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An evaluation of hospital-based health technology assessment processes in the United States.

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AN EVALUATION OF HOSPITAL-BASED HEALTH TECHNOLOGY ASSESSMENT PROCESSES IN THE UNITED STATES

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DEDICATION

This dissertation is dedicated to the memory of my mother

Mrs. Song Cha Skinner

who set a great example for pursuing higher education.

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ABSTRACT

AN EVALUATION OF HOSPITAL-BASED HEALTH TECHNOLOGY ASSESSMENT PROCESSES IN THE UNITED STATES

Scott Skinner

April 17, 2023

This research study explored the practices of hospital-based health technology assessment (HTA) in the U.S., as experienced by healthcare technology management (HTM) professionals. HTA can play an important role in helping to evaluate health technologies at both the macro (e.g., policy) level as well as at the micro (e.g., institutional) level of the public health ecosystem (C. S. Goodman, 2004). HTA seeks to broadly evaluate the effects, properties, and other impacts of various health technologies (C. S. Goodman, 2004). Common goals of HTA are to evaluate the safety, effectiveness, and cost-benefit of health technologies.

A primarily phenomenological approach was used to explore recurrent themes of the HTA as experienced by HTM professionals in the U.S. in 2022. The study at first examines why regulatory processes alone may not ensure the safety and effectiveness of electronic medical equipment (EME), a specific subset of the medical device domain of health technology. A review of an HTA process model developed primarily for a European context is then provided. Evidence-based HTA practices for use in hospitals are also incorporated for review. The study then specifically explores the intra-

organizational phenomenon of how EME is evaluated and selected in various types of hospital organizations. The findings offer insight into how HTM professionals are currently involved in HTA and lay a possible groundwork for exploring best practices in the domain.

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CHAPTER 1: INTRODUCTION

Overview

In modern day hospitals, as with many parts of society in general, technology has become so omnipresent that it can become nearly invisible to the casual observer. Enter any operating room, patient room, or procedural room in a hospital today and technology will be abundantly present and highly varied. Perhaps to the lay onlooker some of the more noticeable technology might be electronic machines that display alphanumeric messages and graphs and that go "beep," seemingly at random intervals. The uninitiated spectator might view these machines with a sense of admiration; they may feel that these machines must be vital, expensive, and, most importantly, able to have a major positive impact on human life. They probably assume the technology they're witnessing has been carefully curated to be the most safe and effective as possible. They may also assume that thorough administrative processes went into evaluating and selecting the technologies, and that only the most beneficial ones were deployed. They may not be aware that evaluating and selecting technology can be an extremely complex process confounded by numerous intra- and extra-organizational factors, such as resource availability. It is the intersectionality of abundant and advanced technologies, along with the other special organizational attributes of healthcare contexts, that can make the healthcare field an excellent setting for evaluation using organizational theory (Reay, Goodrick, & D'Aunno, 2021).

Background

With ever increasing health technologies available for use, hospitals can be faced with a multitude of situations where technology is a key (or closely related) aspect of the decision-making process. These decisions can occur in an imperfect set of circumstances with limited funding, time, and human capital available. External factors, such as for-profit companies advancing technologies that may not live up to their marketing, can be confounding to the decision-making process. Also, a lack of standardized methodologies for how to go about such processes can result in a high degree of variation in the outcomes. In the U.S., where healthcare costs can be exorbitant when compared to other developed countries and where health outcomes can be lagging, developing a better understanding of health technology-related administrative practices of hospitals can inform future practice and research in the domain. In particular, various processes that can go into the evaluation and selection of technology (these processes are known collectively as health technology assessment or HTA), can represent a particular area of interest for hospitals in the U.S.

Problem Statement

Little research exists on current HTA processes used in U.S. acute care hospitals, and none from the perspective of healthcare technology management (HTM) professionals, those who are charged with managing and servicing much of it. Available research on this problem includes HTA practices of a sample of 19 West Coast VHA hospitals published in grey literature in 2003 (Rosenstein, O'Daniel, & Geoghan); a single U.S. hospital participant in one international study of HTA logic, methods, and tools from 2008 (Cicchetti, Marchetti, Dibidino, & Corio); and the potential negative

consequences for technologies when regulatory processes alone may not confirm its safety and effectiveness (Ardaugh, Graves, & Redberg, 2013; Everhart, Sen, Stern, Zhu, & Karaca-Mandic, 2023; Kadakia, Dhruva, Caraballo, Ross, & Krumholz, 2023; Wizemann, Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process, Board on Population Health and Public Health Practice, & Institute of Medicine, 2011). The limitations of prior research do not facilitate broad analysis of the state of, or describe organizational factors correlated with, hospital-based HTA (HB-HTA) in the U.S. This research study will seek to employ empirical evidence and organizational theory to characterize the current state of some administrative processes related to health technologies in hospitals in the U.S.

Conceptual Framework

When hospitals identify that a health technology needs to be evaluated, a multitude of factors could be deterministic in the processes used and the outcomes achieved. Various organizational attributes, such as whether resources are limited or plentiful, the type of internal governing policy, historical preferences for certain tactics or methods, and other attributes, can feed into how health technologies get assessed. One extant model for conducting HTA in a variety of contexts is the HTA Core Model 3.0 (European Network for Health Technology Assessment, 2016). The model contains 9 domains and, while developed for the European Union context, its objective is to be applicable internationally as a standardized methodology for producing and sharing HTA results (Bilekova, Gavurova, & Rogalewicz, 2018; Gyldmark et al., 2018). The HTA Core Model 3.0 can also be used as a lens by which to evaluate individual HTA practices and how closely they are aligned (or not) with a consensus model that has evolved and

matured through iterations. Conceptually, when an HTA need arises, organizational attributes (influenced both internally and externally) may have created an HTA governance model, that in turn sets forth the exact processes used. The processes used can be evaluated vis-à-vis the 9 domains of the HTA Core Model 3.0; that is, to what extent do the exact processes align with the HTA Core Model. The processes used ultimately determines the outcomes of the HTA processes, and what technology is selected. This conceptual framework is represented in Figure 1 below.

Figure 1

Conceptual framework

Purpose of the Study

The study will investigate what HTA processes are currently being used in hospitals in the U.S., as observed by HTM professionals. Using the HTA Core Model 3.0 domains and some evidence-based guiding principles for HB-HTA, the processes will be evaluated for possible correlation with certain organizational attributes. It may be possible to determine factors that predict the extent to which HB-HTA at the organizational (hospital) level in the U.S. is methodologically aligned with the HTA Core Model 3.0 and the guiding principles. The main question is what is the current state of HTA in U.S. hospitals, as observed by HTM professionals? The secondary question is what organizational factors influence the current state? It is hypothesized that hospitals

that are part of multi-hospital systems (which may have greater resource munificence and be more bureaucratic in nature) may have more complex HTA processes.

Research Questions

In this mixed-methods study, the following research questions were developed and investigated:

1) What is the current state of HB-HTA in the U.S. as observed by HTM professionals?
2) How is HB-HTA in the U.S., as observed by HTM professionals, predicted by organizational attributes?

Definition of Terms

The terms used throughout this paper include:

Association for the Advancement of Medical Instrumentation (AAMI): The national professional society for healthcare technology management professionals.

Electronic medical equipment (EME): A category of medical device (see further definition below) that operates based on electronics.

Food and Drug Administration (FDA): The U.S. Food and Drug Administration, an agency of the U.S. Department of Health and Human Services.

Health technology: "The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives" (World Health Organization, 2019).

Health technology assessment (HTA): "A multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle" (O'Rourke, Oortwijn, & Schuller, 2020).

Healthcare technology management (HTM): The professional discipline, formerly known as clinical engineering, that is involved with servicing, supporting, and otherwise managing certain types of medical devices (Dyro, 2004; Jacques & Christe, 2020).

Hospital-based health technology assessment (HB-HTA): HTA done within the context of hospital organizations (Gałązka-Sobotka et al., 2021).

Medical device: An FDA nomenclature for "An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

(A) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes" (U.S. Food and Drug Administration, (n.d.)-b)

Procedures

Mixed methods research was used to accomplish this study. A novel Internet-based survey was developed and administered to a convenience sample of HTM professionals affiliated with a national professional society, with the results being

anonymized. In essence the sampling plan involved clustering and attempting to reach a random sample of the 10,000 members of the professional society. The survey results were analyzed using descriptive statistics and multi-level logistic regression. Concurrently, semi-structured interviews were conducted with a convenience sample of HTM professionals that were recruited through informal networking by the study author and a colleague. The interviews took place via Internet and were recorded. Rich field notes were taken during the interviews, the recordings were transcribed, and the transcripts were analyzed following principles of grounded theory, with the results being anonymized. Grounded theory is the process of conducting qualitative research and developing theories based on inductive analysis (Charmaz, 2006).

Significance of the Study

Hospital administrators and HTM professionals can possibly leverage the results of this study to inform organizational level practices in the field, including but not limited to HB-HTA governance models and tactics. Potentially more importantly, there is an opportunity to guide practice across the existing discipline of HTM or develop a special interest group or society that focuses specifically on HB-HTA practices in the U.S., like what has been done in other contexts (particularly Europe). This study could serve as the genesis for such future focal points.

Limitations of the Study

This study was bounded by its geographical location, participant population, and time. Participants self-reported their experiences and organizational attributes, and it was assumed that participants were reporting honestly and accurately; any inaccuracies

were unable to be ascertained or controlled for. Due to a small sample size, it may be risky to broadly generalize the results of the study.

Organization of the Study

This study is organized into four chapters. Chapter 1 includes a general introduction to the problem statement and background and general overview of the research approach. Chapter 2 reviews the literature on health technologies, HTA in varying contexts, and prior research. Chapter 3 details the research methodology used in the paper. Chapter 4 presents the quantitative and qualitative results of the research. Finally, Chapter 5 summarizes the findings and possible implications for practice and offers suggestions for additional research.

CHAPTER 2: LITERATURE REVIEW

Health Technology

According to the World Health Organization (WHO), "a health technology is the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives" (2019). Varied examples of health technology advancements include the smallpox vaccine that has prevented countless deaths, coronary artery bypass surgical techniques that have greatly reduced mortality and morbidity, and medications that have ameliorated some diseases to the point of being manageable chronic conditions. Conversely, Shi and Singh state that "technological advances have been the single most important factor in medical cost inflation" (2015). Those same authors note that "the development and diffusion of technology are closely intertwined with its utilization" and, outside of cost, that technology growth "has been accompanied by issues of…safety, benefits, and risks." (Shi & Singh, 2015). In the U.S., many types of technology go to market without clinical studies that substantiate safety and effectiveness (Ardaugh et al., 2013). While health technologies can bring powerful benefits, evaluating those benefits vis-à-vis their full consequences represents a general concern for health policymakers.

Regulatory Framework and Medical Devices

One regulatory element which serves to protect consumers and public health relative to many types of health technologies is the U.S. Food and Drug Administration (FDA) (U.S. Food and Drug Administration, 2018). A subset of FDA regulated health

technologies is medical devices, which covers a range of items including disposable products, tests, and electronic medical equipment. Medical devices are given one of three classifications by the FDA: Class I, Class II, and Class III. The higher classed medical devices are perceived as having more risk and are subject to more FDA regulation (U.S. Food and Drug Administration, (n.d.)-d). Class I devices have little potential for harm (examples include elastic bandages and enema kits), are 47% of medical devices, and 95% of them are exempt from the FDA's Premarket Notification 510(k) process (U.S. Food and Drug Administration, (n.d.)-c). Class II devices have more potential for harm (examples include powered wheelchairs and some pregnancy test kits), are 43% of medical devices, and are subject to the FDA's Premarket Notification 510(k) process (U.S. Food and Drug Administration, (n.d.)-c). Class III devices have the most perceived risk (examples include implantable pacemakers and breast implants); are 10% of medical devices; are often life-sustaining, implanted, or have potential unreasonable risk of injury or illness; and most are subject to the FDA's Premarket Approval process (U.S. Food and Drug Administration, (n.d.)-c). Table 1, below, summarizes the FDA medical device classification system.

Table 1

Summary of FDA Medical Device Classification System

	Examples	FDA Approval Required
Class I	Enema kits and elastic bandages	Most are exempt from Premarket Notification 510(k)
Class II	Powered wheelchairs and some pregnancy test kits	Most require Premarket Notification 510(k)
Class III	Implantable pacemakers and breast implants	Most require Premarket Approval

Note. Adapted from "Classify Your Medical Device" (U.S. Food and Drug Administration, (n.d.)-a), "Definitions of Medical Device Classes" (Wizemann et al., 2011), and "Overview of Device Regulation" (U.S. Food and Drug Administration, (n.d.)-d).

The 510(k) section of the Federal Food, Drug, and Cosmetic Act requires that manufacturers of a medical device notify the FDA at least 90 days in advance of marketing a device so it can be considered for Premarket Notification 510(k) or Premarket Approval (Wizemann et al., 2011). The Premarket Notification 510(k) process, passed in the Medical Device Amendments of 1976, was intended by Congress as a short-term expediency-oriented solution to the FDA's administrative task of classifying medical devices, reviewing them, and approving new ones (David R. Challoner, Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process, & Board on Population Health and Public Health Practice, 2011). The Premarket Notification 510(k) process involves the FDA evaluating whether the new device is substantially equivalent to an already marketed product, termed a predicate (Wizemann et al., 2011). New devices are considered substantially equivalent to a predicate if they have the same technical characteristics and intended use, or different

technical characteristics but don't raise new concerns of safety and effectiveness (Wizemann et al., 2011). Fewer than 5% of devices subject to the Premarket Notification 510(k) approval undergo clinical trials (Lenzer, 2018). Conversely, the Premarket Approval process for Class III medical devices requires clinical trials to demonstrate reasonable safety and efficacy (S. B. Goodman, Mihalko, Anderson, Sale, & Bozic, 2016; U.S. Food and Drug Administration, (n.d.)-c; Yang, Iorio, & Day, 2017). The FDA's system essentially results in lower risk (Class I) medical devices being exempted from comparison to a predicate, the highest risk (Class III) medical devices mostly requiring clinical trials, and the middle risk (Class II) medical devices mostly going to market without clinical trials. Concerns have been raised that substantial equivalence to a predicate may not necessarily correlate with safety and efficacy (Everhart et al., 2023). If those concerns are valid, healthcare providers may falsely assume that all versions of the FDA's medical device processes result in an assurance of safety and efficacy based on scientific rigor. As a result, less rigorous organizational level processes might be applied to medical devices that are deemed approved or cleared for marketing by the FDA. With less rigorous organizational level processes, medical devices might be broadly applied to patients with unintended negative consequences.

The metal-on-metal hip implant, which has had a high rate of corrective surgery, represents a particular example of how the Premarket Notification 510(k) process can sometimes be inadequate. Metal-on-metal hip implants, as the name implies, describes implants utilizing metal surfaces on both the ball and socket that wear against one another, causing small amounts of metal to be released into the body (U.S. Food and Drug Administration, 2019). Metal-on-metal hip implants are subject to the Premarket

Notification 510(k) process. According to Ardaugh et al., "many medical devices that pose great safety risks to Americans, including metal-on-metal hip implants, currently enter the U.S. market through" the 510(k) "pathway that is not intended for evaluating safety and effectiveness" (2013).

Ardaugh et al. describe how three major design elements of metal-on-metal hip implants had undergone study as separate features in prior (predicate) devices, but were not studied within the context of the three features being combined into one device (2013). One particular metal-on-metal hip implant with all three combined features received Premarket Notification 510(k) clearance without having had clinical studies performed; this occurrence "reveals serious flaws in the 510(k) procedure. . . which resulted in clearance of a new device that was never shown to be safe and effective" (Ardaugh et al., 2013). These unstudied devices can be problematic. Medical "devices approved through the 510(k) route have been shown to result in an 11.5-fold increased risk for recall when compared" to Premarket Approval (Yang et al., 2017). Kadakia et al. evaluated a group of 510(k) cleared devices that had been recalled from 2017 to 2021 and found that 44.1% of the recalled devices were themselves based on a predicate that had at some point been recalled (2023). Everhart et al. found that new devices based on predicate devices with 3 or more recalls were associated with an 81.2% increase in recall probability relative to the mean (2023). Experts agree that the 510(k) process does add value, but questions remain about how it should be modified, amended, or replaced (*Public Health Effectiveness of the FDA 510(k) Clearance Process: Balancing Patient Safety and Innovation: Workshop Report*, 2010).

Another medical device challenge of the FDA's can be the ongoing monitoring processes for once a product has been approved or cleared for sale. That process, known as postmarketing surveillance, uses a variety of tools for monitoring medical device challenges (David R. Challoner et al., 2011). Those tools collect data related to adverse events and recalls, but are limited by challenges with severe underreporting (Wizemann et al., 2011). Some research has suggested that medical device incident reporting occurs at rates of less than 0.5% of reportable occurrences (Resnic & Normand, 2012). This could mean that inadequate feedback loops might exist to collect and disseminate data on issues, thus limiting the ability to analyze, draw conclusions, and act upon feedback once medical devices are actively being marketed.

Health Technology Assessment (HTA)

With the expansion and cost of health technologies and concerns about its safety and effectiveness, perhaps it was inevitable that a scientific concept would arise for evaluating and selecting certain ones when a range of options exist. Technology assessment (TA) in general started coalescing as a concept in the 1960s due to "an appreciation of the critical role of technology in modern society and its potential for unintended, and sometimes harmful, consequences" (C. S. Goodman, 2004). In 1972, Congress authorized the creation of the Office of Technology Assessment (OTA) with the purpose being to inform congressional policymakers about technology decisions (C. S. Goodman, 2004). As opposed to the more general TA, the notion of health technology assessment (HTA) came to be recognized as its own concept (Benoit & Gorry, 2017). The OTA first published an HTA in 1976, which happened to be about drug bioequivalence (C. S. Goodman, 2004). In 2017 Benoit and Garry found that HTA as a

discipline started to be used significantly in publications in 1990; this effectively establishes HTA and related discourse as recent developments. Interestingly, the OTA was disbanded in 1995 due to changing political winds (Banta & Jonsson, 2009).

HTA has been defined in various ways over time in various contexts. Perhaps the most contemporaneous definition of HTA is as "a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle . . . the purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system" (O'Rourke et al., 2020). Simply stated, HTA seeks to objectively evaluate the positives and negatives of a particular technology so a balanced decision can be made about its application (Shi & Singh, 2015). An analogy sometimes used with HTA is that of an iceberg, where a portion of the iceberg is readily seen and can be characterized, but a significant portion is below the surface of the water and can't be seen. If a particular health technology is an iceberg, HTA intends to characterize both the obvious and not so obvious ramifications it holds.

External defibrillators might represent a relatable example of a medical device and how HTA processes might be beneficial. External defibrillators are nearly universal in acute care hospital settings, are generally recognized by the public because of media portrayal (boxes that have paddles attached to coiled cables and someone yells "clear!" prior to using it to deliver a shock), and they represent a technology that has seen enhancements over time. At one time external defibrillators with automated functions were allowed to enter the market through the 510(k) process (Circulatory System Devices Panel, 2010). Currently, external defibrillators are available that provide real-time feedback on the quality of chest compressions during resuscitation and can actively coach

the user to deliver compressions harder or faster. These features vary in their exact design depending on the make and model. Research has shown that better quality chest compressions can lead to better patient outcomes (Hunt et al., 2018). To this author's knowledge, no randomized clinical trials have been conducted comparing makes and models of defibrillator to one another. External defibrillators can have extremely varied supply costs. Some external defibrillators have a different electrical shock waveform than others; the different waveform types could potentially influence patient outcomes. A diligent HTA process might wrestle with these various quandaries in a multi-disciplinary fashion and work to arrive at a balanced decision based on the evidence that can be found, given the time and resources available.

HTA Governance, United States

If the big bang of HTA occurred in the U.S. in the 1960s and 1970s, one could argue that as the HTA universe expanded it moved away from the U.S. In the U.S., there is currently no national standard methodology for conducting HTA activities; HTA can occur at a variety of the social-ecological levels including the policy and organizational levels and, generally speaking, occurs in an uncoordinated, fragmented, and non-standardized fashion (Shi & Singh, 2015). Banta and Jonsson state that HTA in the U.S. doesn't have clear leadership at the federal level, particularly given the demise of the OTA (2009). The Agency for Healthcare Research and Quality (AHRQ) does have a technology assessment program. However, from 2016 to 2020, AHRQ completed 1 to 2 technology assessments per year, with an arithmetic mean of 1.6 (Agency for Healthcare Research and Quality, 2020). Of the 8 technology assessments completed during that timeframe, 5 only evaluated Medicare populations (Agency for Healthcare Research and

Quality, 2020); thus potentially limiting the applicability of the research to other populations. As such, AHRQ's depth and breadth relative to HTAs appears to be quite limited. Some have suggested that creating a formal HTA body might foster the creation of unbiased evidence that could bring additional value (Mulligan et al., 2020). Payors frequently use HTA elements to develop internal policy on participant coverage, but methods are specific to each payor and "lack transparency" (Mulligan et al., 2020). There don't appear to be any U.S.-based journals or professional societies dedicated to HTA as a broad concept. Narrower aspects of specific technology do certainly get assessed in peer-reviewed, discipline-specific journals (for e.g., radiation oncology devices getting evaluated in the Journal of Applied Clinical Medical Physics). It could be said that HTA in the U.S. is largely rudderless at the national and federal government levels, but it is unclear if or how that is impacting public health. Shi and Singh point out that in the U.S. little is done to limit the expansion of new health technologies because Americans value access to the latest advancements (2015). Thus, the lack of any formal HTA structure may be somewhat a product of predominant values in the U.S.

HTA Governance, International

As the big bang of HTA expanded away from its U.S. epicenter it seems to have mostly ended up in other countries, particularly European ones, where the governments seek to limit access to certain health technologies to control costs (Shi & Singh, 2015). HTA seems to be more organized in Europe in part thanks to a number of HTA-specific collaboratives, journals, and societies (Banta & Jonsson, 2009). In 2021, the European Union (EU) formally ratified a regulation that "creates a structure to carry out joint HTA at the European level," although highly organized informal collaboratives had already

been occurring (Imaz-Iglesia & Wild, 2022). Aside from a desire to centrally control access to health technologies via government measures, it may be exactly unclear why HTA proliferated as a concept in Europe, but societal and cultural circumstances may have increased acceptance. From a health policy standpoint, the presence of nationalized health insurance programs promoting the idea of equitable distribution of limited resources may have provided a substrate on which HTA could flourish.

The European Network for Health Technology Assessment (EUnetHTA) HTA Core Model 3.0 might represent the most mature and advanced methodological construct for conducting HTA in the world today. The EUnetHTA HTA Core Model 3.0 has 9 domains: (1) health problem and current use of technology, (2) description and technical characteristics of technology, (3) safety, (4) clinical effectiveness, (5) costs and economic evaluation, (6) ethical analysis, (7) organizational aspects, (8) patient and social aspects, and (9) legal aspects (2016). The domains represent categorial lenses through which to frame health technologies. Each domain has a subset of questions by which to explore and report out various details on the health technology being assessed. Research has been completed to test the applicability of the HTA Core Model in multiple contexts and with multiple technologies. Pasternack et al. found that "the elementary structure of the HTA Core Model proved useful in preparing HTAs" with topics as varied as Radium-223 treatment in Slovakia, to drug eluting stents and multislice computed tomography in Europe (2009).

As implied by the 3.0 numbering scheme, the current HTA Core Model is the result of iteration of prior models (European Network for Health Technology Assessment, 2016). The first domain, health problem and current use of technology,

explores the conditions being targeted, target populations, epidemiology, and what current technology is available and how it's being used (European Network for Health Technology Assessment, 2016). This domain, thus, sets the stage for the current state and provides key elements of background information necessary to conduct deeper assessment. Specific to medical devices, regulatory information and reimbursement status are included in the research in this domain (European Network for Health Technology Assessment, 2016). An example of background information elucidated in this domain might include that an existing technology is available but compliance with its use is poor, and thus a recommendation might be that a focus on increasing compliance might be more appropriate than introducing a totally new technology (European Network for Health Technology Assessment, 2016).

The second domain is the description and technical characteristics of technology. This domain seeks to describe the technology, its technical characteristics, its position in the technology lifecycle, and requirements for its use including needed structure and training (European Network for Health Technology Assessment, 2016). For example, unique requirements such as extensive training being required could limit the ability for technology deployment. In the case of medical devices, many types require extensive structural resources to function properly, such as specially designed rooms; electrical power, water, and sewage capacity; and proper heating, ventilation, and air conditioning. Procuring these resources could dramatically increase the cost of implementing a technology, beyond just the technology itself.

The third domain is safety and is a concept that mirrors the use of the Hippocratic oath in the physician community. That is, first, to do no harm. According to the

EUnetHTA model, “safety is an umbrella term for any unwanted or harmful effects caused by using a health technology” (2016). Simply put, ways that safety can come into play include technologies that have the potential to cause mortality or morbidity. The root causes vary for the ways health technologies could cause harm include poor design, improper maintenance, operator error, and improper selection of patients (European Network for Health Technology Assessment, 2016). One of the topics of the safety domain is to assess risk which is defined as “the probability of harm” (European Network for Health Technology Assessment, 2016).

The fourth domain of the EUnetHTA HTA Core Model 3.0 is that of clinical effectiveness, and it seeks to answer the questions of “can this technology work?” and “does this technology work in practice?” (European Network for Health Technology Assessment, 2016). The assessment of this domain works with the definitions of (1) efficacy as “the extent to which a technology does more good than harm under ideal circumstances,” and (2) effectiveness as “whether a technology does more good than harm when provided under usual circumstances of health care practice” (European Network for Health Technology Assessment, 2016). This domain seeks to quantify the magnitude to which both positive benefits and negative factors exist and, ultimately, to calculate the net benefit (European Network for Health Technology Assessment, 2016).

The fifth domain concerns costs and economic evaluation. This domain seeks to perform a comparative analysis of available options “in terms of both their costs and consequences” (European Network for Health Technology Assessment, 2016). The domain recognizes that resource munificence varies and that certain technologies cannot always be provided in every possible situation. A simple example of the type of decision

weighed in this domain might be whether to deploy a quaternary technology at a small, regional hospital, or to concentrate the technology in larger, referral hospitals where greater economy of scale (such as cost efficiency) might exist. Specific economic evaluation tools possibly used in this domain include (1) cost-effectiveness analysis, (2) cost-utility analysis, (3) cost-consequence analysis, (4) cost-benefit analysis, and (5) cost-minimization analysis (European Network for Health Technology Assessment, 2016). The domain seeks to use existing evidence when and where available (European Network for Health Technology Assessment, 2016).

The sixth domain is regarding ethical analysis and is broadly considering the technology within the context of personal and professional beliefs, standards of conduct, and principles and rules (European Network for Health Technology Assessment, 2016). It seeks to use "prevailing societal values" to frame considerations of technology (European Network for Health Technology Assessment, 2016). In this domain especially, the HTA Core Model 3.0 recognizes that consideration of health technologies is more than just a purely technical exercise. The model does recognize that the weight of ethical consideration can vary greatly depending on the nature of the technology. An example in this domain might be a new disease screening technology that is more sensitive but might lead to overdiagnosis and overtreatment (European Network for Health Technology Assessment, 2016). Differences of race, gender, and sexual orientation (if applicable) might be wrestled with in this domain, as well.

The next (seventh) domain concerns organizational aspects where the situational context of resources gets considered for the technology (European Network for Health Technology Assessment, 2016). Individual resources include "material artifacts, human

skills and knowledge, money, attitudes, and work culture" (European Network for Health Technology Assessment, 2016). There are three lenses by which to frame the domain and they include (1) intra-organizational factors, (2) inter-organizational factors, and (3) health care system level factors (European Network for Health Technology Assessment, 2016). These frameworks evaluate things such as "work processes and patient/participant flow, quality and sustainability assurance, centralization, communication and cooperation, managerial structure, and acceptance of a technology" (European Network for Health Technology Assessment, 2016).

The eighth domain involves patients and social aspects. Patient aspects include the persons who receive or use a technology, such as patients, individuals, and caregivers (European Network for Health Technology Assessment, 2016). Social aspects relates to grouping of individuals or patients that might be of specific focus in relation to the technology (European Network for Health Technology Assessment, 2016). The domain recognizes that the impact of technology can go far beyond the specific care context in which it is applied. Patients may have preconceived opinions of technologies that may be far ranging. In some cases, they may have unrealistic expectations of technologies they're aware of; in other cases, they may not be aware of technologies that could be highly beneficial.

The ninth and final domain is legal aspects. This domain of the EUnetHTA model is intended to focus on applicable rules and regulations. These rules and regulations exist to "protect the patient's rights and societal interests" (European Network for Health Technology Assessment, 2016). Such rules and regulations can exist at the national, regional, and local levels and they can shape technology decisions, in some

cases helping or preventing adoption. This domain is an example of where the Core Model 3.0 has been designed with a European context somewhat in mind, where much of the guidance in the model refers to European councils, conventions, treaties, directives, and regulations that influence technology decision-making in that environment. Certainly, there are core elements of the legal domain that are germane to any context, even when operating outside of Europe.

HTA Governance, Organizational

As opposed to broader HTA, hospital-based health technology assessment (HB-HTA) is the administrative process by which health technology is evaluated and selected for use at an organizational level. HB-HTA might seek to resolve degree of fit for a health technology in specific hospital organizations and the populations they serve, and to elucidate concerns not contemplated by more general HTAs and bodies such as the FDA. Multidimensional evaluation of health technologies using available evidence can help address potential tunnel vision. Ineffective HB-HTA of EME could result in the selection and application of technologies that are less safe, less effective, more expensive, or have other complications, for the specific organization and its patient population.

One nuance with HB-HTA is that it may occur informally depending on the situation. For example, in a certain hospital nursing unit a nurse leader and a physician may decide to select a standard model of wound dressing for that physician's patients. The physician and nurse leader may view such a decision as one that involves little risk and thus little need for formality. The two consult the hospital's supply chain department and are provided details on two similar wound dressings that are both readily available as part of the organization's supply formulary. The two wound dressings are similarly

priced, and they appear to have the same clinical features. The nurse leader and physician decide to trial the cheapest wound dressing on three patients. The success of the trial will be measured by a subjective opinion from the physician. After the trial the physician decides that the dressing worked acceptably on all three patients and a final decision is made to standardize to the dressing. The nurse leader and physician decide not to write-up a report summarizing the selection process or outcome. In this example, HB-HTA has occurred informally at a functional level and the technology itself (dressings on wounds) was not under debate, and the actors could proceed directly to evaluating and selecting from available options. In other situations, the technology itself may be very much in debate. For example, a novel technology might just be entering the marketplace and, even though it may be FDA approved or cleared, it represents a new paradigm that has no comparison.

Technologies more complex than a wound dressing might receive more rigorous HTA in hospitals due to thresholds such as cost or risk. For example, the surgical services department purchasing a $1,500,000 surgical robot may be a decision that requires higher lever approval than what the department leader is delegated to make. In some organizations a purchase of this size may need approval from the hospital's board of trustees. In that case, there may be set criteria for what information the board must have presented to them prior to authorizing such a purchase. These criteria might include elements such as an estimate of the impact on patient outcomes, a calculated return on investment (ROI) prediction, intangible considerations such as having to refer fewer patients to hospitals outside of the community, and overall fit with for the purchase with the organization's mission, vision, and values.

The idea that the process of evaluating and selecting health technology in hospitals is a process of such importance that it deserves a universal title might be in debate. In some hospitals, new technologies are vetted through a process known as value analysis (VA). In VA, "practitioners gather the relevant information about the technology, review the published literature, and then network with their clinical colleagues to garner support for initial implementation," as described by physicians in The Journal of Thoracic and Cardiovascular Surgery (Engelman, Boyle, & Benjamin, 2018). Earlier, in 2010, the VA model was described as "economic analytical tools that can help you make direct, comparative value assessments and purchasing decisions about competing products for your facility" in a hospital supply chain publication (Feldstein & Brooks). These definitions strongly echo HTA; it is unclear why the VA terminology emerged and why existing HTA models weren't co-opted. An argument could be made that, definitionally, any activities to evaluate and select a health technology in a hospital is a form of HB-HTA.

Confounding Factors

A number of factors potentially confound the evaluation and selection of medical devices in hospitals. Like any complex organization, multiple internal and external variables influence the effectiveness of administrative processes such as HTA. Perhaps one factor of major significance is that administrative processes seldom are afforded perfect resource inputs through which to achieve their desired outcomes. One study that validated the HTA Core Model reported that the 9 domains weren't always fully completed, and "the typical reason given was time pressure" (Pasternack et al., 2009). Beyond deadlines that have limited resource inputs, other resource challenges may exist.

One hospital may choose to invest in dedicated resources for HTA, while others will deploy those responsibilities to individuals whose main role is something other than HTA. This can be particularly challenging when, for example, clinicians are pulled into an HTA project, assigned significant additional work, and must continue to perform their regular patient care responsibilities. Conversely, some physicians view HTA as a "drawn-out process," taking too long and being overly cumbersome (Engelman et al., 2018). The tug of war between completing an HTA expeditiously while ensuring an appropriate level of quality is a key challenge.

Various forms of vendor bias can also be a major confounder to effective HTA, especially as it relates to the clinical effectiveness domain (European Network for Health Technology Assessment, 2016). Health technology vendors usually have goals of increasing shareholder value, as opposed to hospital goals of achieving certain levels of clinical outcomes. Hospitals, as consumers of health technology, must ultimately establish acceptable terms in which to engage vendors in the market. But because of fundamentally disparate goals, health technology vendors may bias the process by which technology is evaluated and selected. For example, health technology vendors might selectively curate evidence that supports their technology but fail to reveal evidence that doesn't (European Network for Health Technology Assessment, 2016). Other vendor biases can occur at more of a market level, and include leveraging regulatory processes to limit competition (Feldman, Bloomfield, Beall, & Kesselheim, 2022). Some vendor biases directly involve internal stakeholders. Burns et al. found that physician preference for orthopedic implants was "heavily influenced by technology/implant factors and sales/service factors" (2018). More generally, Ioannidis posits that financial conflicts of

interest (such as vendor supported research) increases the bias in research findings and are very common in the biomedical domain (2005). Ultimately, vendors create and market technologies that can have major positive impacts on health, but vendor goals may not align with hospital goals and associated biases can be important considerations.

The complexity of the health technology itself can confound the process of evaluating and selecting it. Devices may not have been designed thoughtfully "using human factors principles to account for the human-machine interface" (*To Err is Human: Building a Safer Health System*, 2000). Thus, processes may have to be developed and used to evaluate the human factors. In one example where HTA was used to evaluate infusion pumps for a hospital, a series of clinical simulations were designed and carried out to measure user factors (Poder, 2017). The sociologist Charles Perrow also described how increasingly complex technology, with more risks, "will inevitably have system accidents" (1999). Perrow defines system accidents, or normal accidents, as a result of complex interactions and automated interdependencies of technologies that result in multiple unexpected interactions of failures (1999). Infusion pumps might represent a prime subject for such system accidents; modern versions of infusion pumps have software to help ensure proper medication dosing (Poder, 2017). Infusion pumps may have to communicate with other systems, such as an electronic health record, to help do things like program drug dosages. Such interactions add complexity that can create additional potential points of failure.

Prior Research

Prior research evaluating the state of HB-HTA in the U.S. has been very limited. A novel survey conducted by Health Technology Assessment International in 2007 and

2008 only had a single U.S.-based organization participate (Cicchetti et al., 2008). In 2003 a small, informal study was done of 19 west coast VHA hospitals that was published in grey literature (Rosenstein et al.). Neither study aspired to assess HTA practices through the lens of a pre-existing, widely utilized methodological construct. The general problem then is, while there is an international body of literature surrounding HTA methods and in situ processes, there's a gap in the research regarding what HTA processes are used in U.S. acute care hospitals.

In acute care hospital settings, electronic medical equipment (EME) represents a subset of the device form of health technology. Generally well-known examples of EME includes external defibrillators, infusion pumps, ventilators, and physiologic monitoring systems. EME can be a significant enabler to hospital-based care and quite pervasive in that environment. A sample health system can provide some frame of reference to this pervasiveness. As of February 10, 2021 that organization had 43,770 active devices in its medical equipment inventory, most of which met the EME criteria. The inventory had recorded original purchase prices totaling $339,347,663 and the health system had the clinical staffing capacity to care for 1,500 patients ("beds in operation") which equated to an average of more than 29 devices per staffed bed. Every staffed bed, then, had a $226,232 share of original medical equipment cost. Some of this medical equipment is directly involved in patient care at the individual level, while others are more indirect (such as in centralized laboratories where analyzers perform tests on samples taken from multiple patients). Still other devices are highly specialized and only applied to patients who meet very specific criteria (for example, linear accelerators used to treat cancers and certain other diseases). This exemplar health system provides tertiary and some

quaternary levels of care, and its programs might be like many other health systems across the country. In summary, EME is ubiquitous in many acute care hospitals, and it represents a significant investment of organizational resources.

The increasing complexity of EME gave rise to the profession of clinical engineering in the 1970s (Dyro, 2004). Clinical engineering, contemporaneously known as healthcare technology management (HTM), is a discrete discipline that was developed in response to the increasing amount of technology and the need to calibrate, maintain, and otherwise support and manage it in the context of patient care environments (Dyro, 2004). HTM has evolved into a complexity management exercise for EME in U.S. acute care hospitals, where managers in the domain can be highly involved with recommendations involving EME acquisition decisions (Stiefel, 2012; Wang et al., 2006). Given that, HTA processes for EME have the potential to be visible to, involved with, or even overseen by HTM professionals.

With the continued expansion in the types, complexity, and potential interactions of EME, one could state that starting in the mid-twentieth century and continuing to present an industrial revolution style expansion of EME occurred. The increased complexity of EME has brought benefits of higher quality diagnosis and treatment, but it has also brought new threats that can increase errors, as identified in the *To Err is Human* report issued by the Institute of Medicine (Kohn, Corrigan, & Donaldson, 2000). That report highlights that technologies which present too much information (information overload), that have not been standardized, or were not well designed can increase the probability of use errors (Kohn et al., 2000).

CHAPTER 3: METHODS

Overview

The objective of this mixed methods study was to conduct primary research to evaluate the current state of HB-HTA of EME in the U.S. and explore possible relationships between organizational attributes and the intra-organizational methods for HB-HTA, all as viewed from the perspective of HTM professionals. The study was divided into two components, the first being the development, testing, execution, and analysis of a survey instrument with subsequent quantitative analysis including multilevel descriptive statistics and logistic regression. The second component was qualitative and phenomenological in that it sought to characterize the experiences of participants (Creswell, 2014). To that end, semi-structured interviews of HTM professionals, using the constant comparative method, and with subsequent analysis using grounded theory as described by Charmaz, were carried out (Charmaz, 2006).

Research questions

It may be possible to identify relationships between certain organizational characteristics and the specific administrative processes used for HB-HTA of EME. For example, organization size and academic affiliation (or not) could influence whether dedicated resources exist for HB-HTA of EME, or whether multi-disciplinary teams are pulled together on an ad hoc basis. It may also be possible to suggest best practices for advancing HB-HTA of EME. If, for example, research shows that having a formal, written strategy for HB-HTA of EME is highly prevalent but not universal, that could be

offered as a best practice recommendation. The hypothesis to be tested is that some organizational attributes influence the administrative processes used for HB-HTA of EME. The research questions were:

1) What is the current state of HB-HTA in the U.S. as observed by HTM professionals?
2) How is HB-HTA in the U.S., as observed by HTM professionals, predicted by organizational attributes?

Significance

The absence of robust HB-HTA methods could allow EME into an organization that creates negative effects on patient outcomes. EME is increasingly complex and its prevalence continues to increase in acute care hospital settings, which can place additional demands on limited resources and potentially confound existing HB-HTA efforts. By improving the understanding of how different hospitals go about HB-HTA of EME, future strategies for strengthening HB-HTA might be identified. Results of this research could be married with external work to further advance standards and best practices.

Unique Features and Innovation

This has the potential to be groundbreaking research. Currently, there appears to be no standardized approach for evaluating the state of HB-HTA of EME in the U.S. Also, there is limited research describing the current state of HB-HTA (of EME or any other type) in the U.S. This research has the potential to add to the body of knowledge in an area that has not been well studied.

Theoretical Frameworks

In Donabedian's approaches for evaluating performance looking at structure, process, or outcomes, the process domain "focus(es) on the quantity or quality of activities carried on by the organization" and the structure domain "assess(es) the capacity of the organization for effective performance" (Scott & Davis, 2007). This research proposes to evaluate the processes of HB-HTA carried out relative to EME as it is occurring in varied organizations. Scott and Davis opine that process data is often more readily obtainable, but its limitation is that it is often weakly correlated with outcomes (2007). Scott and Davis go on to state how "if process measures are once removed from outcomes, then structural indicators are twice remote" (2007). Given that, fundamentally, HB-HTA of EME is a process, the scope of this research will seek to evaluate process variation vis-à-vis various organizational demographic (structural capacity) attributes. The limitations of evaluating process and structure will be discussed in the final results.

Diffusion theory is often leveraged for research related to adoption of new methods or technologies. Diffusion is itself a "process that occurs among people in response to learning about an innovation" (Dearing & Cox, 2018). As innovations are typically learned about and adopted over time, time is a key variable of consideration. Some organizations are quick to adopt certain changes (early adopters) while others are slow or even resistant to change (laggards). The degree to which an innovation is agreed upon by peers as a standard of care, and supported with evidence (or not), can certainly help determine the trajectory of diffusion. Given the fairly recent history of HTA, it might be considered a practice that is still diffusing into the realm of ordinary practice.

This research seeks to understand the state of HB-HTA of EME in the U.S. from a unitary point in time (specifically, during a 2-month survey window in 2022). It is expected that organizations will have a more or less involved process for HB-HTA of EME that can be characterized by using the 9 domains previously mentioned.

The Consolidated Framework for Implementation Research (CFIR) is a theoretical framework that seeks to unify key constructs from various implementation theories "that facilitate translation of research findings into practice, primarily within the healthcare sector" (Damschroder et al., 2009). The CFIR is made up of five major domains, including (1) the intervention, (2) inner setting, (3) outer setting, (4) the individual involved, and (5) the process by which implementation is accomplished (Damschroder et al., 2009). These domains influence implementation, and Damschroder, Aron et al. state that thus "the CFIR can be used to guide exploration into the question of what organizational factors influenced implementation" (2009). While the CFIR presents domains that "are believed to influence" implementation, it "does not specify the interactions between those constructs" (2009). The CFIR framework has been used by researchers, including one example that evaluated organizational characteristics of Veterans Affairs clinics with low or high use of a particular health technology (Gören et al., 2016).

Research Phasing

The research was performed in seven phases: 1) conduct a literature review to better understand the current landscape of HB-HTA in the U.S. and abroad, 2) develop and test a cross-sectional data collection tool [survey instrument] to evaluate specific practices across the 9 domains of HTA as identified by the EUnetHTA HTA Core Model

3.0, 3) execute the survey instrument, 4) analyze the survey instrument data, 5) conduct qualitative research [phone interviews] to elucidate further meaning of survey responses for a random sample of respondents, 6) analyze phone interviews, and 7) summarize and discuss the results. Steps 3 and 5 were performed concurrently. The target audience was members of the Association for the Advancement of Medical Instrumentation (AAMI), as many of them are hospital-based HTM professionals who have line of sight to, or perhaps play a key role with, HB-HTA of EME in their organizations. AAMI has more than 10,000 members, although it is not clear how many of those are "hospital-based" due to the association not releasing detailed member demographics (Association for the Advancement of Medical Instrumentation, 2023).

Power Analysis (survey)

An analysis was performed to determine the necessary sample size of the survey with inputs of 10,000 for population size, ± 5% for sample error, 95% for confidence level, and 0.5 for standard deviation. Utilizing a reference table generated by Price et al., a necessary sample size of 370 was determined for reaching power (2005).

Sample size (semi-structured interviews)

Sample size within the context of qualitative research comes down to a matter of opinion, and a general concern is that the sample size may be too small from which to draw appropriate conclusions (Sandelowski, 1995). Phenomenological studies can have recommended sample sizes as small as 6 to 10 participants (Sandelowski, 1995). According to Creswell, a sample size of up to 10 participants may be appropriate for studies involving lengthy interviews (2013). Given the resource and time constraints of

this study, a target sample size of 10 participants for conducting one-hour, semi-structured interviews was selected.

Researcher Context

Several factors influenced the selection of the topic and the individuals surveyed and interviewed for the project. With more than 16 years of experience as someone who has practiced HB-HTA, and more than 13 years of experience as a member of the HTM professional community, I have been positioned to anecdotally observe the variation in administrative processes across different organizations. I have become fascinated with the process of how people, in intra-organizational contexts, go about evaluating and selecting technology. With additional doctoral level study completed in public health, organizational theory, and sociology, I developed a framework by which these elements could be studied and analyzed. These personal factors also represent a form of potential bias that had to be considered throughout the course of the research.

Survey Instrument

A survey instrument was developed following a review of relevant literature. Independent variables included an initial qualifying question of "is your hospital located in the U.S.?" that, if responded to in the negative, would end the survey. Other independent variables included system-affiliated or free-standing, number of staffed beds, for-profit or non-profit, dedicated children's hospital or not, accreditation by The Joint Commission or not, HTM approach being in-house or not, academic (teaching) hospital or not, faith-based (have a religiously oriented purpose) or not, and federal hospital or not.

Dependent variables were developed after evaluating a set of guiding principles for good practices in HB-HTA by Sampietro-Colom et al. (2016) and the HTA Core Model 3.0 (European Network for Health Technology Assessment, 2016). All of the dependent variables were set to a binary, yes or no response. The first dependent variable was "does your hospital have a written policy, standard, or plan that specifies how electronic medical equipment is evaluated and selected? This would be more than a generic procurement policy that states capital thresholds and approval authorities." Sampietro-Colom et al. describe having a clear mission, vision, and values for the HTA function (i.e., overarching philosophy) (2016). The second dependent variable was "at your hospital, is an assessment of relevant clinical evidence (such as peer reviewed publications) completed as part of the process of evaluating and selecting electronic medical equipment?" as the HTA Core Model 3.0 describes conducting a systematic review of evidence (European Network for Health Technology Assessment, 2016). The third dependent variable was "at your hospital, is there clear leadership dedicated to overseeing the evaluation and selection of electronic medical equipment?" as Sampietro-Colom et al. describe having clear leadership at the top of the HTA function (2016). The fourth dependent variable was "at your hospital, is a multi-disciplinary team used to evaluate and select electronic medical equipment?" as Sampietro-Colom et al. describe involving all relevant stakeholders (2016). The fifth dependent variable was "at your hospital, is the healthcare technology management (HTM) department, sometimes known as Clinical Engineering or Biomedical Engineering, invited to participate in the evaluation and selection of electronic medical equipment?" as Sampietro-Colom et al. describe involving all relevant stakeholders (2016). The sixth dependent variable was "at

your hospital, is the Information Technology (I.T.) department invited to participate in the evaluation and selection of electronic medical equipment?" as, again, Sampietro-Colom et al. describe involving all relevant stakeholders (2016). The seventh dependent variable was "at your hospital, as part of the process of evaluating and selecting electronic medical equipment, is a written report created that describes the methods used and the outcomes?" as Sampietro-Colom et al. describe using "good methods…in a way that can be adapted to other hospitals (transferable)" (2016). The eighth dependent variable was "at your hospital, as part of the process of evaluating and selecting electronic medical equipment, is a total cost of ownership/return on investment calculated? Potential ownership costs include but aren't limited to capital investment/depreciation, training costs, ongoing maintenance/repair costs, ongoing consumable costs, and ongoing software costs. Potential return on investment factors include but aren't limited to reimbursement (if applicable), improved quality, and decreased readmissions" as a total lifecycle calculation wholistically considers the technology, not just unidimensional aspects such as upfront investment, and consistent with the HTA Core Model 3.0 domains of cost and economic evaluation (2016). The ninth dependent variable was "at your hospital, as part of the process of evaluating and selecting electronic medical equipment, are clinical user simulations (not involving patients) conducted, when feasible?" as Sampietro-Colom et al. describe considering the "local context's characteristics" (2016). The tenth dependent variable was "at your hospital, as part of the process of evaluating and selecting electronic medical equipment, are patient trials/pilots conducted, when feasible?" as, again, as Sampietro-Colom et al. describe considering the "local context's characteristics" (2016). The eleventh and last

dependent variable was “at your hospital, as part of the process of evaluating and selecting electronic medical equipment, is feedback gathered from other hospitals that implemented the same technology?” This question sought to find out if inter-organization collaboration occurring, as Sampietro-Colom et al. describe “links with key allies and partners should be proactively identified and promoted” (2016).

A preliminary draft of the survey instrument was created using the Qualtrics website and a link was emailed to 14 professional contacts on August 9, 2022 for testing. The recipients were asked to keep track of how long it took to complete the survey; if the questions made sense and, if not, how they might need to be clarified or re-worded; if they saw any problems or concerns with the target population completing the survey; and if they had any general recommendations for changes or additions. Of the 14 recipients, 7 responded and provided detailed feedback. Respondents stated the time to complete the survey ranged from 3 to 10 minutes. Multiple respondents were concerned with the questions that forced a yes or no selection before the survey would advance. Specifically, the concerns were that answers were potentially more nuanced than yes or no. To that point, multiple respondents suggested additional responses such as “sometimes,” “usually,” and “don’t know.” There is extensive literature discussing the addition of such options and the statistical complications this can create, such as a “don’t know” option being coded as a missing response and causing all of the individual’s responses to be discarded. Krosnick et al. found that “no-opinion answers may be due more to satisficing rather than optimizing and might therefore be best discouraged rather than encouraged” (2002). To address the “sometimes” and “usually” concerns, the qualifier term

"routinely" was added to pertinent questions about process. The final survey instrument may be viewed in tabular form, in its entirety, in Appendix 1.

The original aim was to have AAMI directly support this research project and to that end a research grant was submitted to them in December of 2019. In April of 2020 it was decided that AAMI would not fund the research. Later, the vice president of HTM at AAMI was approached about the survey being distributed to its membership. AAMI declined to send the survey directly to the membership or provide the membership contact list, but did agree to let the survey be posted on AAMI's blog. The sampling would thus be random but limited to those AAMI members who view blog posts or monitor blog listserv emails. A link to the survey instrument was posted to the AAMI blog on August 23, 2022 at 5:00 AM EDT, with a brief summary describing the study, its confidential nature, and the estimated length of time to complete it. The survey was later posted to a social networking website for business professionals (LinkedIn) where it was shared 5 times by other individuals. As of September 24, 2022 statistics on the Qualtrics website indicated the survey had been completed 69 times. To increase the response rate, the survey was further promoted in a podcast for HTM professionals that was published on September 27, 2022. This did not yield any additional responses.

Results of the survey were extracted from Qualtrics on September 24, 2022 at 11:00 AM EDT. Of the 69 survey responses, 13 were found to have been taken during the preview period and were discarded. Of the remaining 56 survey responses, 8 were found to have answered the qualifying question ("Is your hospital located in the U.S.?") "no" and were discarded. Of the remaining 48 survey responses, 22 were found to have abandoned the survey after completing the first question and were discarded. This left 26

completed survey responses for analysis (far fewer than the optimal sample size of 370 identified in the power analysis). Yes or no responses were re-coded to 1 or 0, respectively, apart from beds in operation which was a continuous variable.

The results of the survey were evaluated using multilevel logistic regression for each of the processes identified as dependent variables (the dependent variables being those identified above and the covariates [controlling] variables being the organizational attributes including but not limited to number of beds in operations, teaching status, for-profit or non-profit status, etc., as identified above).

Semi-structured Interviews

An interview script was developed following John Creswell's methods (2014) and considering grounded theory approaches that are both systematic but flexible (Charmaz, 2006). The script was designed to develop rapport with the participant, lead the participant through a series of questions and follow-up (clarifying) questions, allow for themes that might arise organically through the interview to be explored further, and thank the participant for their participation. The interview script can be found in Appendix 2.

A convenience sample of participants were recruited using informal networks of AAMI members among the author and an acquaintance who was previously a member of AAMI's board of directors. Because the online survey did not capture the respondent names or contact information to protect confidentiality, the survey was not used as an interview recruitment tool. Potential participants were contacted via email, provided with a general description of the research, its aims, and the interview process. As participants were confirmed, they were provided with a research preamble that was reviewed and

approved by the Institutional Review Board (IRB) of the University of Louisville. Prior to starting each interview, participants were asked if they had reviewed the research preamble and if they had any questions or concerns, to which all of the participants acknowledged they had reviewed it, and none of the participants had any questions or concerns. The preamble is included as Appendix 3 at the end of this document.

The data gathering involved recording audio from each interview and taking rich field notes. Following the interviews, the audio recordings were transcribed using a professional online transcription service. The field notes and recordings were coded with memos to identify conceptual categories (thematic elements). Direct quotes from participants were highlighted when they seemed to underscore key examples or phrasing exemplar of certain themes.

Expected Results and Impact

This study could further show that HB-HTA in the U.S. is highly varied and is dependent on certain organizational attributes and specifically identify what those attributes are. This could set a baseline from which additional research may be conducted.

Hypotheses

Possible hypotheses to design the study to test for include but are not limited to the following:

1. Larger sized organizations will use more of the administrative processes related to HB-HTA of EME, including permanent dedicated staff as opposed to ad-hoc committees or the intermittent outsourcing of the function through a consultant

2. Academic versus non-academic based organizations will have significant variation in HB-HTA of EME
3. Certain organizations might approach HB-HTA of EME at the facility level versus others who might approach it at the enterprise/corporate level

Limitations

The AAMI membership to be surveyed may not have an accurate understanding of the HB-HTA processes (dependent variables) or organizational characteristics (independent variables), which may limit the validity of this planned research. Perhaps the primary potential confounding factor is that no standardized set of processes exists for HB-HTA in the U.S., and no existing sampling instrument is known to exist. The HB-HTA guiding principles selected for this research were developed in and primarily for a European context, which represents a significantly different social, cultural, governmental, and organizational construct.

How Results Might Affect Other Research Areas

Public health researchers interested in organizational theory, quality, cost, and outcomes could be potential consumers of this research. The research could possibly be repeated by others using a different sampling techniques to further validate the findings. It may be repeated at a later date to further understand evolving trajectories of HB-HTA of EME. This research could prompt broader conversation about HTA at the national level and/or national standards for how it is conducted.

Compliance

This research was conducted following generally accepted methods in the public health and sociological domains. The research only involved surveys and interviews and

no human trials or clinical investigation was in scope. As such, the study was reviewed and exempted from being subject to further review by the University of Louisville's IRB. All research will be held confidential and protected using methods approved by the University of Louisville's IRB.

CHAPTER 4: RESULTS

Quantitative

After discarding non-U.S. based responses, total useable survey observations were 26, as previously described. The variables were exported from the Qualtrics.com website and imported into and evaluated using Stata 17.0 basic edition, copyright 1985-2021 by StataCorp, LLC. Table 2 below provides a listing of the variables, measures, and descriptive statistics including means and standard deviations.

Table 2

Variables, Measures, and Descriptive Statistics

Variables	Measures	0, N (%)	1, N (%)	Other
Independent Variables				
SystemAffil	Is your hospital system-affiliated (part of a bigger corporation) or free-standing? (1, system-affiliated; 0, free-standing)	8 (30.77%)	18 (69.23%)	
BedsinOper	How many staffed beds (not licensed beds) does your hospital have?	-	-	N = 26, min = 120, max = 6,500, mean = 1,061.19, s.d. = 1,583.79
ForProfit	Is your hospital for-profit (owned by investors)? (1, for-profit; 0, otherwise)	22 (84.62%)	4 (15.38%)	

Table 2 (continued)

Variables	Measures	0, N (%)	1, N (%)	Other
ChildrensHosp	Is your facility a dedicated children's hospital? (1, dedicated children's hospital; 0, otherwise)	21 (80.77%)	5 (19.23%)	
TJCAccredit	Is your hospital accredited by The Joint Commission? (1, in-house; 0, otherwise)	4 (15.38%)	22 (84.62%)	
HTMInhouse	Is your healthcare technology management (HTM) program in-house (that is, not outsourced to a separate company)? This program or department is sometimes called Biomedical Engineering or Clinical Engineering. (1, in-house; 0, otherwise)	2 (7.69%)	24 (92.31%)	
Teaching	Is your facility an academic (teaching) hospital? (1, academic hospital; 0, otherwise)	11 (42.31%)	15 (57.69%)	
FaithBased	Is your hospital faith-based (that is, have a religiously oriented purpose)? (1, yes; 0, no)	21 (80.77%)	5 (19.23%)	

Table 2 (continued)

Variables	Measures	0, N (%)	1, N (%)	Other
DOD	Is your hospital owned and operated by the federal government (the Dept. of Defense, the Dept. of Health and Human Services, or the Veterans Health Administration)? (1, federal hospital; 0, otherwise)	24 (92.31%)	2 (7.69%)	
Dependent Variables				
Policy	Does your hospital have a written policy, standard, or plan that specifies how electronic medical equipment is evaluated and selected? This would be more than a generic procurement policy that states capital thresholds and approval authorities. (1, yes; 0, no)	7 (26.92%)	19 (73.08%)	
Evidence	At your hospital, is an assessment of relevant clinical evidence (such as peer reviewed publications) routinely completed as part of the process of evaluating and selecting electronic medical equipment? (1, yes; 0, no)	10 (38.46%)	16 (61.54%)	

Table 2 (continued)

Variables	Measures	0, N (%)	1, N (%)	Other
Leadership	At your hospital, is there clear leadership dedicated to overseeing the evaluation and selection of electronic medical equipment? (1, yes; 0, no)	8 (30.77%)	18 (69.23%)	
MultiDisc	At your hospital, is a multi-disciplinary team routinely used to evaluate and select electronic medical equipment? (1, yes; 0, no)	6 (23.08%)	20 (76.92%)	
HTMInvited	At your hospital, is the healthcare technology management (HTM) department, sometimes known as Clinical Engineering or Biomedical Engineering, routinely invited to participate in the evaluation and selection of electronic medical equipment? (1, yes; 0, no)	4 (15.38%)	22 (84.62%)	

Table 2 (continued)

Variables	Measures	0, N (%)	1, N (%)	Other
ITInvited	At your hospital, is the Information Technology (I.T.) department routinely invited to participate in the evaluation and selection of electronic medical equipment? (1, yes; 0, no)	8 (30.77%)	18 (69.23%)	
WrittenReport	At your hospital, as part of the process of evaluating and selecting electronic medical equipment, is a written report routinely created that describes the methods used and the outcomes? (1, yes; 0, no)	12 (46.15%)	14 (53.85%)	

Table 2 (continued)

Variables	Measures	0, N (%)	1, N (%)	Other
TCO	At your hospital, as part of the process of evaluating and selecting electronic medical equipment, is a total cost of ownership/return on investment routinely calculated? Potential ownership costs include but aren't limited to capital investment/depreciation, training costs, ongoing maintenance/repair costs, ongoing consumable costs, and ongoing software costs. Potential return on investment factors include but aren't limited to reimbursement (if applicable), improved quality, and decreased readmissions. (1, yes; 0, no)	8 (30.77%)	18 (69.23%)	
Simulations	At your hospital, as part of the process of evaluating and selecting electronic medical equipment, are clinical user simulations (not involving patients) routinely conducted, when feasible? (1, yes; 0, no)	8 (30.77%)	18 (69.23%)	

Table 2 (continued)

Variables	Measures	0, N (%)	1, N (%)	Other
PatientTrials	At your hospital, as part of the process of evaluating and selecting electronic medical equipment, are patient trials/pilots routinely conducted, when feasible? (1, yes; 0, no)	9 (34.62%)	17 (65.38%)	
Feedback	At your hospital, as part of the process of evaluating and selecting electronic medical equipment, is feedback routinely gathered from other hospitals that implemented the same technology? (1, yes; 0, no)	7 (26.92%)	19 (73.08%)	

The useable responses being 26 was far less than the 370 sample size needed to achieve power among the 10,000-member total population size. Despite power not being obtained, multilevel logistic regressions for each of the dependent variables were attempted. Nearly universal across the iterations was a lack of statistical significance, possibly due to the small sample size and lack of variation in the sample (i.e., the sample being comprised mostly of organizations using the HTA processes that were included in the study). The results are shown below in Table 3. Further modeling was attempted using a bootstrap approach; this also resulted in a lack of statistical significance.

Table 3

Results of Multilevel Logistic Regressions for Each Dependent Variable

	SystemAffil	BedsinOper	ForProfit	ChildrensHosp	TJCAccredit	HTMInhouse	Teaching	FaithBased	DOD
Policy	0.3448733* (0.0193456-6.148059)	1.000347* (0.9991792-1.00157)	0.8083798* (0.021893-29.84872)	(omitted)	1.069227* (0.0139629-81.87725)	(omitted)	1.194007* (0.0961387-14.82914)	0.8791204* (0.0196338-39.36335)	(omitted)
Evidence	0.6964527* (0.0523072-9.237304)	1.001659* (0.9992144-1.00411)	(omitted)	2.99861* (0.0615933-145.9843)	0.8279868* (0.0182792-37.50509)	1.776111* (0.0182792-37.50509)	0.6216114* (0.0441719-8.747657)	0.661006* (0.0139935-31.22368)	2.714381* (0.0488765-150.7446)
Leadership	0.5737207* (0.0350805-9.382872)	1.001376* (0.9988628-1.003895)	2.359717* (0.0445156-125.0856)	(omitted)	0.5631057* (0.0064419-49.22288)	(omitted)	0.2955731* (0.0176225-4.957497)	0.4946329* (0.0109065-22.43264)	(omitted)
MultiDisc	0.7129208* (0.0319981-15.88393)	1.000485* (0.9986002-1.002373)	0.7606752* (0.0169976-34.04164)	(omitted)	1.089439* (0.0133085-89.18188)	(omitted)	0.4139061* (0.0221561-7.732327)	0.2789334* (0.0048891-15.91383)	(omitted)
HTMInvited	(omitted)	1.00487* (0.9980951-1.002884)	1.138793* (0.0196054-66.14761)	(omitted)	(omitted)	(omitted)	4.10e-08* (0)	4.13e-08* (0)	(omitted)
ITInvited	1.687739* (0.0520499-54.72556)	1.00005* (0.9986585-1.001443)	(omitted)	(omitted)	4.12e-08* (0)	(omitted)	0.7836111* (0.0369691-16.6097)	5.56e-09* (0)	0.1720877* (0.0025561-11.58568)
WrittenReport	1.421395* (0.0999363-20.21651)	1.00061* (0.9990327-1.00219)	2.95e-36	9.96e+25	5.85e+17	(omitted)	0.5752026* (0.0477544-6.928333)	5.49e+17*** (1.52e+16-1.98e+19)	(omitted)
TCO	0.9457324* (0.0590743-15.14042)	1.001126* (0.9989703-1.003287)	3.019022* (0.0789883-115.3904)	1.692515* (0.0658192-43.52236)	0.228788* (0.0063724-8.214155)	3.44428* (0.0452146-262.3725)	0.2760667* (0.016987-4.486527)	0.1569716* (0.0056421-4.367206)	1.2278* (0.0264368-57.0224)
Simulations	0.2082101* (0.0086215-5.028293)	1.000445* (0.9988567-1.002035)	2.42811* (0.0536242-109.9451)	(omitted)	0.6123383* (0.0073483-51.02634)	(omitted)	0.1101212* (0.0060966-1.989086)	0.2392537* (0.0044004-13.00834)	(omitted)
PatientTrials	0.897581* (0.0629702-12.79417)	1.000593* (0.9989094-1.00228)	1.266661* (0.0312075-51.4116)	(omitted)	0.8346303* (0.0105777-65.85656)	(omitted)	0.4504943* (0.0367124-5.527969)	0.4919855* (0.0112043-21.60337)	(omitted)
Feedback	0.0040172* (7.18e-07-22.47324)	1.004698* (0.9975223-1.011925)	174.5469* (0.022418-1359024)	(omitted)	0.461651* (0.0000373-57.11993)	(omitted)	1.21e-11*** (6.38e-15-2.29e-08)	6.54e-10	(omitted)

Note. Refer to Table 2 for variable measures. 95% confidence intervals in parentheses. ***p < 0.01, **p < 0.05, *p < 0.1

Qualitative

Ten hospital-based HTM professionals participated in the semi-structured interviews which were conducted in 2022 via Microsoft Teams with each lasting approximately one hour. Audio recordings were made of each interview which were later professionally transcribed. This resulted in more than 74,000 transcribed words (when including language from both the participants and interviewer, as well as name identifiers). All of the participants self-identified that (a) their primary function was HTM professional duties, and (b) that they were involved in the evaluation and selection of EME. The demographics included persons based in a variety of states, both females and males, and with varying organizational characteristics. Genders of the participants were 20% female and 80% male, which is similar to a 2022 survey of HTM professional

demographics which reported 17.56% female, 81.09% male, and 1.35% non-binary (Association for the Advancement of Medical Instrumentation, 2022). Table 4, below, provides basic information about the participants. Pseudonyms are utilized to protect confidentiality.

Table 4

List of Participants

Pseudonym	Gender	Title	Organization type
Larry	M	Director	Pediatric hospital
Alex	M	Manager	Hospital system
Ralph	M	Director	Hospital system
Steve	M	Vice president	Hospital system
Edward	M	Vice president	Hospital system
Henry	M	Director	Hospital system
Eleanor	F	Manager	Hospital system
Bob	M	Manager	Hospital system
Chris	M	Manager	Hospital
Debbie	F	Manager	Hospital system

Note. Further details surrounding each participant's organization type are withheld for the sake of confidentiality.

All ten of the participants were able to describe details of the intra-organizational processes used to evaluate and select EME within their hospitals. Some participants described process variations depending on the type of EME, the clinical users of the EME, whether the EME type was new to the organization, the funding source for the

EME, and various other factors. Some participants said that certain processes for HB-HTA of EME were well defined, while other processes were left to personal preference. Participants reported a wide range of type of involvement in the processes from controlling and leading them, to being well-integrated participants with some aspects, to being less well-integrated participants with other aspects. Overall, the group seemed to be involved in numerous aspects of HB-HTA of EME in their organizations, and certain thematic elements started to emerge as common to the group. Major themes arose, each of which was mentioned by multiple participants. The nine major themes were COVID-19 impact, multi-disciplinary committees, negative experiences, organizational changes, organizational substrates, power by proxy association, power self-acquisition through incrementalism, process definition, process exceptions, and value analysis.

COVID-19 Impact

Three participants described how the COVID-19 pandemic had impacted the HB-HTA processes within their organizations. Ralph stated novel situations arose that involved different EME selection tactics than used prior to the pandemic. In one case, his hospital purchased higher levels of technology than in the past, as a means to handle more higher acuity patients, if necessary. He also described how older technology started being retained for back-up, implying that in the past it wouldn't have been retained.

> The other thing that COVID has added to this is we had to convert a lot of areas over from say an observation area to an ICU type function. And then you're scrambling to get the right kind of monitors and do all of this. So the last couple of years, when we're buying and we're upgrading, say an observation (or) ED (or) OB area, and normally we didn't have a very high-level monitor in there. We're

buying a higher-level monitor so that, it's not if it's going to happen, it's when it's going to happen (another situation that involves a surge in patient volumes). We're able to just go, all right, we're now in that mode and we don't have to run around moving monitors from this area to that area. And we're saving a lot of our older monitors.

Edward also described how the COVID-19 pandemic had morphed the EME selection process, specifically as it relates to vendor presentations. Vendor presentations where essentially transformed to being fully virtual, as opposed to in-person in the past.

And for most of them now because of our COVID requirements, we don't do onsite demonstrations. We do a virtual demonstration where they actually live, do a presentation where they show how their equipment works. And the doctors and techs can ask eight million questions about this and that. "Can we see this? Can we see that?" Then we come back together and we evaluate the RFP, the demonstrations, the presentations, and come to a conclusion.

Another participant, Chris, described how the COVID-19 pandemic created supply chain challenges and some technology wasn't readily available. In response, his hospital looked at juggling priorities through a negotiation process.

COVID posed an interesting challenge for that because a lot of places had nine-month back orders so I couldn't do it with some technology and I ended up, because I'm aware of the capital plan, I went to (department name). I talked to them this year about some of their equipment and said, "Look, I have a project that I can't spend a million dollars on this year because it's just not going to land. It's going to be next year money anyways, so I'd like to buy one of yours. Let's

> buy the (EME type) that you are requesting next year and we'll flip the justifications. We'll bring your VP in. Let's have a conversation with them, make sure that that VP and the Nursing VP are on board with playing ball with each other and saying, I'll give you this if you give me mine next year, and it all makes sense."

Chris went on to describe short-term negative impacts on the availability of capital funds for the purchase of EME, and how it confounded the organization's prioritization process for routine replacement of EME.

> COVID basically put a lot of our capital on hold because we had to address funds towards whatever the COVID need was. We had to buy more beds. That was by no means part of the plan; wasn't part of a replacement plan or anything. We were shoveling money towards a fire and we couldn't (sic) the fire that was going to happen down the road. And now we have a lot of equipment that we have and the support states that are challenging the support (because funding wasn't available to replace it sooner), so much so that it's too much in any given capital year to replace or even reasonably request. So it becomes a question of, "alright, how do we prioritize this?" And that's already the highest priority.

Multi-disciplinary Committees

Half of the participants described committee structures that were comprised of persons from varying disciplines. While it was unclear who the typical conveners were of such structures, using a consensus-based process where stakeholder feedback was considered seemed to often be an extant part of HB-HTA. Larry noted that they had a device management committee, that is "a multidisciplinary committee made up of

different areas of IT, biomed infection control, facilities." He talked about how research is conducted, and "any relevant documents" get submitted to the device management committee for review. Larry went on to describe how the committee routed approvals.

> Once each of these areas has their questions fully answered, then it'll be approved through the committee and then go back to the department, the director to obtain the signatures. They get these signatures; everybody signs off on it as it comes through. But then it'll go back to the vice president to be looked at because during this process, Facilities (Plant Operations) and Biomed have the opportunity to add cost. If we're putting in a new X-ray (sic) or replacing a(n) X-ray machine, any construction that has to be done, any codes that have to be updated and new construction or construction that would be relevant to this would have to be added to the cost of the equipment; the physicist reports, the surveys, those type things would be added into the cost.

Ralph also described a committee structure routinely in use at his hospital as it relates to HB-HTA.

> I will have to say, the organization as a whole has historically kept Clinical Engineering in the loop and we have a committee, it's called the technology management committee. So any equipment, medical equipment, new equipment over $50,000 or replacement equipment over $250,000. And that's changed when I got here. It was $25,000 when I first got here for both. Goes in front of this committee to vet out for total value to the organization. Several different factors we look at to give us a total value score, and then, based on what the capital money is, we just kind of go down and either red line stuff, green light something,

yellow light a few that may or may not, depending on how the things go. And then things that are definitely redlined. And based on all the input we give, the clinical input, the financial side of it, and then that comes out of this committee to go to the different areas for when they decide to actually buy it.

Ralph also voiced that the committee structure acted as a venue for HTM to have a voice in HB-HTA.

During our committees, being a voice there just to understand, questioning the service side of things. But then when it actually comes to deciding which model of a CT are we going to buy, why do we want this particular manufacturer/model versus this one, and try and take and just be a piece of the information so that all the holes in the cheese line up in a positive way so that we're getting the right piece of equipment for the right reasons and not strictly clinical or not strictly Biomed or financial. You got to put all of this together and give it and make a sound decision. And at the end of the day, the decision may not be what Clinical Engineering says we want, but we gave you the information, then the system (organization) made a decision, and now my job is to support it, and whatever that takes to keep that equipment going.

Steve was yet another participant who described committee structures in place to conduct HB-HTA of EME. In particular, Steve described the authority of the committee structure to make binding decisions that must be followed.

Now, the next layer is there is a system-wide committee, a technology standardization committee, and decisions about system standards all are made by this committee. It's a multidisciplinary committee that has physicians and

Nursing and Informatics and Biomed and Sourcing and just a full range of people who might have input. And so this technology standardization committee, their responsibility is to make system standards decisions. And then if that committee makes a decision on, say defibs, so then that is the system standard. Everybody has to buy it. Nobody gets to deviate without special permission. So if you were to say, how do we make decisions about if we're replacing all defibs (sic), that committee makes the decision on what the product is, obviously with input from the clinical staff, right? But that's the committee that decides it. And then everybody has to follow that standard with whatever funding might be available.

Steve went on to describe how not only was the committee structure empowered to make final decisions, but to control the processes through which the committee operated.

And so, this committee led the effort to look at the choices on the market, coordinate the demonstrations from the vendors and do the clinical analysis and the technical analysis. And then all that information and all the feedback from all the stakeholders came back to that technology group and they made a decision.

Edward also related details of how committee structures were used at his hospital system, with a particular focus on the patient aspect.

On a new technology, all of those are going to have to be reviewed by what we call our (proprietary committee name redacted). That's what that stands for. And they start off with filling out a template that we give them, where we want to know just a few things about this technology before we even begin anything. What they do, then, is they fill that out and then they have to present that to the

(proprietary committee name redacted). And it's everything from just the basics, "What is it? What is its intended goals going to be?" A lot of cost performance stuff, a lot of stuff like, "What could this do in terms of the competitive landscape out there? What does it do in terms of clinical care? Is this going to be an outcomes-based product? Or how is this going to benefit the patient?" That's usually, we try to pride ourselves being very patient-centric, and so generally most conversations in (organization name redacted) lead with, "What good is this to the patient?" You look at that, and work your way, really, from that perspective.

Edward went on to describe additional rigors of research that must be done and submitted to committee.

We work very hard on establishing what evaluation criteria and the measurement systems are going to be, and then set forth to go do that. So, it is a documented process. There's a little bit of discipline to it, and it's not really, you don't get to just make your decisions on a whim. You've got to fill out the tool, you've got to provide the results of that, and you're going to come back to the committee, and you're going to share your results along with your recommendation to move forward.

Larry also described the particulars of including certain persons in the committee processes; specifically, physicians. He stated that when physicians get engaged in the work they get very involved in the work.

And that's one stipulation that I have as a doc is that, "If you're going to be involved in one of these committees, you don't just get to be half involved, you

better be prepared to go through end to end, because if you're going to start at the beginning, I need you all the way through it." And so that's been interesting, too, because your mouthy people that just want to mouth off don't typically want to commit. So, they self-select their way out of there, and then the people that really want to be there and participate are. And so that's, again, where we get a lot of academic health. The academics love to do stuff like this. It feels like clinical research to them in a way and they just do. And so they're great allies in a process like this, although not exclusively all the docs that participate. I don't want to make it sound like that, either.

Eleanor also described committee structures in her hospital system, where certain requests started at the local level, and eventually make their way to a corporate level. She described that HTM was not always involved in the higher-level committee process.

So, for a typical equipment replacement, it does start at the delivery network level still, where they put together their prioritization list that gets arced up through to the system capital committee. Once it hits the system capital committee, along the way, there may or may not have been Clinical Engineering involvement. We are definitely working to get that involvement on the push up to the system capital committee as opposed to it coming back down.

Eleanor described how this approach sometimes led to late- versus early-stage involvement in the HB-HTA processes, potentially causing delays and urgency in formulating HTM's opinions on the matter.

If it reaches the committee, they will ask for Clinical Engineering input on the equipment and then at that point, then we have to do some backtracking to do all

of that research that ideally would've been done upfront on the backend now. So, there are some of those delays there. And if equipment comes through that capital committee as an emergency replacement, we have to look at it immediately as opposed to during their monthly review. So those are the very one-off devices.

Eleanor also described some nuances in satisficing organizational culture with both corporate level controls but allowing for some local autonomy.

So, we rely on the clinical delivery networks to make both not low-level decisions but more intimate decisions with the equipment. It's very culture driven. But again, that's why we are pulling everything into that system committee because while we want them to have some of the autonomy and say in their priorities, if there is a system standardization that we recognize exists or needs to exist, we'll definitely pull in the service line leaders from the other delivery networks to help make that decision. So, they'll say our anesthesia machines need to be replaced. That's our top priority, but they're only going get them if they fall in line with the system standard.

Eleanor went on to express some frustration with some lack of process definition for the system capital committee.

Sometimes—we have an office of project management—sometimes they would lead the evaluation (of EME). It is definitely disjointed and not the same every time. I would love for there to be some guidelines around that from the system capital committee.

Eleanor also described how committee outcomes weren't well memorialized or communicated.

> Yeah, I would say the biggest issue I have personally with the process right now is that there is no really good tracking on what has been approved as part of the system capital committee process. It basically relies on people's memories to be like, "hey, didn't we just approve something similar to this a couple weeks ago?"

Debbie was the last participant who focused some commentary on committee structures being used for HB-HTA.

> We have a centralized process that we use across all of (organization name redacted), and I was responsible for rolling that process out to all of the markets, building the structure behind it, making sure people were trained, following protocols, charters in place, et cetera, et cetera. Very committee-heavy and decision by quorum.

Debbie went on to describe some relationship from local entities to the more corporate structure. "The (committee name redacted). That is a multidisciplinary governing committee within each (organization name redacted) market," she said. Below the multidisciplinary governing body, she described the existence of additional committees.

> Then below that we have a multi committee system where each committee has a specialty. Maybe they're surgical specialists, maybe they're radiology specialists, and each committee is then co-chaired by a physician leader and an operations leader, and then has subject-matter experts participating in that, and our clinical systems engineers are directly responsible for coordinating the work of those committees, analyzing inventories, measuring equipment utilization, and figuring out how we can put new workflows in place to help us (sic) utilization, helping us

build those priorities under this consistent framework that we have through the (committee name redacted) about the language and the workflow for prioritization. All of that rolls up to governance, again, regardless of whether it's lifecycle replacement, net new growth, or this transformative technology for final endorsement and decision before being funded and then executed on.

Debbie made a point of stating how committee members are asked to be delegates for the stakeholder groups they represent.

What the ask is, is that when they participate in these committees, they're not just thinking of their own needs, they're thinking of the region's needs, and we're getting them outside of, this is what I do in my individual practice, and we're asking them to think about "how do you know that you have the right number of devices? How do those devices scale based on caseload, based on membership growth in the organization, based on population changes or demographic changes that might come over time?" What we're asking is that the committee members, those individuals who participate, are thinking about what's the right allocation strategy so that regardless of where they practice as an individual, we're ensuring that the (organization name redacted) experience and the quality of care that we provide is equalized by the types, counts and accessibility of the equipment that we have so that you know could be in (city name redacted) or (city name redacted) and get the same type of care that you would in (city name redacted) or one of the wealthier suburbs in which we operate compared to maybe one of the more urban or less wealthy neighborhoods in which we have centers. It's not about what do the individual facilities need. It's about how do we measure

> equipment utilization so that we make sure that all of our facilities get what they need across the board and we don't end up with certain sites who know how to game the system or know how it works and other sites that don't, and then we end up with a disparate quality of care as a result.

Debbie described how individuals don't always have available time to spend in the committee structures.

> Again, it's decision by quorum, decision by committee, and we try to keep the committees a reasonable size. We don't want 300 people trying to make one decision. At the same time, we want to make sure we have the right decision makers who can help us enforce the outcomes, educate their peers, et cetera. These committees are essentially by volunteer. They don't always have admin time that the organization gives them, which is one of our challenges, to be frank. The organization says, here's the process we're going to use, but figure out how to do it on your own time. That's the nature of how (organization name redacted) has grown over time.

Debbie at one point added, "if you're catching onto a theme, (organization name redacted) loves to do things by committee."

Negative Experiences

A majority of participants (six) described situations where negative outcomes occurred with EME within the context of HB-HTA. Larry described a situation where the hospital decided to convert pulse oximetry technology from vendor A to vendor B, but the decision did not play out as expected.

Yeah, I guess one of the things that's really come up over the years since I've been here is the (manufacturer A/ manufacturer B) thing. We've standardized to (manufacturer A). And at one time, we decided we're going to start going with (manufacturer B). We started buying in that direction. And we quickly found out that the change was costing us a fortune in disposables, having two processes. We were going to do it over a number of years and that didn't work out. We ended up taking out (vendor B's) equipment we installed and going back to (manufacturer A). And then agreeing to review every five years the technology and the needs and see if we wanted to go in a different direction and go with (manufacturer B). We did this, about two years ago was our last review. And now we've had a big push with a (manufacturer B) rep that used to work with the nurse that used to work for the hospital, that's now working for (manufacturer B) and she's working with physicians on the backhand. And her predecessor years ago was told never to come back in the hospital; written a letter from a CFO, saying never to come back to the hospital. But she's about one step away from that.

Alex described a situation where he wasn't proactively involved in the assessment of a new surgery technology being looked at.

There is another piece of effort as well, that just happened a couple of weeks ago, actually. They were trying to buy a new functionality robot. It's not like the (manufacturer C), it's designed for other functionalities and there is two different vendors. So, the end users in the OR, they did choose two different vendors to select one of them. They went either with the (manufacturer D) or with

(manufacturer E). They did the demo, they did everything and we were not aware of it. We are trying to standardize, but still people think that they have the right to go out and get any information, call the vendors, let them come in, do a demo for the equipment. And we weren't aware even just to check in to make sure that the device is okay to be demoed. But accidentally, going through the hallway, I saw the OR director who's responsible for that order and she tells me, “hey, by the way, we're looking at buying a robot and I have two options that we’re looking at. We don't know which one we need to go with. Would you care to take a look at it?” And I was like, it shouldn't be an option. It shouldn't be like would you care. It should be, I have to take a look at it. So definitely please send me the information after. I’ll take a look at it. And then she says, "but by the way, we are meeting in two days.” So she told me on Wednesday and they're meeting on Friday to take a final decision, which one they want to select. So, I said, “okay, even though that's a very short notification, short notice, for something big that needs lots of effort to review the technicalities, but I'll make sure to give some value back to you guys.” So, I did the analysis, I did the review and provide them the feedback. I wasn’t able to attend that Friday meeting. But then on Monday I received all the feedback of how happy everyone was in that meeting, because it was all the chief medical officers, and our finance leads, and it's like a $1.6 million device they want to buy, and my feedback was the sole source for them to take a decision. They didn't have any other input besides, “oh, I like this how it looked like. I like how the vendor said this can do.” So, the only actual data that can be compared, was the input I gave them because it was (a) technical

evaluation, taking into consideration also the cost. And even though my choice was for the more expensive device, not the cheaper device, but I gave them why this is a better option going forward... you're paying extra now, but you're going to be saving down the road, and including the service cost as well, and the cost of the life of the device, it made sense, and this is how they chose this is how they took the decision. So, I met with them afterwards and I said, "you know, this is what we can bring to the table. So, you shouldn't go out and try to seek and find vendors and try to take a decision and just accidentally give me that information. That should be part of the process." So, we are doing something, but we're way far off of where we should be. And to conclude on that, I do agree that any capital process, and when I say capital requests, I don't totally agree with saying that any capital process should be within HTM. It's not just capital. Any medical device requests should be sent to the HTM department.

Steve detailed an experience where a decision made a number of years ago didn't work out as intended.

So, our organization made a decision three years ago to engage in a 10-year committed contract with (manufacturer F) for imaging equipment, 10 years. So, (sic) we got a bigger discount on their equipment because of that commitment and the dollar commitment, and that commitment included mammo. And it turns out that (manufacturer F's) mammo equipment is junk and everybody hates it.

Henry described a situation where HTM was involved in a process, but the outcome was initially flawed because of incorrect information.

> And one of the things this year was a bunch of stretchers, and one of the locations we found out had imported improperly to the CMMS (computerized medical device inventory management) system. So, because the number didn't transfer when we acquired the location, so the date that we acquired it was when it was put in for all these stretchers. And when you're looking at 60 locations, 40 hospitals and a bunch of imaging centers and urgent cares and all of those things, you might not catch that. You might not catch the pattern that can tell you, "hey, this stuff didn't transfer that." So, actually what happened is one of our Biomed II's reached out to me and then I reached back out to her direct. Well, she had told her direct report as well, but, "hey, these need to be replaced. These stretchers need to be replaced." And so when we had that meeting, he had gone back, followed up, came back to me and said, "Hey Henry, these are a lot older than we thought. These are not from 2015. A lot of these are from 2001, 2002, and they're falling apart." And this is a director that has three different hospitals. So, they're small hospitals but they're still three different hospitals. And so we were able to move them up the ladder, so to speak, put them ahead of a couple other hospitals that we were just more preventative than anything and be able to replace their fleet of stretchers, it being a smaller hospital. Had it been one of the big hospitals, we would've had to do partial replacements. But it really does make a difference.

Eleanor described a situation where EME arrived at the hospital and HTM had not been involved in the assessment or it and didn't know it was coming.

> Oh yeah, I got a call this morning from my OR staff saying that 50 of these standalone SpO_2 (pulse oximetry) monitors showed up, which are one vendor, and we are literally standardized everywhere else with another vendor. How these came in is a mystery. I still don't know.

Chris described how sometimes EME was selected without more broad, multi-disciplinary involvement.

> Radiology, for example, (was) signing multi-year purchasing agreements for devices and not really involving all the team members, like IT security. Not doing the multi-team approach, which creates this siloed-based structure where decisions are made and the other teams can't even weigh in and they can't add to the topic of the conversation.

Chris also described the purchase of EME, specifically ventilators, where HTM pointed out some concerns, but they weren't incorporated into the final decision.

> We bought vents because ours were starting to reach a point where we were uncomfortable with the amount of repairs we had to do with them, and the clinical staff elected to stay with the same exact vendor, the same exact product, just to refresh the inventory essentially to get to a level state where we weren't having massive repair efforts. And it was the cost-effective strategy, but in my opinion at the time, and what I tried to express to the clinical team, is they were locking themselves into a technology that was dated and that newer technology existed that provides additional benefits to other alternative therapies where you can now bolster your inventory to basically do all these other therapies and have one device to use it all. So they agreed that that was nice, but, "Chris, isn't that a

> waste of money? That costs more. Why do we need to do that?" And I tried to explain to them and show them the cost assessment that as we start to sunset other technology, you just bolster your inventory, you're going to have less in aggregate of all the devices and be relatively cost neutral. Don't consider cost being the threshold here. They still elected to move that way. Going into the pandemic, high flow was the technology needed and (the) ventilators (we had purchased) weren't the best (because high flow wasn't built in) and we were heavy on vents and we needed to buy more high flows. Nope, we couldn't get enough of them. They were kicking themselves afterwards so, you know, you can't get the stakeholders to do what you want. You can only explain to them the benefits and I try to always explain that having a multiple backup scenario is the best approach. Having essentially contingency plans is something that we need in healthcare because we can't plan for the unknown. I think the pandemic proved that, so I have a lot of clout here now that's just pandemic driven where I can say, "Well, we need contingency options," and we plan for them now and we build it out.

Organizational Changes

Several participants described how intra-organizational changes, such as the acquisition of another hospital, or changes in organizational structure, confounded HB-HTA processes. Alex described how a change in leadership caused some of the prior structures in place to dissolve, and processes reverted back to the way they were previously.

Now for the OR manager or director, we've worked with her in the past, we used to have monthly meetings to review her capital requests, what she's planning, and we give her advice of what we can see in the next year or next five years, that you might need to start looking at replacing and budgeting for her budget. But change in leadership eliminated some of the positions that were attending those meetings. That meeting just kind of got forgotten. So it wasn't (sic) an intention, it was just that she went back to how she used to do things before we established that connection after the absence of the leadership that were kind of governing that meeting.

Ralph described the acquisition of a hospital and how challenges arose in aligning their processes to the established ones in the existing organization.

So about two years ago we bought a hospital down the road and brought them into the system and they're in (another state). And (the other state) has some really funky…rules about reimbursements and financials and all this other stuff. So, we've got to keep them in many ways separate from us than what we're doing here with a lot of what we're doing, plus it takes time to merge all of your different stuff and getting them on the same platforms and the same processes that we're doing. And any time you get a hospital like that, there's a staff changeover as well. We're taking some of our leadership, going down there. They're leaving or they're doing whatever. So, you have a little bit of cross talk. So, what's going on now is they have one interventional lab, IR lab down there. And historically they didn't really have good strong facilities. We have a strong facilities department, we have a design and construction area department. They had five

people in their facilities (department). It's kind of a rural hospital. And no design and construction. So now they come in and it's like, well, one, they want to replace their IR lab and their Mac-Lab (hemodynamic monitoring system). Okay, that's fine. Mac-Lab was old, all of this. And instead of bringing the IR lab to the right people, they went and took the Mac-Lab to the IT group, which is fine, but they included the lab, the IR lab, into that evaluation with the IT group. Well, the IT group didn't evaluate the IR lab, of course, but they didn't tell them we're not evaluating the IR lab. They basically said, here it is. This is what you want to get. Okay, well what about the IR lab? So, the people who were there, they have a (manufacturer G) unit, and they wanted, okay, we're going to stick with (manufacturer G).

Edward, when speaking about hospital acquisitions that occur and how those can sometimes involve friction of cultural adaption, made some statements based on his experiences.

I'll say about just cultural adaptation if you will, on a merger. Generally, what I find is (cultural friction) to be true with leadership, for sure. The higher you're up in the organization, the more quickly you're going to have that kind of mindset…. As you get closer to the point of care, though, that's not like that. That takes some work. And we've been through a few of these, I'm sure you have as well, but that has always been part of our MO is that we usually know in the beginning, the meetings with leadership are easy. It's just a matter of explaining, and showing, and they'll forget and here's who you call when you forget what I just told you, and that kind of thing. It just, it's very, very easy. The work is really at the point

> of service, it's really getting care bought into it, physicians in particular. The physician that practiced badly yesterday and wanted his own private stash of equipment is going to be no different after the merger. You just have to work with them, and it's not going to work like that anymore. And really, like we do with the other, I think like I said in the beginning, you have to pivot off some of your narratives. So, the last thing a doctor really wants to be bombarded with is how you're going to improve his cost per case, and this, that, and especially when you're dealing with preference items. So again, we go at it with very clinically minded debate on how we're going to work on outcomes together, how we're (working with) you wringing out variation. We're really looking to ramp up quality control and just again, going that way. That's typically our pitch. And we've learned that how to appeal that, I think to, well, it's like anything else when you speak, it's knowing your audience. Healthcare is not a one size fits all audience, again preaching to the choir. You know that. But you really got to tailor what it is that you're saying depending on who's listening.

Organizational Substrates

Two participants described how strategy set by senior leadership helped to promote the inclusion of HTM into HB-HTA processes. Edward described some organizational strategy that both informed how he approached things, but empowered his work.

> When you acquire facilities, of course there's a little bit of that cultural stuff at adaptation, if you are putting that nicely, that you have to do as you're all trying to assimilate. Our CEO has built an organization, really from the beginning of

(hospital system name), that was designed of what we call an operating company model versus a holding company model. And so, it is an expectation. If we acquire you, if you're part of the group, you don't get to be you anymore, you're (hospital system name). And so the processes of (hospital system name) are coming to you and really, what we do, and it's known, it is known before we negotiate. Because if somebody has a problem with that culturally, you're probably not going to end up with us, (that's) just the way it is. And so with that said, then really all we have to do is really just go in and educate people on, "okay, well, this is what we do and how we do it. And this may look a little different in there." And we try to understand a little bit how they did it before so that we can explain, "here's how it's going to be different, and what we think the perceived value might be." Now, not to be too arrogant, because sometimes you'll ask somebody a question and they got a better answer than the one that you have. And so maybe you change a little bit with the way that you're doing things. I just put that out there because I'm very open to that, whether it's just service delivery or if it's whatever. Hey, all the good ideas don't originate out of (hospital system name), that's the thing. So if we can make it better, we will. But a lot of times what I find with capital, anyway is that people usually have a pretty poor process. And so generally what we're installing is going to be beneficial. And it's just a matter, again, working with finance, making sure that the capital pools are adjusted so that new facilities that you acquire yet to participate in some way. And then after that it's just, you know, run your process.

Bob also made specific reference to an operating model as opposed to a holding model. Bob said "we've gone from a holding company to whatever they call it, operating company. So actually, the head of equipment capital is part of Clinical Engineering." But he did go on to mention exceptions, such as joint ventures where "they can do whatever they want; they don't contribute to our capital."

Power by Proxy Association

One participant described how their own power within the HB-HTA context was positively influenced through support from the senior leader to whom they ending up reporting to. Alex described how this wasn't necessarily a function of formal power, but of the personality of the particular leader who was in place. He described how his previous leader (the previous senior VP), was happy to remain with the status quo.

> Once we got new leaders and new senior VP, he's coming in fresh with fresh ideas. He understands what HTM is and the value that they can bring. So, he was a very strong advocate and whenever we present something that does make sense, he can understand the value and where we're coming from, and how we can benefit the organization.

Power Self-Acquisition through Incrementalism

Four participants detailed how they grew their power and influence over time as it relates to involvement with HB-HTA processes. Steve detailed how his influence has grown over time.

> When I came here, nobody knew me. I was nobody. And now, basically no money gets stuck without somebody asking me about it. And I have no authority, but I have a lot of power because people listen to me. And so, I had to

demonstrate a value. And they come to me now. I don't have to go to them and say, "hey, you really need to do X, Y, and Z." They come to me and say, "What should I do?" or, "how should I move forward?" or, "what do you recommend?" or, "is this proposal that a department is giving to the administration, is this legitimate or not?" I'm the sort of BS detector to read it and give them an objective assessment. So, I read the business plan, and I say, "yep, that's wrong. This is right. They're overstating this. That patently falls." Yep.

Steve went on to describe the process of acquiring power as somewhat iterative over time.

Our job is not to decide. Our job is to make sure that the organization understands the risk and the implication of their decisions. Now, if they ask us to decide, which in my case, they have. They said, "here's a bucket of money, you use your best judgment essentially and buy what we need." Okay. But beyond that, I just say, "here's the request." And in my organization, every request for medical equipment I look at, and every major request over 500,000 (dollars), I do an analysis and write up an assessment and a recommendation to send to the committee that decides. And then I go to those committee, those meetings, and they read my recommendation and everybody knows, okay, "Steve said...." And they can ignore it or they can accept it. Largely is, it's what my reputation is or what my credibility is. And I've been fortunate that I have developed the credibility that they generally do what I suggest they do. But that didn't come automatically, right? And so this is the other thing that I think is useful for HTM to recognize this. Look, you don't get listened to, and you're not credible just

> because you're HTM, but you have to place yourself in the environment, in the meetings and in the conversations with the clinical or administrative teams to develop the credibility. So, if nobody's listening to you, it's because you haven't figured out who and how to talk to. If they're not listening, it's because you haven't made your voice invaluable.

Alex also described how at his first employer, he wasn't able to become more involved in the EME acquisition process. But he's been able to grow his influence at his current employer.

> This was one of the shocks I faced when I saw that the Biomeds are kind of a very limited functionality of, you just do this (repair and maintenance of EME) and we'll take care of everything else. And I was very vocal about it. My first employer didn't like how vocal I was, which led me to leave them, because for me, I see I have all this knowledge, this is my specialty, this is my skill. Why would you even think about acquiring, or trying to change something, or change medical devices or look at the new practice, what type of devices do you need? Why do you go and have the vendors meet with the end users and sell them things? Do you know, do you have any idea that they have no clue what they're talking to? Do you know who is the one capable of telling you what is the best option for you? I'm here anyway. You're paying me. Why don't you use me? And nobody liked that, because "no, no, it's not your job." We do whatever we want. And the rep comes to the doctor and he feels that good relationship and now the doctor wants this device.

Ralph also described an incremental approach to becoming more involved in the EME acquisition process.

> When you're at the table, one (concept) is, how you get yourself invited to the table is different than once you're at the table. But once you're at the table is making sure you're bringing value. Because a lot of times I could be sitting at the table, but if I'm not bringing any information forward, I'm not challenging the norms or I'm not doing whatever and I'm not doing it just to do it. But you have to be there to say, well, wait a minute, you want to replace this device that's three years old, it makes no sense because it's physician preference. We're not going to go that way and having the intestinal fortitude to actually stand up and do that. And having the fortitude to actually speak your mind and bring it, but you can't just say it, where's the data behind it? Or hey, you know what? I don't have the data right now, but let me gather it and send it to the group and show you why I'm saying what I'm saying. And being able to do that. I mean, again, it's being able to bring value. And if you're not bringing value and you're just a lump on a rock, well, that's not going to help.

Ralph also described how Clinical Engineering at his organization oversees certain categories of EME.

> So Clinical Engineering centrally manages the ownership of IV pumps, defibrillators, like the (model name of endoscope reprocessor), patient monitoring, things like that. All of the high-volume stuff, clinical, and we want to manage as a system. Clinical Engineering, we own that. So, our job is to put together, so like defibs, we just replaced defibs, right? I mean, two months ago.

So, the process started year and a half ago getting the right teams together, all the physician input, nursing people on the team, the who we're going to get, what devices we're going to get. And then also, we have a group called the (team name) in (organization's name), and that group is trainers and they have usability factor people. I mean, they look at all of this. And then we have a thing called the (simulation) lab, which is a virtual education training lab. So, they're the ones that train the new people that come in, the physicians keep their skill sets up, they got all the mannequins and all that stuff in there. And so, we get a couple of these loaners, we take them down there, they put all this stuff through their paces to see which one everyone wants. And I'll pick on defibs in particular. As we went through all of this, the usability choice was, hey, we like the (manufacturer I) defib. Okay, great. However, then you come back and then we got to shake that common sense and financial thing. All right, well, our financials are, it's going to cost us about 1,500,000 (dollars) more just to buy those defibs. Plus, our operational costs are going to be about three times what we're going to pay with the other vendor on an annual basis. So, the decision financially was yeah, we're not going to go with them. We're going to go with (manufacturer J) and we're going to buy them. And then now you have the other problem where (manufacturer J), couple of years ago we bought the (model 1), and then they came out a year after we bought them and said, ah, we're no longer going to sell the (model 1). And now, so for our transports, we went to the (model 2), which is an aged platform. It's been out there for a little bit. So, we're like, we're really hesitant about buying this platform if in a year you're going to come out and tell

me you're no longer going to sell it, and now I'm relegating third party market and all of this. So, we went back and forth with them (on that issue).

Edward described how initially HTM's influence at his organization was limited, but that he saw an opportunity to have influence across acquisition processes for all types of EME, what he refers to as "all play."

> Well, I think the thing that we were aiming to get at first was we were all play, is what I would call it, in a lot of different things. Not so much on the supply side, but we certainly had that on capital. On the non-imaging side of capital, we had, in a very informal way, have had quite a bit of influence, that without really any processes and stuff like that, we were able to get agreement and consensus on consolidating. In medical imaging, and OR, and some of what I'll call the high revenue places, not so much. And so yeah, I think the idea was, is that we knew that we were just missing out on lots of value by (not) being all play. That that's just not really a way to do any kind of expense related management, for one. One of the arguments that I made, so it's interesting when you talk to physicians about expense management, you get a lot of yawning, most people don't care unless it touches on an item to them. It doesn't influence much of the what they want mentality. So, I did change the argument a little bit of that with them and said, "we've got a clinical quality problem. You don't realize that any variation that you introduce really influences patient outcomes. And I don't think that's good for (organization name) and I don't think you want that, either. So let's tackle the problem from that angle first." Again, now it becomes centric and we're going to pick up supply chain benefits and all these other things by default.

Chris made a more general comment about his role as an HTM leader, relative to being involved in such things as the process of evaluating and selecting EME.

> In all honesty, I think this job is completely not technical. I mean there's technical aspects, don't get me wrong. To succeed at this job, I don't think you need to be technical. I think you need to be more political and socially adept than anything else.

Process Definition

Four participants described how their organization had made an effort to define HB-HTA processes and memorialize them into a policy and/or checklist. Larry stated they had a regular process documented for acquiring groups of EME, and a separate flowchart for single purchases. Edward described a standard template that had to be filled out with certain information. Henry described a standard format used to request vendor proposals, with each section's content owned by a subject matter expert group. Eleanor described having a "generic process," with a goal of following the same basic steps each time it is performed.

Process Exceptions

Two participants described how their HB-HTA processes included allowances for exceptions to be made due to certain circumstances. Edward stated that exceptions happened and described how the process considers that fact.

> So yeah, I'm not too worried when we have to make an exception…. Sometimes it's just such a one-off, it just doesn't cleanly fit into category. It could be something we have to buy to recruit a top-notch surgeon, and it's not our standard, but "okay, we just got to do this." Or it could be a board member does something.

> There's always things in there, and because we do clinical research—there's another thing—you bring in stuff and that just because it's supporting a research project, and you just got to understand that research is going to be a little bit independent of these type of things. So those again would be some example exceptions in there. I think every organization has it, but obviously you don't want that to be your everyday occurrence.

Henry described a situation where technology variables influenced the process to select EME for replacement; specifically, when manufacturer support no longer was available for a certain EME sooner than expected. "And there are exceptions," he said, adding "we recently had four, and it was just four, ICU beds that had been purchased from (manufacturer H) that within six years they weren't making parts for them."

Value Analysis

The term "value analysis" was used by two participants. Larry described having a "value analysis department" at his children's hospital. He said EME that's going to be trialed, or when the organization is looking to make a switch from one product to another, such decisions must go through a value analysis process. Larry described the value analysis function at his hospital system as being separate from the supply chain/purchasing function, and that it had dedicated support staff. Edward described having a value analysis team and that in the past it was "all supply chain," but that now he participates in the process because there is a combined team (between HTM and supply chain) that evaluates EME decisions.

CHAPTER 5: SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Introduction

This dissertation study was aimed at understanding the current state of HB-HTA in the U.S. as experienced by HTM professionals. This study was able to achieve some of its stated goals, in some aspects with less sophistication than desired. While a survey was administered, it failed to reach power and may be biased, and its findings must be viewed with that in mind. The findings of the survey, including descriptive statistics and attempts at multilevel logistic regression, were presented in Chapter 4. Conversely, semi-structured interviews uncovered both intra- and extra-organizational factors that can give influence to the processes of HB-HTA. The findings of the interviews were also presented in Chapter 4. This chapter will focus on summarizing the study, discussing its thematic findings including key elements, discussing potential implications for practice, and offering recommendations for future research in this domain.

Discussion of the Findings

Research Question 1

What is the current state of HB-HTA in the U.S. as observed by HTM professionals?

This study established that, in the limited sample that did not reach power, the majority of survey respondents are using the HB-HTA processes selected from (a) Sampietro-Colom et. al's guiding principles, and (b) the EUnetHTA HTA Core Model 3.0. In the sample, 84.6% of the responses indicated that HTM was routinely involved in

the hospital's HB-HTA. However, this may indicate selection bias in the limited sample size, meaning that HTM professionals not routinely involved in HB-HTA did not participate in the survey. Drawing statistically based inferences from relationships of dependent variables to independent variables was not possible due to not reaching power and lack of statistical significance across multilevel linear regression attempts and subsequent bootstrap methods. Given these factors, the hypotheses were neither able to be confirmed nor denied. From a qualitative standpoint, rich information was gathered through interviews that highlights nine major themes with regard to how HTA is occurring in some U.S. hospitals.

Research Question 2

How is HB-HTA in the U.S., as observed by HTM professionals, predicted by organizational attributes?

HTM professionals who participated in the semi-structured interviews were universally involved in the HB-HTA processes at their organizations. As such, interviewees described their personal experiences with HB-HTA processes from a first-person account. Each of the participants seemed able to articulate detailed descriptions of the HTA processes used, which processes were codified and which ones weren't, and aspects that might be personally frustrating. The phenomenological study suggests that a variety of themes might directly or indirectly influence the HB-HTA processes used. The semi-structured interviews elucidated a number of themes, some of which were repeated among different participants and were discussed in Chapter 4, and which will now be discussed in more interpretive detail.

Thematic Elements

COVID-19 Impact

Several interview participants described how the COVID-19 pandemic had influenced HB-HTA processes. These ranged from more basic impacts (such as having to modify vendor presentations from in-person to virtual and dealing with short-term delays in acquiring new EME) to more enduring impacts where one hospital described making EME purchases while considering that another pandemic surge of patients could happen at any time. All three of these elements describe factors in the external environment that influenced the HB-HTA processes. This is consistent with the concept of contingency theory, whereby organizational decisions are influenced by environmental conditions (Scott & Davis, 2007). Environmental conditions could also be termed the "outer setting" as described in the CFIR construct ("Consolidated Framework for Implementation Research," 2021). Ultimately, the data suggests, at least in this context, that internal administrative processes need to remain flexible so they can morph as needed to external conditions.

Multi-disciplinary Committees

Half of the interview participants described doing the work of HB-HTA through a committee structure, some of which were described as permanent vehicles for certain dynamics of EME evaluation and selection. Such an approach might be considered a classic organizational form for a project team (Scott & Davis, 2007). Multiple participants stated that multi-disciplinary committees served as a vehicle for considering multiple, complex factors associated with EME, such as potential infection control or facilities construction implications. One participant described the binding decision-

making abilities that a committee had been empowered with. Another participant described how committees can empower HTM professionals with a natural venue to provide input and build influence. Yet another participant described how committees weren't always effective and productive in achieving outcomes.

Negative Experiences

Somewhat unexpected was that a number of the participants described examples of negative outcomes with their HB-HTA. While it may be easy to assume that no administrative process would be infallible and that errant decisions are going to be made from time to time, some of the negative outcomes seemed fairly significant. Some of the negative experiences seem to have arisen from factors that weren't easily ascertainable prior to implementation. Other negative experiences might have been prevented through more diligent HB-HTA processes. Scott and Davis describe how Perrow argues that complex systems can have "unexpected interactions of failure" and how these are perhaps "inevitable" (2007).

Organizational Changes

Hospitals can be dynamic organizations that might be subject to constant change. Several participants described how organizational changes shaped HB-HTA processes. One participant discussed how when another hospital was acquired and brought into the existing organization, the acquiree wasn't immediately aware of the normal processes and resources available to it for HB-HTA. This resulted in a technology not being appropriately assessed (as stated by the participant), at least initially. Another participant described how a leadership change (elimination of some leadership roles) caused a de-evolution of HB-HTA processes, again, at least for a while.

Organizational Substrates

Two of the interview participants described how their organizations had had a new strategic direction set by senior leadership to be an operating versus a holding company, and how this somewhat empowered more systematic review processes of varying types, including but not limited to HTA. Individuals engaging in actions to achieve changes enabled by new guiding logic falls into the realm of institutional logic, where organizing principles guide behavior of individual actors (Reay et al., 2021).

Power by Proxy Association

One participant described gaining power in the HTA process through a sponsoring senior leader. Power within organizations can come in either informal or formal contexts (Scott & Davis, 2007). That is, power in informal groups can be based on individual characteristics, while power in formal groups can be associated with positions or levels, regardless of individual qualities (Scott & Davis, 2007).

Power Self-Acquisition through Incrementalism

Four of the interview participants described gaining power over time, relative to HTA processes. One participant stated "…I have no authority, but I have a lot of power…." According to that participant, he gained influence over time through continually demonstrating valuable input in the context of HTA. Another participant more humbly stated that his role was to facilitate an objective process, and to let the data and science speak for itself. Two participants spoke to the concept of being self-aware of continuing to add value to maintain power within the context of HTA. Said in the vernacular, one has to initially earn his or her seat at the table, but then one has to continue to earn to keep his or her seat at the table.

Process Definition

Four interview participants volunteered that they had some sort of codified process for going about HTA in their hospitals. One could argue that such systems are ways to help make rational decisions in complex organizations, a bureaucratic approach to organizing (Scott & Davis, 2007).

Process Exceptions

Two of the interview participants stated that exceptions occur with HTA, sometimes to do with elements such as political reasons (e.g., satisfying a certain physician) or due to developments that weren't initially contemplated (e.g., a technology being sunset much sooner than anticipated). If thinking about HTA as a process in terms of a complex system (vis-à-vis Perrow), perhaps these examples would be classified as "normal accidents" that are bound to happen.

Value Analysis

None of the participants used HTA as the nomenclature for the processes of evaluating and selecting EME within their organization, while value analysis was mentioned by two participants as being an aspect of evaluating and selecting EME. If HTA as an academic concept arose in the U.S. in the 1970s, it does not seem to have been adopted by name as the standard conceptual framework for evaluating and selecting EME in U.S. hospitals, if this limited sample is representative. In this sample of interview participants, it would seem the concept has not been diffused into HTM professionals or their organizations overall. A possible reason for this is that HTA conceptually may be limited to more academic settings where there is sufficient resource munificence to support its practice. Other factors could include a lack of a national HTA

agency, U.S.-based HTA societies, and U.S.-based HTA publications. Also, as described previously, some of the factors that helped promote HTA conceptually in Europe may not influence administrative processes the same way in the U.S.

Possible Implications for Practice

HB-HTA is an administrative process that is occurring in complex social settings where interactions and exchanges with individuals and groups are occurring. Rational models for conducting HTA may need careful tailoring to the organization's structure and culture, especially when the models have been designed for other contexts (e.g., Europe). HTA processes may be confounded by, among other things, time and resource limitations, a dearth of objective information on which to base decisions, political factors, and the power positionality of participants. Those who are wishing to gain more involvement in HB-HTA in their organization may wish to consider several tactics. Gaining entry to multi-disciplinary committees and being cognizant of continually adding value in that context is one aspect. Another aspect might be using negative experiences to build narratives for why being included in future processes could prevent past errors. Some tactics seem to be based off immutable factors that may not be modifiable from the individual level, such as the organizational substrate of being an operating company versus holding company or having delegated authority from a higher leader. Some persons may find that starting small and building influence incrementally over time can be successful in gaining more involvement with HTA.

Recall that 84.6% of the survey respondents stated that HTM was routinely involved in the organization's HB-HTA processes, although this could be a result of a biased sample that did not meet power. If the small sample is representative, it may be

appropriate to conjecture that most hospitals find value in involving HTM in HB-HTA, and thus to advance such inclusion as a suggested standard practice. Conversely, two of the least frequently reported HTA processes in the survey were (a) routine generation of a written report [53.85%], and (b) routine assessment of relevant clinical evidence [61.54%]. By not memorializing the HTA processes used and the outcomes achieved (and somehow disseminating such information across organizations), hospitals may be limiting their ability to have shared learnings from their experiences, and to continue to iterate and improve HTA processes. Also, slightly more than one-third of the survey respondents not including a clinical evidence review may be concerning if most hospitals are looking to implement technologies based on rigorous science. Although not one of the least frequent processes, around 3 out of 10 survey respondents were not routinely including IT in the HB-HTA processes. This may be concerning given that IT considerations for things like Internet-connected medical devices is "paramount for patient's safety, effective treatment, and to ensure . . . privacy" (Karunarathne, Saxena, & Khan, 2021).

In 2023, it was posited in Health Affairs Forefront that the expanded use of HTA in the U.S. could address some of the $1 trillion of non-value added healthcare spending (Padula, Reid, & McQueen). HTM professionals can potentially serve in key roles in participating in and/or leading HTA processes within hospitals in the U.S. Becoming more involved in HTA might be facilitated by factors such as strategy set by senior leadership and formal power positionality. Multi-disciplinary committees can be important domains where HTM professionals can have a voice in HTA, while being cognizant of adding value in such venues and others can be used over time to grow

HTM's power in the organization. While codifying certain HTA methods into policies and procedures may be helpful, practitioners might be cognizant to allow for HTA processes to change based on the external environment, as with the example of the COVID-19 pandemic. Negative experiences with HTA might be treated as learning opportunities to continue to iterate HTA processes and recognizing that no set of processes will be able to perfectly handle every situation may be important. Lastly, it may be appropriate to abandon the supply chain driven terminology of value analysis and begin referring to the evaluation and selection of EME as HTA and to begin co-opting the body of HTA literature more into hospital-based practice in the U.S. Care might need to be taken to ensure that such policy changes doesn't result in unintended adverse consequences.

Recommendations for Future Research

One obvious pathway for future research is to conduct a more effective survey as was attempted in the quantitative aspect of this research, with a focus on reaching power and on being inclusive of those HTM professionals who are not as well involved in HTA. An alternative approach would be to expand the survey outside of HTM professionals to include others potentially involved with HB-HTA. While the qualitative study here uncovered certain themes related to HTM professionals participating in HTA, it fell short of ascertaining more about how HTM professionals exactly influence HTA processes. As potential next steps in exploring best practices for HB-HTA in the U.S., additional research could be also designed around processes as related to specific organizational outcomes.

Of particular interest might be the common mention of multi-disciplinary committee structures and how, even with those structures, negatives outcomes are sometimes occurring. Is it that, given complex technology, "normal accidents" are going to occur? Is it that ineffective HTA is leading to sometimes negative outcomes? Is it that various factors confound the HTA process and sometimes allow incorrect decisions to be made? DiMaggio and Powell posit that organizations tend to model themselves after like organizations in an attempt to gain legitimacy or achieve success (1983). Are, then, multi-disciplinary committee structures truly effective for conducting HB-HTA or are they attempts at satisficing the idea of following norms, distributing potentially risky decisions across more individuals, and/or being politically inclusive and transparent with processes? Are there more effective models for HB-HTA and how it is lead in organizations?

Closing

How much resources hospitals commit to HTA may represent a key internal policy decision when deciding upon allocation of limited resources. EME represents a very significant investment of organizational resources, and sometimes the outcomes from it are unexpected and/or negative, despite attempts to vet it prior to organizational entry. HTM practitioners occupy a unique place in the crossroads of health technologies and how they are evaluated, selected, used, and managed throughout their lifecycle in hospital organizations. Some HTM professionals have been able to become deeply involved in HTA within their organizations which is no doubt helping to improve the selection of EME based on safety, effectiveness, cost, and other factors. The findings in this study potentially represent the genesis of more cross-pollination of HTA and

organizational theory concepts into the HTM profession, which may have perhaps historically been more focused on the science of maintaining and supporting EME and meeting basic regulatory requirements.

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APPENDIX 1: SURVEY INSTRUMENT

This survey is intended for those employed in the healthcare technology management (HTM) field, sometimes known as Clinical Engineering or Biomedical Engineering, and who are working in a U.S. based hospital.

Variable	Description	Measure	Actual Question	Comments
☞ The first set of questions will ask you about the primary hospital that you work at.				
Independent	U.S. based	1, U.S-based; 0, otherwise	Is your hospital located in the U.S.?	If no, survey ends
Independent	Organizational characteristics, system	1, system-affiliated; 0, free-standing	Is your hospital system-affiliated (part of a bigger corporation) or free-standing?	
Independent	Bed size	Number of staffed beds	How many staffed beds (not licensed beds) does your hospital have?	Those self-reporting may have a propensity to estimate this number
Independent	Profit status	1, for-profit; 0, otherwise	Is your hospital for-profit (owned by investors)?	
Independent	Pediatric vs. adult	1, dedicated children's hospital; 0, otherwise	Is your facility a dedicated children's hospital?	
Independent	Accreditation type	1, The Joint Commission; 0, otherwise	Is your hospital accredited by The Joint Commission?	
Independent	Healthcare technology management approach	1, in-house; 0, otherwise	Is your healthcare technology management (HTM) program in-house (that is, not outsourced to a separate company)? This program or department is sometimes called Biomedical Engineering or Clinical Engineering.	Outsourced HTM programs may be less likely to be integrated into HTA processes because they are vendors
Independent	Teaching status	1, academic hospital; 0, otherwise	Is your facility an academic (teaching) hospital?	Some universities have HTA units
Independent	Faith-based	1, yes; 0, no	Is your hospital faith-based (that is, have a religiously oriented purpose)?	Does having an altruistic motive and culture influence HTA?
Independent	Federal status	1, federal hospital; 0, otherwise	Is your hospital owned and operated by the federal government (the Dept. of Defense, the Dept. of Health and Human Services, or the Veterans Health Administration)?	

Variable	Description	Measure	Actual Question	Comments
☞ The remainder of this survey will ask about the processes used to evaluate and select electronic medical equipment (e.g., external defibrillators, ventilators, and infusion pumps) at your hospital. ***This survey is focused on how hospitals go about selecting a make/model to replace existing electronic medical equipment.***				
Dependent	Sampietro-Colom et al. Guiding Principle 4 (2016)	1, yes; 0, no	Does your hospital have a written policy, standard, or plan that specifies how electronic medical equipment is evaluated and selected? This would be more than a generic procurement policy that states capital thresholds and approval authorities.	Sampietro-Colom et al. describe having a clear mission, vision, and values for the HTA function (i.e., overarching philosophy)
Dependent	HTA Core Model 3.0 (2016), clinical effectiveness domain	1, yes; 0, no	At your hospital, is an assessment of relevant clinical evidence (such as peer reviewed publications) routinely completed as part of the process of evaluating and selecting electronic medical equipment?	The HTA Core Model 3.0 describes conducting a systematic review of evidence
Dependent	Sampietro-Colom et al. Guiding Principle 5 (2016)	1, yes; 0, no	At your hospital, is there clear leadership dedicated to overseeing the evaluation and selection of electronic medical equipment?	Sampietro-Colom et al. describe having clear leadership at the top of the HTA function
Dependent	Sampietro-Colom et al. Guiding Principle 3 (2016)	1, yes; 0, no	At your hospital, is a multi-disciplinary team routinely used to evaluate and select electronic medical equipment?	Sampietro-Colom et al. describe involving all relevant stakeholders
Dependent	Sampietro-Colom et al. Guiding Principle 3 (2016)	1, yes; 0, no	At your hospital, is the healthcare technology management (HTM) department, sometimes known as Clinical Engineering or Biomedical Engineering, routinely invited to participate in the evaluation and selection of electronic medical equipment?	Sampietro-Colom et al. describe involving all relevant stakeholders
Dependent	Sampietro-Colom et al. Guiding Principle 3 (2016)	1, yes; 0, no	At your hospital, is the Information Technology (I.T.) department routinely invited to participate in the evaluation and selection of electronic medical equipment?	Sampietro-Colom et al. describe involving all relevant stakeholders
Dependent	Sampietro-Colom et al. Guiding Principle 2 (2016)	1, yes; 0, no	At your hospital, as part of the process of evaluating and selecting electronic medical equipment, is a written report routinely created that describes the methods used and the outcomes?	Sampietro-Colom et al. describe using "good methods…in a way that can be adapted to other hospitals (transferable)"

Variable	Description	Measure	Actual Question	Comments
Dependent	HTA Core Model 3.0 (2016), costs and economic evaluation domain	1, yes; 0, no	At your hospital, as part of the process of evaluating and selecting electronic medical equipment, is a total cost of ownership/return on investment routinely calculated? Potential ownership costs include but aren't limited to capital investment/depreciation, training costs, ongoing maintenance/repair costs, ongoing consumable costs, and ongoing software costs. Potential return on investment factors include but aren't limited to reimbursement (if applicable), improved quality, and decreased readmissions.	A total lifecycle calculation is performed that wholistically considers the technology, not just unidimensional aspects such as upfront investment
Dependent	Sampietro-Colom et al. Guiding Principle 1 (2016)	1, yes; 0, no	At your hospital, as part of the process of evaluating and selecting electronic medical equipment, are clinical user simulations (not involving patients) routinely conducted, when feasible?	Sampietro-Colom et al. describe considering the "local context's characteristics"
Dependent	Sampietro-Colom et al. Guiding Principle 1 (2016)	1, yes; 0, no	At your hospital, as part of the process of evaluating and selecting electronic medical equipment, are patient trials/pilots routinely conducted, when feasible?	Sampietro-Colom et al. describe considering the "local context's characteristics"
Dependent	Sampietro-Colom et al. Guiding Principle 11 (2016)	1, yes; 0, no	At your hospital, as part of the process of evaluating and selecting electronic medical equipment, is feedback routinely gathered from other hospitals that implemented the same technology?	Is there inter-organization collaboration occurring? Sampietro-Colom et al. describe "links with key allies and partners should be proactively identified and promoted"

APPENDIX 2: SEMI-STRUCTURED INTERVIEW SCRIPT

Introduction

Good morning, participant. First, thank you for taking the time to speak with me today.

First, I want to make sure you reviewed the consent form I previously emailed. Did you review it and do you have any questions? Also, I wanted to remind you that your responses will be kept confidential and that no identifying information will be shared. Do you consent to proceeding with the interview, including me recording today's conversation?

Main Interview

First, can you tell me about your role there at the hospital…what your position is and responsibilities are?

Thank you. Can you spend a few minutes describing, in general, the process by which electronic medical equipment is evaluated and selected there at your hospital? Examples of such equipment are external defibrillators, ventilators, and infusion pumps. Specifically, I'm interested in how hospitals go about selecting a make/model to replace existing electronic medical equipment. I'm interested in the process in general; try not to think about a specific device.

Thank you, participant, for that information, that's very helpful. Now can you tell me more about some of the details you provided? You touched on several processes, but I found 3 to be particularly interesting. I'm interested to know more details about those 3, and why they occur the way they do.

1. Process 1
2. Process 2
3. Process 3

Is your hospital part of a larger system/integrated delivery network? Are the processes you described standardized across the larger organization and/or centrally controlled at the corporate/headquarters level?

Does your hospital have a desire around standardization of electronic medical equipment? Do you think that influences the processes you described? If so, how?

Have you had any experiences where your current processes to evaluate and select electronic medical equipment didn't achieve the intended results? For example, the equipment selected didn't work out well once fully implemented, or the team had difficulty achieving their goals? Tell me more about those experiences.

What 1 or 2 things do you think are most important in the process for evaluating and selecting electronic medical equipment?

Is there anything you would like to add? Do you have any questions for me?

Conclusion

Thank you again, participant, for providing these answers today. I truly appreciate your time.

APPENDIX 3: RESEARCH PREAMBLE

ORGANIZATIONAL CHARACTERISTICS OF U.S.-BASED HOSPITALS CONDUCTING HEALTH TECHNOLOGY ASSESSMENT

Dear Participant:

You are being invited to participate in a research study. The purpose of this study is to collect data about current practices for evaluating and selecting electronic medical equipment in hospital settings as experienced by healthcare technology management (HTM) professionals. This study is conducted by Bob Esterhay and Scott Skinner of the University of Louisville.

Your participation in the study will involve completing an online survey and/or participating in an interview. The survey will take approximately 15 minutes to complete and the interview will take approximately 30 minutes to complete. There are no known risks for your participation in this research study. The information you provide will be analyzed to determine relationships, if any, between organizational characteristics and hospital-based health technology assessment (HB-HTA) processes. Survey responses will be stored at Qualtrics.com where they will be maintained in a password protected electronic format. Interview recordings, transcripts, and notes will be stored in an encrypted, password protected hard drive. The information collected may not benefit you directly. The information learned in this study may be helpful to others. Once completed, summarized results of the study may be shared with you.

Individuals from the Department of Health Management and Systems Sciences, the Institutional Review Board (IRB), the Human Subjects Protection Program Office (HSPPO), and other regulatory agencies may inspect these records. In all other respects, however, the data will be held in confidence to the extent permitted by law. Should the data be published, your identity will not be disclosed.

Taking part in this study is voluntary. By answering survey and/or interview questions you agree to take part in this research study. You do not have to answer any questions that make you uncomfortable. You may choose not to take part at all. If you decide to be in this study you may stop taking part at any time. You will not lose any benefits for which you may qualify.

If you have any questions, concerns, or complaints about the research study, please contact: Bob Esterhay (principal investigator) at 502-417-8475 or bob.esterhay@louisville.edu or Scott Skinner (co-investigator) at (502) 681-3942 or scott.skinner@louisville.edu.

If you have any questions about your rights as a research participant, you may call the Human Subjects Protection Program Office at (502) 852-5188. You can discuss any questions about your rights as a research participant , in private, with a member of the Institutional Review Board (IRB). The IRB is an independent committee made up of people from the University community, staff of the institutions, as well as people from the community not connected with these institutions. The IRB has reviewed this research study.

If you have concerns or complaints about the research or research staff and you do not wish to give your name, you may call 1-877-852-1167. This is a 24 hour hot line answered by people who do not work at the University of Louisville.

Sincerely,

Bob Esterhay (principal investigator)
Scott Skinner (co-investigator)

CURRICULUM VITA

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EDUCATION & TRAINING:

B.B.A., Marketing
McKendree College
2001

M.B.A., Healthcare Administration
University of Louisville
2004

Ph.D. in Public Health Sciences, Specialization in Health Management and Policy
University of Louisville
2023 (expected)

PROFESSIONAL EXPERIENCE:

Director of Capital Equipment Planning
Sodexo CTM, LLC
2022 to present

System Director, Clinical Engineering
Norton Healthcare, Inc.
2009 to 2022

Director, Capital Asset Management
Norton Healthcare, Inc.
2005 to 2008

Regional Vice President, Operations
Universal Hospital Services, Inc.
2004 to 2005

PROFESSIONAL
EXPERIENCE
(continued): District Manager
Universal Hospital Services, Inc.
2001 to 2004

AWARDS: Technology Management Council Best Practice Award
Association for the Advancement of Medical Instrumentation
2011

PROFESSIONAL SOCIETIES:

American College of Clinical Engineering
American College of Healthcare Executives
Association for the Advancement of Medical Instrumentation

CONFERENCE PRESENTATIONS SCHEDULED:

2023, June. Skinner, Scott. "Health Technology Assessment in Hospitals: Current Practices and Future Directions." Association for the Advancement of Medical Instrumentation, Long Beach, CA.

2023, July. Skinner, Scott. "Coordinating Medical Equipment Donations Through an NGO: Lessons Learned from Kentucky, U.S." Japanese Association for Clinical Engineering, Hiroshima, Japan.

2023, August. Ayers-Comegys, Morgan and Skinner, Scott. "Capital Equipment Planning: Getting (and Keeping) a Seat at the Table." North Carolina Biomedical Association, Pinehurst, NC.