the survey. Physicians who selected the CPG concordant option, rated the effectiveness and efficiency of this option as marginally higher compared to physicians who chose other options.
Case-2. Treatment of unprovoked monomorphic ventricular tachicardia	Overall, only 13% of participants selected the CPG recommeded option In comparison, 60% of participants selected a CPG discordant option -	Selection of discordant option influenced by: - Difference in interpretation of 'low level' troponin elevation resulting in a primary vresus secondary prevention implantable defibrillator indication - Competing CPG recommendations	 For this scenario, participants rated safety and medicolegal factors as greater influences on their decisions compared to other scenarios. Based on the life- threatening nature of ventricular tachycardia, participants rated costs lower irrespective of

ordering a wearable cardioverter- Marketing of the benefits of the wearable cardioverter defibrillatormanagement option chosendefibrillator.benefits of the wearable cardioverter defibrillator-These were difference in ratings compared to other companies.by medical device companiesThese were difference in ratings compared to other companies.Strict insurance rules for implantable defibrillatorcontext; no difference based on choice of management strategy implantations in the first 90 days after surgeryordering a undefibrillator-Marketing of the chosenordering a to other cardioverter-Marketing of the within this case.ordering a to other cardioverter-Marketing of the within this case.ordering a to other cardioverter-Illustrates the difference
cardioverter defibrillator.cardioverter defibrillator by medical device companiesThese were difference in ratings compared to other cases - based on the case context; no difference based on choice of management strategy implantations in the first 90 days after surgery-These were difference in ratings compared to other cases - based on the case context; no difference
defibrillator.by medical device companies. - Strict insurance rules for implantable defibrillatorratings compared to other cases - based on the case context; no difference based on choice of management strategy within this case.90 days after surgery- Illustrates the difference
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- Strict insurance rules for implantable defibrillator implantations in the first 90 days after surgery - Illustrates the difference
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defibrillatormanagement strategyimplantations in the firstwithin this case.90 days after surgery- Illustrates the difference
implantations in the first within this case. 90 days after surgery - Illustrates the difference
90 days after surgery - Illustrates the difference
(where the cost may not in rating of factors
be re-imbursed). between cases.
Case-3. 55% chose Reasons for guideline - Highlights the perceived
Evaluation of echocardiogram discordant decisions: disconnect between
uncomplicate (CPG - Echocardiogram is non- guideline
d syncope with no high(CFOP Lenocatorogram is non- invasive, harmless to theguidennerecommendationinvasive, harmless to therecommendations and
risk features against an patient, provides a wealth real-world practice.
for structural echocardiogram) of information about - To improve uptake,
heart disease 30% chose tilt heart structure and guideline panels may
of history and table testing function reassures and to consider
physical exam (conditional patients, insurance pays physician values and
recommendaiton for it. preferences in their
by CPG Also generates revenue deliberation when
recommendations) and productivity making
- Some strong opinions recommendations.
regarding futility of tilt - Considering
table test and socioecological factors
disagreement with CPG may improve
recommendations implementation efforts
Case 4. 81% chose to Reasons for guideline - Treatment is also
Evaluation discharge patient discordant decisions heavily influenced by
of non- (CPG -Missed myocardial local hospital practice,
cardiac recommended) infarction is a leading insurance coverage.
chest pain Factor rating cause of litigation in the - A concern voiced
different between emergency room setting. during the interviews was
those who chose to - Likely driven largely by that many such patients
discharge and the fear of a lawsuit. come back repeatedly
those who chose -In most hospitals, with chest pain – tests
further testing protocols in place for can have a therapeutic
/observation additional cardiac testing impact and be cost-saving
before discharge in the long run
Cost - 91% feel out-of General agreement that - Participants in the
Considerati pocket expenses out-of-pocket costs survey noted a need for
ons are crucial to should be considered additional teaching on the

	1	I	
	consider when	during decision-making	topic of cost and cost
	making decisions.	- Much frustration	effectiveness.
	- 60% do not feel	regarding opaque nature	- Recommendations for
	well informed on	of costs and difficulty	teaching on cost and
	costs	obtaining specific patient	value considerations
	- 69% opine that	out-of-pocket costs.	during medical educaiton
	costs should be	-Cardiologists conflicted	in chapter-5
	considered in	about considering patient	- Additionally, current
	individual patient	versus societal	teachers / clinicians are
	decision making.	cost/benefit	not well versed with
	- 62% discussed	-Physician cost profiling	these topics and there is a
	costs infrequently	was another resson	need for ongoing
	with patients	mentioned for	professional development
		considering costs and	to be proficient in this
		cost effectiveness	area
Tension	- 81% of	- Cardiologists develop	- To be successful, efforts
between	cardiologists	strategies to work in an	to change clinical
missed diagnosis and	reported	environment of	practice need engagement
overtesting	experiencing a	restrictions placed on	of practicing
8	conflict between	their practice by external	cardiologists and
	limiting	forces such as insurance	consideration of socio-
	unnecessary tests	agencies, cost profiling,	ecological factors that
	and missed	hospital practice	influence clinical
	diagnosis at least	restrictions, medicolegal	decisions
	somewhat	concerns and patient and	
	frequently	peer expectations.	

Abbreviations: CAD: Coronary Artery Disease; CPG: Clinical Practice Guidelines; OOP: out-of-pocket; MI: Myocardial Infarction

The following paragraphs further elaborate on the findings based on an integrated

analysis of quantitative and qualitative responses to individual cases vignettes.

Case-1: Outpatient follow-up of a patient with asymptomatic coronary artery disease

(CAD). Cardiologists rated the seven factors similarly, including local hospital practice

and medicolegal concerns (rated lower than the other factors) irrespective of management

option chosen. The majority chose some form of further testing and supported this

decision using several lines of reasoning. These included patient preference for testing

(this rationale was used repeatedly for stress testing and echocardiograms even if the patients had no obvious indication for testing based on clinical assessment) especially if insurance covered the test costs. Some cardiologists noted their prior experience of having diagnosed worsening physiology before it caused symptoms, and used this justification to perform tests when not clinically indicated.

Variability of recommendations in CPG by different professional societies (as noted in Chapter-3 - Table-1, ²¹) contributed to some variability in practice. It was clear from the interviews that insurance reimbursement algorithms and decisions played a significant role in the pattern of testing in a given setting. For instance, as reported by several cardiologists practicing in one city, the major insurance companies in that location reimbursed stress tests with myocardial perfusion imaging every three years for patients with a diagnosis of coronary artery disease, leading most cardiologists to perform stress tests every three years on their patients with coronary artery disease. This example illustrates the shaping of community norms based on ecological influences in the community which in turn influence clinical decisions by community physicians and may contribute to overuse.

<u>Case-2</u>: Treatment of unprovoked monomorphic ventricular tachycardia (VT) in a patient with underlying CAD and low level troponin elevation. The majority chose to prescribe a wearable cardioverter defibrillator (WCD) on the survey. During the interviews, it became clear that in the setting of VT, cardiologists frequently interpret any level of troponin elevation to be secondary to a myocardial infarction (MI) and automatically assign the VT to be in the setting of a MI. This has tremendous implications for the next

step in treatment since evidence-based guidelines for management are different if the VT is considered to be secondary to an ongoing MI versus the VT being the primary event leading to low-level troponin elevation. For the former (VT in the setting of an MI), current recommendations are to wait (for 40 days after an MI or for 90 days after coronary artery bypass grafting) before deciding on implantation of an internal cardioverter defibrillator (ICD) for primary prevention^{22,23}, whereas for the latter (unprovoked VT requiring an ICD for secondary prevention) an ICD is recommended (Class-I recommendation) for secondary prevention²² before hospital discharge (Guideline recommendations described in table-1 in Chapter-3) ²¹.

Interviews with electrophysiologists (three of the 21 cardiologists interviewed) revealed that this misinterpretation of low-level troponin elevation leading to a misclassification of VT requiring primary versus secondary prevention ICD occurs periodically in clinical practice. Sometimes it is difficult to convince the referring cardiologist that the patient needs an ICD for secondary prevention. They stressed a need for improved education and awareness of this misclassification by cardiologists.

This delay in ICD insertion is reinforced by strict insurance company criteria and rules for ICD implantation. Several cardiologists noted that the insurance companies will not pay for an ICD in the first 90 days after coronary artery bypass grafting irrespective of initial presentation with unprovoked sustained VT. This finding once again illustrates the role of ecological factors in driving community norms and clinical practice, in this instance leading to inappropriate use of a WCD instead of an ICD. Cardiologists rated safety and medicolegal concerns higher in this case than in other cases, highlighting the

perceived apprehension felt with managing patient with life-threatening arrhythmias in general.

Case-3: Evaluation of a patient with uncomplicated syncope with no clinical findings suggestive of structural heart disease. Although the ACC/AHA guidelines ²⁴ recommend against performing an echocardiogram in patients with syncope when there is no concern of structural heart disease based on history and physical exam findings, the majority chose to perform the test. Interviews highlighted the reasons cardiologists chose echocardiograms including lack of confidence in their physical exam findings (cannot assess for presence of significant structural heart disease based on physical exam), expectation of testing by patients, family and referring physicians, easy availability of a test that does not harm patients and provides a wealth of information on the structure and functioning of the heart and is reimbursed by insurance companies. Several cardiologists also voiced their disagreement with guideline recommendations for tilt-table testing. The recommendations (a recommendation against an echocardiogram and a conditional recommendation for tilt-table testing) in the syncope guidelines increased some cardiologists' skepticism with use of CPG recommendations in daily clinical practice. They referred to these recommendations when stating that CPG writing panels consisted of 'ivory-tower' academics out of touch with the realities of busy clinical practice.

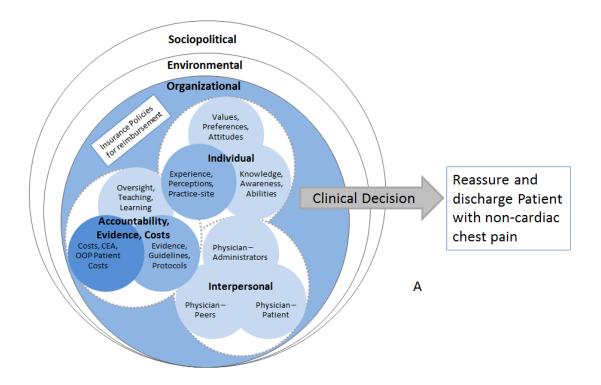
<u>Case-4</u>: Emergency room disposition of a patient with non-cardiac chest pain who requests further testing/observation for fear of a missed cardiac diagnosis: Although this vignette was designed to be clearly non-cardiac chest-pain and the majority chose to discharge the patient, 19% of participants chose another option including prolonged

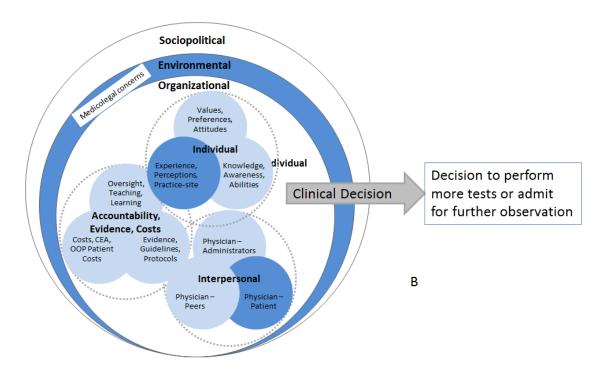
observation and additional testing. The rating of the seven factors for guideline concordant and guideline discordant responses was statistically significantly different (p value for interaction <0.0001). The cardiologists who chose to discharge (guidelineconcordant) rated cost concerns higher and those who chose to do more tests/admit for observation rated medicolegal concerns and local hospital practice higher.

In the interviews, some cardiologists mentioned patient driven testing/admissions suggesting that, if patients were not satisfied with the evaluation, they would return frequently to the emergency room with these complaints - and suggested that the tests become therapeutic interventions. Others suggested that insurance companies in their region did not cover inpatient work-up and patients were satisfied with this explanation for discharge. These differences highlight the variable influence of a variety of factors leading to different clinical decisions.

Figure-1 illustrates the difference in ratings mapped to the ecological framework based figure described in Chapter-4 (Figure-1 in Chapter-4). Cardiologists who discharged the patient (Figure-1A below) rated cost-considerations higher and during interviews suggested that strict insurance policies (included in organizational factors in Figure-1) facilitated discharge of patients with non-cardiac chest pain. Cardiologists who chose to perform further testing/observation rated medicolegal concerns (included in environmental factors in Figure-1) and local hospital practices (practice-site in the figure) higher. It was also suggested that many times, a high level of patient concerns over symptoms and the possibility of repeated presentation to the emergency department if a 'thorough evaluation' was not performed led to these choices (Figure 1B).

Figure-1: Factors influencing decision to discharge a patient (A) or do further tests /observation (B) in a patient presenting with non-cardiac chest-pain. Increased depth of the coloring suggests a stronger influence on the decision.





Displaying the results in this format may help to understand and communicate the variable influence of different factors based on the context and the complexity of interconnected factors leading to guideline concordant or guideline discordant decisions and assist with designing effective strategies to change practice leading to high-value care.

Strengths and Limitations of this Body of Work

The use of a sequential, explanatory mixed methods study strengthened the overall rigor of this study in several ways. Either method alone would not have provided the breadth and depth of understanding provided by the combination and integration of these methods. The clinical vignette based survey results allowed me to study the relative influence of different factors in clinical decision making; these findings were further explored in depth using a qualitative descriptive study. Additional strengths include

focusing on specific contextual scenarios to collect quantitative and qualitative data in order to explore the contextual influences on decision-making. The primary researcher has over 16 years experience in clinical cardiology; in addition the clinical vignettes were developed by experienced cardiologists with backgrounds in clinical cardiology practice, research and teaching.

Triangulation of data types (quantitative and qualitative), improved credibility of this study and double coding of the open ended responses from surveys ensured that all key concepts requiring further exploration were included in the qualitative interview guides. Double review of a set of interview transcripts for the qualitative component ensured identification and labelling of key constructs. Use of peer debriefing offered fresh perspectives and additional insights.

This mixed-methods study includes many of the elements of construct validation proposed in the validation framework by Dellinger and Leech.²⁵ Chapter-2 describes the rationale for using the study design and justifies design suitability of this sequential explanatory study. Sample integration and sequential legitimization along with interpretive rigor (theoretical consistency, interpretive agreement and integrative efficacy) further enhance study quality. Another strength is the participation of a diverse group of cardiologists in different practice settings increasing the transferrability of these findings.²⁶ Including interview data from neonatologists' interviews allowed for data triangulation and improved the credibility and transferability of the findings.²⁶

The work also has limitations. A sample of 106 cardiologists completed the survey. Since the survey was distributed in several ways including websites with an open invitation to participate, I was unable to calculate an overall survey response rate. A response rate of 20% for Cardiosurve[®] September 2017 participants, although low, is similar to the response rate in several recent studies, both on surveys administered to the general public (between 21% in 2006 and 9% in 2016)²⁷ and physicians.²⁸ Furthermore, studies using clinical vignettes published in the literature have included similar²⁹ or fewer number of clinicians.³⁰ Although a response rate of 20% may suggest a potential for respondent bias, our results include heterogeneity of responses and opinions to indicate participation by a diverse group of practicing cardiologists.

We sought assistance from the Canadian Cardiovascular Society (CCS) to distribute the survey to their members, the survey was posted on the CCS website. The response rate and resulting Canadian sample was significantly smaller than the US cohort. Due to the small Canadian sample, our results primarily reflect the US context of care which is very different from the Canadian context. Including a larger sample of Canadian cardiologists including some in private practice would have allowed us to compare and contrast the practice influences between the two countries. Due to the smaller Canadian sample, the teaching and learning Chapter includes only American cardiologists and neonatologists.

Because we focused our inquiry in the specific field of cardiology, our results may not be generalizable in full to other specialty areas. However, the factors we have

identified can give future researchers in other fields insights into the types of issues that they might explore.

Implications and Recommendations

In this section, I will present recommendations for medical education, practice, policy and future research. The results of studies included in this thesis demonstrate the layers of cost and influence in the healthcare system leading to clinical decisions. Physicians function under these influences and make decisions based on variable contextual combination of influences.

Implications for Medical Education

The need for improved education on this topic was expressed unsolicited by cardiologists in the comment section of the survey, underscoring the perceived need for increasing teaching related to cost and value in medical education. Emergence of this important issue in this phase of the study guided our decision to include focused questions on medical education and decision making in the second, qualitative, phase of this mixed methods study. By including questions related to teaching needs and necessary content to improve physician knowledge and application of cost and value considerations in clinical decision making (Chapter 5). Overall, based on an analysis of this specific data set embedded within the overall context of this mixed methods study, my

Undergraduate Medical Education:

- 1. Introductory content, embedded into classroom teaching and/or self-study modules on the current healthcare financing structure including implications for individual patient and societal costs. Recommended content for classroom teaching includes basic knowledge of healthcare financing including government programs administered by the Centers for Medicare and Medicaid Services, employer-sponsored health insurance options and choices available on the openmarket. Benefits and drawbacks of these alternatives and implications for out-ofpocket patients' healthcare costs need to be considered. An introduction to the principles of cost-effectiveness analysis and its use in healthcare may be offered as an optional elective course at the undergraduate and/or graduate level. Modes of classroom teaching include lectures followed by small group discussions incorporating active learning strategies and assignments with specified intended learning outcomes for each session. A sample course syllabus for an elective course on cost-considerations in medcial decision-making is included as an appendix to this chapter. Case-studies of patient vignettes including costs of different clinical decisions in disease management and associated out-of-pocket patient costs are recommended to impart practical knowledge of cost considerations in clinical decision-making.
- 2. Develop learner knowledge about the importance of assessing quality of evidence and develop skills in critically appraising a broad range of study. In addition to a class lecture followed by small group discussion, case studies focusing on the

application of learned content may be beneficial. These concepts should be taught in the classroom and integrated into bedside teaching opportunities related to clinical decision-making during patient care rounds.

3. Effective communications skills are essential to include patient's values and preferences into decision-making. Classroom and bedside teaching should include content on key tasks in communicating with patients, deficiencies in communications, reasons for these deficiencies and the skills needed to elicit patient's problems and concerns. Effective teaching methods³¹ to improve communications skills include interactive demonstrations, role playing with other students and role modeling during patient encounters. Students should practice these skills and receive peer and faculty feedback for continuous improvement.

Graduate Medical Education:

- Knowledge and skills learnt in medical school regarding evidence assessment, communication skills and cost considerations should be reinforced during graduate medical education with a focus on application during patient encounters and in clinical decision-making. Supervising faculty should possess the knowledge and expertise to evaluate and provide effective feedback to trainees in order to support further development of these essential skills.
- 2. Classroom and bedside teaching on coding and billing, healthcare financing and reimbursement structure and cost profiling should be included as part of graduate training to all trainees. Electives on the business of medicine including nuances of

health insuracne markets, physician reimbursement and the knowledge and skills needed to supervise a medical practice should be offered to trainees with interest in advanced learning of these topics.

Practice Implications

The results emerging from the mixed-methods study in this thesis clearly indicate the strong contextual influences that play an under-appreciated role in clinical decisionmaking. Current practice incentives are often pervese, thus compromising the value of healthcare, in part through promoting unnecessary testing and treatment. This is true not only for fee-for service providers but also for providers working in 'academic settings' where their productivity is determined by the number of procedures they perform and the number of patients they see which in turn is related to their reimbursement and the protected time for other endeavors such as time available for research. This needs to change if cardiologists and other physicians are to focus on providing high-value patientcentered care. Fundamental reorganization to the practice incentives are essential to bring about meaningful change in decision-making.

Policy Implications

This section will discuss implications for healthcare financing, guideline development, and the medicolegal environment. A brief section on the essential component of patient and community engagement is included at the end of this section since it was brought up by many participants. Strategies to improve high value care should carefully consider what they wish to achieve, study the problem and the current

perceptions and opinions that lead to overuse or low-value care. Factors sustaining overuse should be carefully considered and acceptability and feasibility of the proposed strategy to improve the value of care should be assessed before implementation.

The US currently spends almost 18% of its GDP on healthcare.³² A significant portion of this spending is related to administrative costs associated with billing and insurance related activities.^{33,34} Simplifying the healthcare financing structure and implementing a single payer system will eliminate many of the ecological influences on overuse.

Clinical practice guideline development:

The results of our studies suggest that most physicians are aware of guideline recommendations, disagree with many recommendations and believe that they practice evidence-based medicine even when their practice is discordant with evidence-based guidelines. The results of cases 2 and 3 reveal some potential downsides of guideline recommendations. In case-2 concerning recommendations for the treatment of ventricular tachycardia, different guideline recommendations within the same guideline recommend different treatment options for a patient based partly on physician interpretation of the importance of laboratory tests. Improved clarity of recommendations with special attention to the alignment of guideline recommendations across a guideline may help with implementation of evidence-based high-value care. Optimizing the content and presentation of guideline recommendations is essential to increase adaptation with implications for patient outcomes.

Similarly, guideline committees may wish to consider physicians' and patients' values and preferences in developing recommendations. An example explored in this thesis is considering the reasons for widespread use of echocardiograms before making strong recommendations against its use. Not considering and addressing the realities of clinical practice in CPG-recommendations including patients' demands and concerns and medicolegal issues physicians face when they make decisions jeopardizes its 'face-validity' and the confidence practicing physicians have in guidelines. This may lead to alienating clinical practitioners from guideline-recommendations. They may consider that the guideline-recommendations have been developed by professionals out of touch with the realities of clinical practice and decide not to use any guideline recommendations - that would be unfortunate.

Increased representation of physicians recruited from the frontlines or physicians working exclusively in clinical practice on guideline development committees is recommended. Practicing physicians have first-hand knowledge of the various contextual influences on decision-making that is invaluable in developing implementable evidenceinformed guideline recommendations. Considering contextual factors may result in guideline recommendations that are acceptable to practicing physicians and improve their adoption in clinical practice. Additionally further qualitative studies of the rationale for various guideline discordant practice patterns in the community may assist with making guideline recommendations that consider the contextual factors driving decisions by practicing physicians. Considering the example of use of echocardiograms in patients with uncomplicated syncope - evidence for improved diagnosis of the cause of syncope

may not be the only reason to consider while making recommendations about the use of echocardiograms in this instance. Considering patients' anxiety associated with a syncopal episode and the reassurance provided by an echocardiogram may be factors guidelines need to incorporate when making recommendations. Similarly physicians' lack of confidence in excluding a structural heart disease diagnosis based purely on their physical exam skills in the setting of a litigious environment may be a consideration.

Medicolegal concerns:

Medicolegal concerns were identified as a motivation for excessive testing and need to be mitigated to decrease overuse and to improve the value of care for patients. Physicians with experience practicing in both a tort reform state in the US (South Carolina) and a non-tort reform state (New York) commented on the difference this makes in decision-making about ordering unnecessary tests. Tort reform with a decreased threat of unsubstantiated lawsuits may significantly decrease 'defensive medicine'.

Patient and community engagement:

Patient expectation of increased testing especially if they have insurance (return on investiment) was noted frequently as a cause of overuse. Increased patient and public engagement is essential for meaningful shared decision making and limiting low-value care practices.

Implications for Future Research

The findings from my study indicate that sociocultural factors have a strong influence on decision-making. The sociological literature is replete with articles on the continuous social transformation of the medical profession³⁵ and social construction of illness,³⁶ evaluation and treatment; this needs further study in specific medical contexts to understand the interactions of these constructs with unnecessary testing and treatment. The influence of the interaction of these social contextual factors within the complex healthcare environment needs further research. Surveys using larger and more representative cohorts of physicians and qualitative methodologies including focused ethnography may reveal additional insights. Focused ethnography^{37,38} includes impartial observations of clinical practice and the process of making decisions and may provide additional insights to decision-making beyond what can be obtained by interviews with physicians. Methods to optimize physician incentives to encourage patient-centered, efficient and evidence-based care need further study before implementation. Research into effective patient and public engagement into healthcare is essential for effective implementation of high-value care

Conclusions

The most significant contribution of the work from this thesis is a comprehensive understanding of the influence of contextual factors in clinical-decision making within the defined context of four common clinical scenarios in cardiology. In daily clinical practice, while evidence-based guideline recommendations are considered important by physicians, they play a secondary role in decision-making. Contextual influences frequently supersede evidence-based CPG-recommendations in decision-making.

We have identified a network of factors in the individual, interpersonal, organizational, environmental and sociopolitical domains that influence medical decision-making. Understanding the relative influence of these factors including strong cultural and social drivers of decisions is essential to design successful implementation strategies to achieve high-value care. Efforts to improve implementation of high-value care must consider these contextual factors to be successful in their efforts. Teaching and learning curricula need to incorporate topics of cost and value considerations in decisionmaking. Future research is needed to improve our knowledge of methods to optimize healthcare utilization, to provide high-value patient-centered care and limit escalating healthcare costs.

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Appendix-2 Cost Considerations in Medical Decision Making Sample Course Syllabus

Class Meeting:	Wednesdays from May 8 to July 31, 2019 9 AM to noon - Edu Building, Room 3207
Instructor:	Veena Manja (email-vmanja@ucdavis.edu)
Office Hours:	By appointment
Prerequisites:	This course is open to students enrolled in the UC Davis medical school or in any field of graduate medical education at UC Davis

At the beginning of the course, you will be expected to identify a management strategy in an area of healthcare of your interest to evaluate its cost effectiveness. Throughout the course, you will be expected to use this example in your discussions of factors that need to be examined when considering costs and economic impact of disease management.

Course Format: The course will consist of 12 three hour sessions. Sessions will include a 45 minute lecture followed by small group discussions. One session (July 19) will be dedicated to student presentations on a topic of their choice pertaining to costs of health care.

Course Description: This three-unit course focuses on the costs and quality of healthcare, on economic principles that have been used to assist with healthcare decision making and the impact of using these tools on delivery of healthcare.

This course is designed to provide the basic knowledge of costs and outcomes of healthcare in the United States (US) compared to other countries with comparable resources and provide a basic knowledge of health economics with a focus on cost effectiveness analysis methods.

Cost effectiveness is increasingly used in the medical literature and in policy deliberations in the US. This has not been included in the medical curriculum until recently. Knowledge of the methods will promote an understanding of the evidence that is presented in the literature; assist with quality assessment of the evidence and use of this body of evidence.

Course Intended Learning Outcomes:

By the end of this course, students should be able to:

- 1. Describe and discuss the performance of US health care system compared to other 'organization for economic co-operation and development' (OECD) countries in terms of costs and quality of healthcare delivered.
- 2. Compare the use of cost effectiveness analysis in policy decision making in the US and other OECD countries
- 3. Explain the basic premise of cost effectiveness analysis and its application in medical decision making.
- 4. Conduct a cost effectiveness analysis based on recent methodological guidance.
- 5. Discuss the pros and cons of integrating cost and value considerations in medical decision making.

Required Course Materials: Required and additional readings will be posted on the class website

Course Assessments:

Assessment	Due Date	Weight
1. Participation in Class	Ongoing	10 %
2. Facilitate class discussion	Based on the	10 %
during one class based on weekly	schedule	
readings		
3. Paper proposal outline	June 5, 2019	10 %
4. Presentations	July 17, 2019	30 %
5. Final Paper	July 31, 2019	40 %
		TOTAL: 100%

1. Participate in class discussions. Absences must be made up and permission sought in advance. Missing more than two classes may be grounds for failing the course.

2. Facilitate a 30 min class discussion based on the readings for the week. All students are expected to come prepared to class, the role of the facilitator is to keep the class engaged and stimulating and moderating discussions. Assessment will be based on the knowledge of the class readings as well as the effort to engage students in the discussions.

3. Prepare an outline of the final paper including the topic area, management question for which you intend to conduct the cost effectiveness analysis, an outline of the model and a list of assumptions, and proposed sensitivity and subgroup analysis. This outline should be a maximum of 1 page long (single spaced, Times New Roman font 12 with 1 inch margins).

4. Presentation on a topic addressing the cost implications of health care. You may choose a topic of your interest, including a review of economic analyses, comparison of health care financing in different countries and jurisdictions and its impact on health care

delivery, different model of reimbursement and their impact on healthcare, patients' out of pocket costs, cost considerations at various levels of healthcare decision making or another topic of your choice. You may discuss your choice of topic with the instructor before you finalize the topic and receive feedback. The presentations are scheduled during class on July 17th. Marking rubric will include points for quality of slides, content, presentation, addressing questions and discussion.

5. The final paper must be a full cost effectiveness analysis of the management strategy you chose at the beginning of the course. This will include a brief description of the topic, rationale for choosing this topic, model outline, assumptions, data sources, sensitivity and subgroup analysis, interpretation of results, and discussion. The marking rubric will consider the following fields (marks of 1-5 for each field poor -1, fair -2, good -3, very good -4 and excellent -5): clear statement and description of the topic, rationale for cost effectiveness analysis of the management strategy, choice of modeling technique, appropriate assumptions, choice of data sources, choice of subgroup analyses, sensitivity analyses, interpretation of results, discussion and conclusions and overall quality of the paper.

Submission of Course Work:

All coursework should be submitted on the Avenue assignment page. Please submit by the due date. If an extension is needed due to extenuating circumstances, please discuss with the instructor before the due date.

Course Schedule:

At certain points in the course it may make good sense to modify the schedule outlined below. The instructor reserves the right to modify elements of the course and will notify students accordingly (in class and post any changes to the course website).

week 1 - May 0, 2019					
Topics:	Course Overview and Introduction				
Readings	• 2014 Update: How the U.S. Health Care System Compares				
Completed:	Internationally. Report of the commonwealth fund. 2014.				
	• Karen Davis KS, David Squires, Cathy Schoen. Mirror,				
	Mirror on the Wall, Martin AB, Hartman M, Benson J, Catlin				
	A. National Health Spending In 2014: Faster Growth Driven				
	By Coverage Expansion And Prescription Drug Spending.				
	Health Aff (Millwood). 2016;35(1):150-160.				
Due:	Choose a disease management strategy that you wish to conduct a				
	cost effectiveness analysis in a topic of your interest, be prepared to				
	briefly discuss the topic during small group discussions				

Week 1 - May 8, 2019

Week 2 – May 15, 2018

Topics:	The need to consider costs			
Readings	• Himmelstein DU, Thorne D, Warren E, Woolhandler S.			

Completed:	 Medical bankruptcy in the United States, 2007: results of a national study. <i>Am J Med.</i> 2009;122(8):741-746. Rosenbaum L, Lamas D. Cents and sensitivityteaching physicians to think about costs. <i>N Engl J Med.</i> 2012;367(2):99-101. Anderson JL, Heidenreich PA, Barnett PG, Creager MA, Fonarow GC, Gibbons RJ, et al. ACC/AHA statement on cost/value methodology in clinical practice guidelines and performance measures: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and Task Force on Practice Guidelines. Circulation. 2014;129(22):2329-45.
Due:	Refine the topic for your final project and formulate a PICO question for the cost comparison and cost effectiveness
	for the cost comparison and cost effectiveness

Week 3 – May 22, 2019

	VV CCK 5 11/14y 22, 2017
Topics:	Cost effectiveness analysis methods
Readings	• Neumann PJ, Sanders GD. Cost-Effectiveness Analysis 2.0. N
Completed:	Engl J Med. 2017;376(3):203-205.
	• Battista RN, Cote B, Hodge MJ, Husereau D. Health
	technology assessment in Canada. International journal of
	technology assessment in health care. 2009;25 Suppl 1:53-60.
	• CADTH. Canadian Agency for Drugs and Technologies in
	Health. https://www.cadth.ca/about-cadth/how-we-do-
	it/methods-and-guidelines, 2017.
Due:	Choose a modeling strategy and start an outline of methods for your
	cost effectiveness analysis – paper proposal due June-5, 2019

Week 4 – May 29, 2019

Topics:	Assessing the quality of economic evaluations and cost effectiveness
	analyses
Readings	• Walker DG, Wilson RF, Sharma R, Bridges J, Niessen L,
Completed:	Bass EB, et al. Best Practices for Conducting Economic
	Evaluations in Health Care: A Systematic Review of Quality
	Assessment Tools [Internet]. Rockville (MD): Agency for
	Healthcare Research and Quality (US)2012 Oct
	• Chiou CF, Hay JW, Wallace JF, Bloom BS, Neumann PJ,
	Sullivan SD, et al. Development and validation of a grading
	system for the quality of cost-effectiveness studies. Medical
	care. 2003;41(1):32-44.
	• Limone BL, Baker WL, Mearns ES, White CM, Kluger J,
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	effectiveness models of pharmacologic stroke prevention in

	 atrial fibrillation. Journal of clinical epidemiology. 2014;67(10):1093-102. Evers SM, Hiligsmann M, Adarkwah CC. Risk of bias in trial- based economic evaluations: Identification of sources and bias-reducing strategies. Psychology & health. 2014:1-20.
Due:	Discuss the reasons for choosing your topic for the final paper and its relevance during small group discussions. Paper proposal due before midnight on June 5, 2019

	Week 5 June 3, 2013
Topics:	Conducting a cost effectiveness analysis – the model structure
Readings Completed:	 Brennan A, Chick SE, Davies R. A taxonomy of model structures for economic evaluation of health technologies. Health Econ 2006;15:1295-310. Caro JJ, Moller J. Decision-analytic models: current methodological challenges. Pharmacoeconomics 2014;32:943- 50.
	• Tsoi B, Goeree R, Jegathisawaran J, Tarride JE, Blackhouse G, O'Reilly D. Do different decision-analytic modeling approaches produce different results? A systematic review of cross-validation studies. Expert Rev Pharmacoecon Outcomes Res 2015;15:451-63.
Due:	Based on the readings, refine your model structure and be prepared to discuss the rationale for your decisions in class Paper proposal due before midnight June 5, 2019

Week 5 – June 5, 2019

Week 6 – June 12, 2019

	Week 0 – Sune 12, 2017
Topics:	Conducting a cost effectiveness analysis – the assumptions
Readings	• Frederix GW, Severens JL, Hovels AM, Raaijmakers JA,
Completed:	Schellens JH. The cloudy crystal ball of cost-effectiveness
	studies. Value Health 2013;16:1100-2.
	• Frederix GW, Severens JL, Hovels AM, Raaijmakers JA, Schellens JH. Reviewing the cost-effectiveness of endocrine early breast cancer therapies: influence of differences in modeling methods on outcomes. Value Health 2012;15:94-105.
Due:	List the assumptions you used to construct the model and bring to
	class for discussion

Week 7 – June 19, 2019

Topics:	Conducting a cost effectiveness analysis – the parameter inputs
Readings	• Caro JJ, Briggs AH, Siebert U, Kuntz KM, Force I-SMGRPT.
Completed:	Modeling good research practicesoverview: a report of the
	ISPOR-SMDM Modeling Good Research Practices Task Force-
	1. Med Decis Making 2012;32:667-77
Due:	Be prepared to discuss the choice and source of parameter inputs in
	your model

Week 8 – June 26, 2019

Topics:	Subgroup and sensitivity analysis
Readings	• Husereau D, Drummond M, Petrou S, et al. Consolidated
Completed:	Health Economic Evaluation Reporting Standards (CHEERS)-
	-explanation and elaboration: a report of the ISPOR Health
	Economic Evaluation Publication Guidelines Good Reporting
	Practices Task Force. Value Health 2013;16:231-50.
	• Shah A, Shewale A, Hayes CJ, Martin BC. Cost Effectiveness of
	Oral Anticoagulants for Ischemic Stroke Prophylaxis Among
	Nonvalvular Atrial Fibrillation Patients. Stroke 2016
Due:	Discuss the sensitivity analysis that you are considering in your
	model/study

Week 9 – July 3, 2019

Topics:	Putting it all together
Readings Completed:	 Brunetti M, Shemilt I, Pregno S, et al. GRADE guidelines: 10. Considering resource use and rating the quality of economic evidence. J Clin Epidemiol 2013;66:140-50. Damm O, Horn J, Mikolajczyk R, et al. Health Economic Evaluation of Different Vaccination Strategies Against Varicella and Herpes Zoster in Germany. Value Health 2015;18:A588.
Due:	Bring a draft of your final paper, you will have an opportunity to seek feedback and clarification from your peers and teachers

Week 10 – July 10, 2019

Topics:	Incorporating cost and value considerations in decision making
Readings	• Committee on Use of Economic Evidence to Inform Investments
Completed:	in Children Y, and Families. Advancing the Power of Economic
	Evidence to Inform Investments in Children, Youth, and
	Families2016
	• Twardella D, Brenner H. Effects of practitioner education,
	practitioner payment and reimbursement of patients' drug costs

	on smoking cessation in primary care: a cluster randomised trial. Tob Control 2007;16:15-21.
Due:	Bring a draft of your presentation and obtain feedback as needed

Week 11 – July 17, 2

Topics:	Student Presentations

Topics:	• Use of cost effectiveness information in formulating guideline recommendations
	 Future directions with cost considerations
108	 Shemilt I, Mugford M, Drummond M, et al. Economics methods in Cochrane systematic reviews of health promotion and public health related interventions. BMC Med Res Methodol 2006;6:55. Shemilt I, Mugford M, Vale L, Marsh K, Donaldson C. Evidence-based Decisions and Economics: Health Care, Social Welfare, Education and Criminal Justice: Wiley; 2011.
Due:	• Final paper by midnight on July 31, 2019

Week 12 – July 24, 2019

Policy on Missed Course Work, Extensions, and Late Penalties:

It is expected that you will complete and submit coursework and assignments on time, if there is a delay in submission, please discuss this with the instructor before the assignment is due and make arrangements for an alternate date of submission. Penalties may be incurred for late submissions.

Academic Integrity

You are expected to exhibit honesty and use ethical behaviour in all aspects of the learning process. Academic credentials you earn are rooted in principles of honesty and academic integrity.

Academic dishonesty is to knowingly act or fail to act in a way that results or could result in unearned academic credit or advantage. This behaviour can result in serious consequences, e.g. the grade of zero on an assignment, loss of credit with a notation on the transcript (notation reads: "Grade of F assigned for academic dishonesty"), and/or suspension or expulsion from the university.

It is your responsibility to understand what constitutes academic dishonesty. For information on the various types of academic dishonesty please refer to the University Academic Integrity Policy.

The following illustrates only three forms of academic dishonesty:

1. Plagiarism, e.g. the submission of work that is not one's own or for which other credit has been obtained.

- 2. Improper collaboration in group work.
- 3. Copying or using unauthorized aids in tests and examinations.

Academic Accommodation of Students With Disabilities

Students who require academic accommodation must contact Student Accessibility Services (SAS) to make arrangements with a Program Coordinator. Academic accommodations must be arranged for each term of study. Student Accessibility Services can be contacted by phone or email. For further information, consult UC Davis's Policy for Academic Accommodation of Students with Disabilities.

Accommodation for Religious, Indigenous, and Spiritual Observances

Students requiring academic accommodation based on religion, indigenous and spiritual observances should follow the procedures laid out in UC Davis's Policy on Academic Accommodation for Religious, Indigenous, and Spiritual Observances.