EFFECTS OF HOSPITAL STRUCTURAL COMPLEXITY AND PROCESS ADEQUACY ON THE PREVALENCE OF SYSTEMIC ADVERSE EVENTS AND COMPLIANCE ISSUES: A BIOMEDICAL ENGINEERING TECHNICIAN PERSPECTIVE

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I dedicate this dissertation to the memory of my parents—Betty J. Myhre and Sandor Fiedler, and of those friends, family and fellow students whom I have lost during this journey. Though no longer on this earth, they will continue to remain part of me for so many reasons.

ABSTRACT

Active interdepartmental participation of the biomedical engineering technician (BMET) with clinicians is an opportunity to reduce systemic events guided by empirical evidence that 1) establishes adverse events with medical equipment and 2) associates nursing effectiveness with access to functioning equipment. Though prior research has documented interdependency in nurse-physician relationships (and in such non-clinical health support services as laboratory and pharmaceutical departments), few studies in mainstream literature on quality have related medical professional interdependencies to the BMET. The promotion of National Patient Safety Goals, federal legislation (the Safe Device Act of 1990), and recommendations from agencies—The Joint Commission and the United States Center for Disease Control and Prevention (CDC), all point to a multidisciplinary approach for detecting and resolving systemic problems. Therefore, comprehending the interdependent role of the BMET in hospital care is important for reducing persistent problems like Nosocomial Infections (NI) and other adverse systemic events that affect clinical outcomes.

Industry research documents the positive contributions of BMET professional integration into facility management in Management Information Systems (MIS), and empirical evidence has shown that their professional contributions influence nursing performance and thus, patient outcomes. Yet, BMET integration to departments like Infection Control and Central Sterile where BMETs' specific knowledge of medical equipment can apply directly is rare, if not entirely absent. Delaying such professional integration can hamper effective response to offset the Centers for Medicare and Medicaid (CMS) payment reductions that went into effect on October 1, 2008. The CMS denies payment for treatment of infections it deems 'preventable' by

proper interdependent precautions. Infections already under scrutiny as preventable include mediastenitis, urinary tract infections, and catheter-related blood stream infections. Furthermore, formal Medicare Conditions of Participation (CoP) now require hospitals to develop initiatives to reduce medical errors by identifying and addressing threats to patient safety. In both these challenges the medical equipment used in clinical care can adversely affect patient outcomes. Clearly, the health care system must tackle the common healthcare associated infections (HAI) just mentioned as well as others that may be added to the CMS list, or face overwhelming financial costs. Understanding the BMET professional relationship with nursing, given the structural and process considerations of the level of quality (LOQ) as measured by Clinical Effectiveness, Clinical Efficiency, and Regulatory Compliance, will be essential for meeting this challenge.

This study's extensive literature review led to the development of a conceptual hypothesized model based on Donabedian's 1988 Triad of Structure, Process, and Outcome and fused with Integrated Empirical Ethics as a foundation for BMET professional interdependency and for consolidated attack on adverse systemic events. This theoretical integration has the potential to advance quality of clinical care by illuminating the factors directly or indirectly influencing patient outcomes. Primary data were gathered through the Biomedical Engineering Interdepartmental Survey that collected BMETs' professional perceptions of organizational factors (Structural Complexity), process factors (Process Adequacy), and Level of Quality and Control variables yielding information about the individual respondents and the facilities where they work. The unit of analysis in this study is the biomedical engineering technician functioning in hospital support services to ensure patient safety and quality of care. Initial survey results underwent data cleansing to eliminate the impact of missing items. Next, Confirmatory Factor

Analysis applied to the survey data determined the construct validity and reliability of the measurement instrument. Statistically tested regression models identified structure and process factors that may affect the LOQ in terms of systemic adverse events and lack of compliance.

The statistical analysis and assumption tests that confirm internal validity infer that hospital Level of Quality is significantly influenced at R^2=88.1% by Structural Complexity. The combined measurement model and models for each latent construct achieved Cronbach α results >0.7, indicating internal reliability of the Biomedical Engineering Interdepartmental (BEI) survey instrument.

The final measurement models of the latent constructs—structural complexity (six factors), process adequacy (five factors), and level of quality (six factors) are correlated and significant at t>1.96, p<.001 (2-tailed). The Structural Equation Model without controls are correlated and significant at t>1.96 on all factors, indicating an approximate standard distribution at p<.001 level (2-tailed). Goodness of fit model analysis findings indicates that the models reasonably fit the data. The largest correlation is expressed between structural complexity and process adequacy (0.217 to 0.461), p=.01 (2-tailed). Respondent and facility control variables added to the Structural Equation Model are correlated with low impact but not statistically significant.

The findings have implications for theory, methodology, external policy, and internal hospital administrative management. The theoretical contributions of the study include the instrument development, measurement models, and the Structural Equation Model for hospital level of quality. The statistical analysis of the relationships of Donabedian's Triad indicates that both structural complexity and process adequacy are explanatory for the outcome variable of level of quality. Several statistically significant predictors of quality support an integrated

approach to systemic problems. They are Uniform Standards, Inter-Professional Training, Coordination Evidence, Interdepartmental Work and Device Failure Recognition. Moreover, the application of Integrated Empirical Ethics provides a foundation for management resolution that can improve the hospital level of quality by consolidating divergent internal and external controls by providing implementation guidance to overcome medical plurality as empirical evidence continues to emerge. The study defines the outcome measures of Quality—Effectiveness, Efficiency, and Regulatory Compliance in the context of Clinical Engineering.

The study results suggest pertinent external policy recommendations, foremost of which arises from the responses to the item concerning Uniform Standards: "Standards are applied equally across all departments." In the BMET community, only about 20 per cent strongly agree with this statement; approximately 33 per cent agree. Because of divergent ethical and national regulatory policies applied to professional affiliations rather than the medical community at large, a policy adapting regulatory initiatives having the same focus on patient outcomes (e.g., CMS CoP; National Patient Safety Goals) would generate the best initiatives for reducing systemic adverse events and policy conflicts. Finally, results suggest that internal hospital administrators can improve the level of quality through internal process changes, in particular by addressing the process adequacy factor of Regular Meetings for the survey item: "Nursing and biomedical engineering conduct regularly scheduled meetings on equipment issues." Less than 10 per cent of the BMETs surveyed strongly agreed and about one-third agreed that this aspect of interdepartmental teamwork was accepted.

The study confirms the evolution of the interdependent professional dynamic within healthcare exemplified by the combination of multiple predictors of the Level of Quality from Organizational Culture, Level of Coordination and Interdepartmental Medical Device

Management. Hospital administrators can find simple, cost-effective solutions to improve clinical effectiveness (a key indicator of quality) in the components of the intervening variable of process adequacy. For example, statistical evidence shows that regular meetings between nursing and biomedical staff about equipment issues and/or linking the BMET department goals to Organization Objectives are ways to improve quality.

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Finally, I would like to thank the men and women of the Biomedical Engineering Technician community for taking the time to complete the study survey, and for their daily dedication to patient safety. In particular, I thank Mr. Patrick Lynch, Biomedical Support Specialist at Global Medical Imaging in Charlotte, North Carolina for providing the initial contact list of Biomedical Engineering Technicians. My appreciation of this act of trust is especially heartfelt; it is indicative of how the health support services community is truly dedicated to supporting optimal patient outcomes.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ACRONYMS

- BEI Survey - Biomedical Engineering Interdepartmental Survey
- BMET - Biomedical Engineering Technician
- CE - Clinical Engineering
- EC - Environment of Care
- IEE - Integrated Empirical Ethics
- LOQ - Level of Quality
- MI - Modification Indices
- PA – Process Adequacy
- SC – Structural Complexity
- SEM – Structural Equation Model
- SPO – Structure, Process, Outcome

CHAPTER 1: INTRODUCTION

The objectives of this study are to: 1) determine if the modified Structural-Process-Outcome model is measureable, 2) assess the relevance of the survey instrument to the study population, 3) identify hospital structural characteristics and process factors that affect the level of quality (LOQ) in US hospitals, and 4) understand the relationships between the LOQ and three healthcare outcomes (e.g., clinical effectiveness, clinical efficiency, and regulatory compliance).

1.1 Problem Statement and Research Questions

The purpose of this research is posited under Organizational Performance Theory. The theoretical premise elicits a general question: "Can integration of biomedical engineering technicians (BMETs) in the general hospital environment of care (EC) contribute to improved quality performance by reducing the likelihood of systemic adverse events and compliance issues?"

Hospital acquired infections (HAIs) in the United States have been linked to approximately 100,000 deaths and an excessive financial burden of $20-$30 billion due to complications and their subsequent treatment for 2 million patients (McFee, 2009, p.423; Stock, McFadden, & Gowen, 2007, p. 368; Gowen, McFadden, Hoobler, & Tallon, 2006, p. 765; Burke, 2003, p. 651).

Recent findings of a Department of Health and Human Services study of 780 randomly selected Medicare beneficiaries during October 2008, reported by the Office of the Inspector General, estimate that 135,000 patients annually experience at least one

adverse medical event resulting from medical care (Office of the Inspector General, 2010, p. 15). Those 135,000 patients are the 13.5% of Medicare recipients in the retrospective study that received medical treatment and were discharged reporting an adverse event.

An adverse medical event is defined in terms of patient harm under the following criteria: that a medical practitioner has established that an event occurred, and that the event could be categorized as a Serious Reportable Event or as one of Medicare Hospital-Acquired Conditions (HAC). The National Quality Forum defined Serious Reportable Events as those occurring in the administration of pharmaceutical products, in patient care including surgical or other procedures in the general environment of care, and in the use of medical equipment (National Quality Forum, 2007, p.7 as cited in OIG, 2010, p.37). Medicare HACs span infections from the use of medical equipment, from patient falls, or from poor treatment of co-morbidity conditions such as diabetes (Federal Register, 2008, p. 48434, 48471 as cited in OIG, 2010, p. 38). Estimates of the impact of adverse events are deaths numbering "15,000 is a single month" (OIG, p. 19) or approximately 180,000 annually that may at least contribute to patient mortality. The financial impact of temporary morbidity (less debilitating adverse events) approached $4.5 billion dollars annually in 2008 (OIG, p. 27).

Reported morbidity and mortality for the last decade as related to several areas of health care and administration implies that a broad systems approach addressing multiple interfaces between individuals and organizational policy-driven processes must be developed. The justification for this approach includes the moderately successful hand sanitation campaigns (Kevin Sack, New York Times for October 8, 2008) and healthcare

industry guidelines to reduce patient mortality and morbidity from adverse events — specifically medical error and HAIs (Francis, 2008).

Nosocomial or healthcare-acquired infections (HAI) are the most prevalent adverse events in hospitalization and are in the top tier of causes of death in the United States (McFee, 2009; Gowen et al., 2006; McCaughey, 2005). The number of adverse events persists despite the many quality management initiatives that have attempted to reduce them (Burke, 2003). Despite the established link between adverse medical events and medical devices, since the early 1960's the biomedical engineering technicians (BMETs) have had limited opportunities to fulfill their role in risk prevention by addressing problems beyond their duties in medical equipment electrical safety (Cohen, Bakuzonis, Friedman, & Roa, 1995; Anderson, 1992; United States Association of Military Trained BMETs, n.d.). As a result, only a handful of quality measures with the BMET community have been introduced recognizing BMETs as an internal mechanism to improve hospital quality of care (QOC) (Ridgeway, Atles, & Subhan, 2009; Williams, 2009; Dey & Hariharan, 2006; Dondelinger, 2006; Cram, Stephens, & Lessard, 2004).

Schutz-Stubner, Hauer, and Dettenkofer (2003, p. 442) assert that the particular maintenance services that the BMET is qualified to perform are an "indispensible prerequisite for successful disinfection and sterilization." The BMET is the only professional staff member with the ability and authorization to perform a complete cycle of electrical medical equipment's disassembly, cleansing, and return to operational status, under the federal Occupational Safety and Health Act of 1970. The OSHA Act created electrical safety standards for medical equipment. Though a few studies of nursing have noted the reliance on BMET professionals for this important function, significant analysis

of this arena is lacking. Yet, formidable data are available that link nursing performance measurement objectives to "workplace practices [that] include organizational performance, interdisciplinary collaboration, equipment failures, and documentation burden" (Needleman, Kurtzman, & Kizer, 2007, p. 11S).

According to the United States Centers for Disease Control and Prevention (2003), the current procedures for cleaning and transfer of medical equipment between patients by non-BMETs may comprise only superficial cleaning (Hall, 2008) that has minimal effectiveness against bacteria, particularly Methicillin-Resistant Staphylococcus Aureus (MRSA) and various strains of Nosocomial Infection. Though non-BMET personnel adhere to hospital protocols, they are not allowed to disassemble components that may require more elaborate cleansing which limits their ability to perform complete cleansing and sanitation.

Moreover, at present, BMET medical equipment protocols and professional definitions do not identify cleansing as part of the BMETs occupational definition. The generally acknowledged professional duties of a BMET include "maintenance, repair, and calibration of medical electronic equipment found in hospitals, including ventilators, infusion pumps, patient monitors, defibrillators, and ultrasound machines (Bowles, 2008, p.1). For risk prevention, however, the proposition of an integrated BMET role is salient according to industry representatives (Fennigkoh, 2005, Cram et al., 2004; Baker, 2003; Cohen et al., 1995, Anderson, 1992).

Burke (2003) reported that recognition of the causal relationship of NI disease to HAIs had prompted a change in payment by the Centers for Medicare and Medicaid Services (CMS): effective October 1, 2008, they no longer pay for three infections they

have deemed preventable, namely mediastenitis, urinary tract infections, and catheter-related bloodstream infections. Those three diseases account for about 80% of nosocomial infections (Burke, 2003, p. 651). They are grouped in four specific types: 1) urinary tract infection (usually catheter-associated), 2) surgical site infection, 3) bloodstream infection (usually associated with intravascular device use), and 4) pneumonia (usually associated with ventilator use). “For each of the device-associated infections, multiple risk factors are related to the patient, the personnel caring for the patient, the procedures they use, and the actual device” (Burke, 2003, p. 652). As targeted data about those risk factors are gathered, the potential expansion of HAIs excluded from reimbursement may further strain an already constricted industry.

The causal relationships between medical equipment and patient infection that have been widely documented by scholars include but are not limited to cardiac catheters, colonoscopy gastrointestinal endoscopes, stethoscopes, and ventilators (McFee, 2009; Schabrun & Chipchase, 2006; McCaughey, 2005; Burke, 2003). Halcomb, Griffiths, and Fernandez conclude specifically that there is a ‘link between the environment and hospital equipment and the transmission of MRSA within the acute hospital setting” (2008, p. 50) recognized by the U.S. Department of Health and Human Services, Center for Disease Control and Prevention (2003). Schraburn and Chipchase (2006) have provided a systematic review of healthcare equipment as a repository for nosocomial infection. In addition, Henderson (2008, p.294) has attributed the potential for increased risk due to the “blind reliance on the safety and efficacy of new (presumably safer) devices and procedures.” The above findings coupled with the rigor required for successful cleansing and disinfection in complex operational and maintenance procedures

supports the expanded role of the BMETs in effective health care. Currently responsible for preventative maintenance and repair of medical equipment, the BMET may be a key element in a systems approach that would succeed in reducing adverse events such as medical errors and HAI.

Recognizing the complex nature of the healthcare industry in multi-disciplinary environments, this study considers multiple latent and observed indicators derived from the responses to a custom questionnaire distributed to the BMET study population. The study addresses the following research questions:

RQ_1: Are the constructs Structural Complexity, Process Adequacy, and Level of Quality measurable?

RQ_2: What is the relationship between structural complexity and process adequacy?

RQ_3: What is the relationship between structural complexity and the level of quality in the hospital environment of care?

RQ_4: What is the relationship between process adequacy and the level of quality in the hospital environment of care?

1.2 Study Significance

Despite the plethora of evidence that multi-disciplinary teamwork can improve patient outcomes (Edmond, 2009; Hagtvedt, Griffin, Keskinocak, & Roberts, 2009; Fewster-Thuente & Velsor-Friedrich, 2008; Molleman, Broekhuis, Stoffels, & Jaspers, 2008; Xyrichis & Lowton, 2008; D'Amour, Ferrada-Videla, Rodriguez, & Beaulieu, 2005; Yeager, 2005; McFadden, Towell, and Stock, 2004; Connor, Ponte, & Conway, 2002), consideration of the BMET profession potential to improve quality of care, and the relevant empirical studies or non-empirical case studies have appeared only in

biomedical and clinical engineering literature (Williams, 2009; Dondelinger, 2008; Ebben, Gieras, & Gosbee, 2008; Hall, 2008; Wayre, 2008; Bakuzonis et al., 2007; Hunter, 2007; Williams, 2007; Fennigkoh, 2005; Subhan, 2005; Cram et al., 2004; Xu et al., 1997; Moniz, Calvin, & Stankiewicz, 1995; Yadin & Rohe, 1986).

A few policy applications recognizing how the BMET function of preventive medical equipment maintenance contributes to quality efficiencies have made their way to the mainstream literature (Podgorelec, Grasic, & Pavlic, 2009; Dey and Hariharan, 2006; Podgorelec and Kokol, 2001). With Infection Control now a primary target of National Patient Safety Goals (McFee, 2009; McFadden et al., 2004), inclusion of the BMET skill set in the infection control department (historically a nursing domain) receives serious attention due to the link between nursing effectiveness and the availability of operational medical equipment (Needleman et al., 2007; Schutz-Stubner et al., 2003; Carr, 1994; Yadin & Rohe, 1986).

Clinical Engineers (CEs), BMETs, and other medical technology professionals now recognize the necessity to communicate their expertise in patient safety issues so that their unique abilities are made full use of in the healthcare community. Inter-professional information transfer to senior management, administrators, and clinical personnel is critical to furthering effective response to systemic problems. “Keeping the clinical staff informed helps administrators and budget officers better see how safety is an integral element in the delivery of patient care" (Bakuzonis et al., 2007, p. 68-69).

This study aims to address that concern in three ways: 1) use of a custom survey derived from Donabedian’s Triad and existing literature to measure the perceptions of LOQ among a national sample of the BMET population (and future healthcare

professionals); 2) examination of how structural complexity and process adequacy affect the LOQ of hospital care; and 3) using the BMET profession as the unit of analysis to capture the relationship of LOQ, Clinical Effectiveness, Clinical Efficiency, and Regulatory Compliance.

The study aims have two regulatory foundations. First, the United States regulatory body—The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations or JCAHO) has current Infection Control Guidelines IC.8.10 that explicitly recommend organizational collaboration to combat systemic problems by establishing an Infection Control Department (Baran, 2004). Recent studies have found sparse or no evidence of such efforts by clinicians, administration, or health care support services (e.g., biomedical engineering technicians who maintain and repair medical equipment; hospital epidemiologists; facility maintenance staff) (Edmond, 2009; Hagtvedt, et al., 2009; Patel, Srinivasan & Perz, 2008; Anderson, Rasch, Hochlin, Jensen, Wismar, & Fredrickson, 2006; Hota, 2004; McFadden et al., 2004). The second key regulatory impetus is The Joint Commission Environment of Care or EC.4.1 Guidelines (JCAHO, 2001, p.3) that require a healthcare facility to monitor, collect information (EC.4.1.a), and use an integrated organizational response (EC.4.1.b) to conditions that threaten patient outcomes. Directives for collaborative corrective action are also embedded in the intent of EC.4.3, which requires measurements to be reported to a multidisciplinary team responsible for correcting EC problems.

Healthcare administrators have responded to the regulatory pressure by tracking various strains of NI when they appear 48 hours or more after hospital admission or

within 30 days of discharge. But, there has been little empirical research to discover whether the tracking information reaches the appropriate personnel and prompts corrective action. In a reported instance when TJC required response to a sentinel event, unanswered questions persisted: “For example, does it reduce repetition of the event in question?” and “Does it indicate that a significant event at one location is reflective of a general problem?” (Bakuzonis et al., 2007, p.69). Calculation of the number of sentinel events is only the beginning for a comprehensive, in-depth analysis that should drive preventive measures, not simply continue a reactive response.

In 2010, CMS issued a Final Quality Assessment and Performance Improvement (QAPI) program that set forth additional Medicare Conditions of Participation (CoP). The new rules require hospitals to develop initiatives that reduce medical errors by identifying the threats to patient safety. The Final Rule in the Public Register stipulates that events be reported so that knowledge about processes is documented with information technology to ensure actions are taken to solve the problem. Thus, the CoP advocates a complete cycle of identification, solution, implementation, and monitoring for solution evaluation. The CoP update to QAPI also consolidates quality standards across all facilities eligible for Medicare reimbursements, to supersede divergent regulations organizations encounter in private or state accreditations.

TJC’s National Patient Safety Goals (NPSG) effective July 1, 2010 listed goals to improve these problems: patient identification, communication among caregivers, medication safety, health-care associated infections, medication reconciliations across the continuum of care, risk of patient falls, pressure ulcers and general safety. The applications of these goals vary with the types of service (Ambulatory Health Care,

Behavioral Health Care, Critical Access Hospitals, Home Care Hospitals, Laboratory Services, Long Term Care, Medicaid and Medicare Long Term Care, and Office-Based Surgery) and their associated mortality risks.

The NPSG are a basis for system goals in healthcare quality. The most effective professional impact possible through collaboration, communication, and teamwork is essential to those goals (Beckett & Kipnis, 2009). This study's focus is reduction of the risk of iatrogenic illnesses, so its emphasis is on NPSG Goals 2 and 7: "Improve the effectiveness of communication among caregivers" and "Reduce the risk of healthcare-associated infections."

The absence of the BMET profession from the analysis of healthcare quality stands in contradiction to several key circumstances: the evidence that medical equipment is implicated in the increase of HAI (OIG, 2008; Burke, 2003), the necessity to tackle systemic problems like HAI by including all key personnel as recommended by Donabedian (1989); TJC accreditation according to Environment of Care (EC) stipulations that all key personnel be involved in combatting systemic problems, and the rising costs of health care. It follows that hospital management must understand and apply all healthcare professional skills in order to achieve cohesive solutions across the multiple professions at work in the hospital EC.

The lack of biomedical engineering technician (BMET) representation in hospital Infection Control and Central Sterile Departments is confirmed in a pilot study of the BMET community using a convenience sample (Fiedler & Agarwal, 2009). However, the limited BMET integration that has occurred in the Management Information Systems (MIS) departments of hospital organizations (CE-IT Integration from the IT Perspective,

2009) is in partial recognition of their valid contribution to patient health through equipment monitoring, interfacing and implementation (Moorman, 2008; Bakuzonis et al., 2007; Anderson et al., 2006). Researchers emphasize the importance for risk reduction by recognizing the complexity of medical equipment (Beyea, 2009; Chaudhury, Mahmood, & Valente, 2009; Anderson et al., 2006) due to the fact that "device interface complexity is a great predictor of operator errors" (Baker, 2003, p. 188).

The levels of technology inherent in the complexity of medical equipment apply to the adverse events related to medical errors but are not, however, the only causal consideration in systemic infection control. For example, Falagas & Karagerogopoulos (2009, p. 345) note that "relevant infection control measures should focus on reducing patient-to-patient transmission via the inanimate environment, hospital personnel, and medical equipment". Therefore action against systemic problems must consider the organizational environment where patient care is given and the complex interdependencies there among healthcare personnel, medical equipment, and patients. Better development of the inter-professional communication and knowledge translation in a hospital's organizational culture should be a priority (Waterson, 2009; Allegranzi, Storr, Dziekan, Leotsakos, Donaldson, & Pittet, 2007; Connor et al., 2002).

At present the environmental outcomes and regulatory conditions in the hospital EC require increased attention. A balanced approach to patient safety that emphasizes concomitance in addressing medical errors and infection control issues should include an understanding of complex professional relationships and their context (Waterson, 2009; Fewster-Thuente & Velsor-Friedrich, 2008; Molleman et al., 2008; Fennigkoh, 2005). Examination of a practical design for the interdepartmental integration of BMETs with

other medical professionals to meet regulatory requirements, taking into account the interdependent relationships among patients, healthcare personnel, and medical equipment, is called for.

1.3 Study Scope

Previous studies of the level of hospital quality of care with regard to systemic problems have been limited not only by the exclusion of health support services such as the BMET, but also by constrained access to clinical data on HAI tracking, and to financial data such as equipment costs. Though access to dependable data is a pervasive issue in healthcare research in terms of confounding factors (Lindsay, Schull, & Bronskill, 2002), the development of new strategies for healthcare outcomes that incorporate the BMET professional contributions can increase the generalizability of interdependent findings across multiple platforms.

The literature on the relationship of the BMET's contribution to the performance of other healthcare professions is reviewed here. The benefits and potential shortcomings of LOQ in relation to the BMET are discussed. A theoretical framework is constructed for the measurement of outcome/quality indicators in relation to organizational and contextual factors directly related to the maintenance and consequent availability of medical equipment in the hospital EC. Survey respondents' characteristics and facility information are also used as control factors in the analysis. Statistical procedures: correlation analysis, confirmatory factor analysis and the structural equation model, analyze the study variables. The relationships between each predictor variable and LOQ with selected healthcare outcomes recognized in the BMET field, is systematically

analyzed. Clinical effectiveness, efficiency, and regulatory compliance are the measurement indicators for the dependent variable of level of quality. Organizational characteristics of the hospital where the BMET is employed are independent variables. The process of care or process adequacy is considered an intervening variable and analysis in Section 5.6 investigates whether the contextual factor could serve as moderating or mediating in the relationship between organizational factors and LOQ. The results and their implications regarding the theoretical, methodological, and policy applications are detailed and directions for future research are noted.

The BMET is a vital component of the spectrum of healthcare and understanding it means evaluating BMETs' potential to reduce the number of harmful patient events in conjunction with nursing. This assumption is based on two premises: first, that an approach to systemic issues must consider the organizational environment for patient care; second, that the complex relationships among healthcare personnel, medical equipment, and patients in an EC require a full understanding and development of the inter-professional communication and knowledge translation inherent in its organizational culture (Waterson, 2009; Allegranzi et al., 2007; Connor et al., 2002). The examination of a possible design for interdepartmental integration between BMETs and other medical professionals is an opportunity to close a gap in management of systemic problems by better understanding of key personnel and their relationships.

1.4 Theoretical Premise

Donabedian's (1966) Structure-Process-Outcomes (S-P-O) approach to healthcare performance coupled with his quality assurance perspective on systemic problems (1989) suggests that to promote systemic resolutions to problems of organizational performance, it is necessary to incorporate multiple parties within the organization in that effort. The current requirements under The Joint Commission's Environment of Care (EC) specifications and the Safe Medical Device Act of 1990 are strong motivations for integrating key personnel in the effort to eliminate or avoid medical errors and hospital acquired infections (HAIs).

Both theoretical considerations and regulatory conditions demand more attention to the estimated 100,000-180,000 US deaths as well as the financial burden of treatments ($5-$30 billion) that result from such adverse events as hospital acquired infections (OIG, 2010, p. 19; McFee, 2009, p.423; Stock et al., 2007, p. 368; Gowen et al., 2006, p. 765; Burke, 2003, p. 651).

The nursing profession has emphasized patient outcomes through the directives of its Nursing Code of Ethics. However, the BMET occupation has been recognized as well, as indirectly involved with patient outcomes through regulatory objectives for the monitoring and maintenance of the medical equipment essential for the quality of patient care. Because healthcare is driven by accountability objectives and metrics, a second theoretical premise underpins this research—Integrated Empirical Ethics (IEE). Fundamentally, "IEE refers to studies in which ethicists and descriptive scientists cooperate together intensively" to reach a normative solution that balances moral theory

with the empirical data derived and applied in a social practice (Molewijk, Stiggelbout, Otten, Dupuis, & Kievit, 2004, p.57).

Balancing science and ethics through IEE employs science to develop and apply policies that recognize the contributions of individual practitioners, or in this case of professional autonomy, in social practice. Interactive cooperation between participating professionals such as BMETs and nurses can blend moral and scientific objectives to establish practice norms in the EC that embody fundamental priorities across diverse healthcare directives. Those norms should improve patient services and the quality of their care (Molewijk, 2004; Molewijk et al., 2004). Together, the two theoretical premises presented above are used to formulate three major hypotheses as detailed in Chapter 3.

1.5 New Literary Contributions

Examination of the relationship between health support services and clinicians using Donabedian's Triad will illuminate how the dimensions of structural complexity and process adequacy promote quality healthcare in a new era of collaboration. Multiple research variables are included in deference to the fact that when the original Organizational Performance theoretical principles were derived, hospital care was primarily hierarchical and allowed less opportunity for interaction. This study's approach recognizes the continuous need for empirical information to promote successful integration of the healthcare services that address systemic problems in interdependent care. That approach hopes to elicit new factors from the statistical analysis that uniquely combine the representative variables in the primary constructs of structure, process and

outcomes. Therefore, the research anticipates the formation of unique factors as composites of important determinants in the relationships between variables that reflect the complex interdepartmental and professional interactions necessary to pursue the national goals for patient safety specifically, infection control and medical errors.

An account of current research on the quality of healthcare appears in Chapter 2: Literature Review. The Theoretical Framework in Chapter 3 introduces Organizational Performance Theory and the conceptual theoretical model. Methodology, Chapter 4, contains the steps followed to develop a new survey instrument, sampling selection, and the statistical analysis methods: Confirmatory Factor Analysis and Structural Equation Modeling using SPSS, Inc. statistical software. Chapter 5 is a detailed analysis of the results from the Biomedical Engineering Interdepartmental Survey. Finally, Chapter 6 provides Discussion and Recommendations, with specific implications for biomedical engineering technicians and other healthcare support personnel.

CHAPTER 2: LITERATURE REVIEW

The previous chapter introduced the problem statement and research questions, the study's significance and scope, the fundamental theoretical premises, and expected contributions of the investigation. This chapter is a literature review of the empirical evidence for the use of performance metrics in developing the model and hypothesis. The historical application of the major model constructs and the relevance of the observed variables used as proxy measures are discussed.

Testing the hospital organizational level of quality as an indicator of performance is premised on the acknowledgment that successful professional interdependency leads to better quality in healthcare as well as in other industry sectors. In particular, this study seeks to establish the contribution of the biomedical engineering technician in terms of clinical engineering with patient care services associated with nursing. Scholars have noted limitations in healthcare that arise from overlooking the relationship of non-clinical health support to the clinical environment of care. Studies have focused primarily on physician-nurse relationships and to some extent on nurse-pharmacy relationships. Given this scenario, measurements in the literature will be reviewed for their relevance to this study's consideration of indicators of performance and performance as an evaluation outcome, literary evidence validating the performance theoretical framework, and hypothesis development. Further, evidence of the elements of organizational performance in relation to interdepartmental measures of clinical engineering is used to test the relationship of organizational structural complexity and processes in relation to hospital level of quality as measured by effectiveness, efficiency, and regulatory compliance.

Nine independent latent constructs of hospital organizational structure and interdepartmental processes and three dependent latent constructs of the quality of clinical engineering outcomes and their observed variables were extracted by searching an extensive academic online database of peer reviewed articles (MEDLINE, PsychInfo, Education Resource Information Center (ERIC), Social Science Citation Index (SSCI), GOOGLE SCHOLAR) and specialized biomedical and clinical engineering journals (Biomedical Instrumentation & Technology, Journal of Clinical Engineering). The following keywords were combined in multiple searches for pertinent items: organizational performance, patient outcomes, quality, performance metrics, healthcare, evidence-based, outcome measurement, healthcare outcomes, health care, and empirical research.

Multiple empirical examples of organizational performance as an organizational outcome in clinical engineering as well as in and other industries support the model and hypothesis development in this study. The following sections—Organizational Performance in Healthcare and Other Industries, and Organizational Performance in Clinical Engineering—validate the theoretical framework and selection of predictive latent constructs on the premise that quality is an outcome indicator of performance predicted by organizational and operational features measurable by a survey of a national sample of biomedical engineering technicians.

2.1 Organizational Performance in Healthcare and Other Industries

During the last twenty-five years, global competition among industrial leaders that manufacture items ranging from automobiles to personal computers has shifted the focus from traditional financial measurements to less tangible metrics such as consumer or

client satisfaction (Gomes, Yasin, & Lisboa, 2004) or to "culture, communication, and knowledge" in Israeli local government operations (Carmeli & Tishler, 2004). As production capacity limits to improve were realized from individual manufacturing factors that calculated errors in terms of parts per million, and as service industries emerged where administrative process improvements did not apply, the influence of relationships within the work environment and to the client provided an alternative way to measure organizational performance.

Despite variance in organizational performance indicators due to industry perspectives, some general concepts are shared. For example, proponents have spent decades identifying and defining core elements in the organization using policy analysis with "classic economic criteria of effectiveness, efficiency, and equity" (Salamon, 2001, p. 24) to improve levels of product and service delivery in the public and private sectors. Those three criteria can objectively address the fundamental operational status of an organization by answering certain questions. Did the organization meet their stated objectives? Did the benefits exceed the costs? Did the organization manufacture, distribute, or provide goods and/or services to address the needs of the vulnerable populations? In short, the manufacturing vernacular would be to achieve effectiveness by "doing the right things" and then "doing things right" to achieve efficiency (Tenner & DeToro, 2000, p. 93)

The Institute of Medicine (2001) officially established effectiveness, efficiency, and equity as the criteria to evaluate the quality of health care. Historically, Donabedian equated clinical effectiveness to the degree of application of "current science and technology" (1988, p.1743) to improve patient health. On the other hand, efficiency could

be achieved only if practitioners recognized that care should be limited when its' cost exceeded the value assigned to the incremental gains in health. In corporate terms, quality means that best practices are applied, waste is avoided and coordination of care is provided without prejudice (Mayberry, Nicewander, Qin, & Ballard, 2008).

Though not often noted, the formation of interpersonal relationships bound by fundamental ethical standards is another important dimension of Donabedian's timeless approach to organizational performance in terms of quality. "The conduct of the interpersonal process must also meet individual and social expectations and standards, whether these aid or hamper technical performance" (Donabedian, 1988, p. 1744). Steer (1975) also believed that employee relations could be a significant organizational metric. Therefore, it should not be surprising that researchers have extracted structural predictors that rely on relationships (e.g., leadership, organizational culture, coordination, cooperation, integration) and the associated processes (e.g., collaboration, teamwork, communication) that influence various components of organizational performance outcomes. In this study, quality is measured by the perceptions of interdepartmental processes delivering professional services in healthcare that improve patient outcomes (Lohr and Schroeder, 1990; Donabedian, 1988).

Similarly, it is not unexpected that these indicators may have both positive and negative associations with organizational performance. For example, Blegen, Sehgal, Alldredge, Gearhart, Auerbach, and Wachter (2010) positively associate an increase in patient safety with an integrated process across professional boundaries (nurse, physician, and pharmacist) through communication and teamwork. In contrast, Ballard and Siebold

(2006) warn of a potential adverse effect of interdepartmental communication: loss of job satisfaction—which also is a performance measure.

Since the late twentieth century, practices to increase organizational performance through cooperation, collaboration, and integration practices have proven successful in the manufacturing and information systems industries (Flynn, Schroeder, & Sakakibara, 1994; Schonberger, 1983). Cost efficiency objectives (Hwang & Herndon, 2007) accompanied an evolution in the pursuit of healthcare quality—"an integral part of the hospital organizational performance equation" (Raju & Lonial, 2001) in which high standards and goals, interdepartmental coordination, and resource sharing were embraced to increase efficiency (Flood, Zinn, & Scott, 2006). Donabedian (1980, as cited by Hsiao & Boult, 2008, p. 302) characterized high-quality care as an "account of the balance of expected gains and losses that attend the process of care in all its parts" in order to capture the "inclusive measure of patient welfare."

The search for quality in the 'parts' before the "whole" can be fully understood is dominant in the literature. Researchers have focused on hospital units within the organization and on the nurse-physician relationship. For example, Minvielle, Dervaux, Retbi et al. (2005) built an organizational assessment tool modeled from Shortell, Rousseau, Gillies et al., (1991). Minvielle, Aegerter, Dervaux et al. (2008) used that instrument (an organizational performance score derived from five factors including coordination and communication) to assess the influences of organizational culture on the nurse-physician relationship in Intensive Care Units (ICUs) in Paris, France. Minvielle et al. (2008) used comparative organizational performance scores to suggest changes in the cultural values in the ICU that could lead to improvements. Morey, Simon, Jay et al.

(2002) extended the concept of nurse-physician pairs to also include atypical participants like technicians, admitting nurses, and patients in their study on error reduction in emergency departments in nine hospitals designated as civilian, military teaching or community. The authors conclude that formal training in teamwork ("working together does not equal teamwork"—Morey et al., 2000, p. 1572) can help form behavior and attitudes that reduce errors that can harm patients.

Other researchers have isolated many facets of organizational performance outcomes. Principal outcomes of healthcare organizational performance include patient and organizational safety (Blegen et al., 2010; Morey et al., 2002); patient outcomes (Beckett & Kipnis, 2009; Schmalenberg, Kramer, King & Krugman, 2005); professional performance such as nursing (Mark, Salyer, & Wan, 2003). With few exceptions, most studies emphasize the nurse-physician relationship; while some extend to non-clinical areas like Pharmacy.

Opposing views on two other organizational performance outcomes—patient satisfaction and regulatory compliance, are evident. For example, several researchers believe that patient satisfaction is a positive performance indicator for coordination, collaboration and communication (Fewster-Thuente & Velsor-Friedrich, 2008); for collaboration, knowledge management and teamwork (Yeager, 2005); and for nurse-physician coordination (Corser, 1998). However, contrasting findings resulted for researchers in Taiwan who surveyed 661 patients from gynecology, surgery and internal medicine (Cheng, Ho, & Chung, 2002) and from a national survey in the United States: Consumers' Experiences With Patient Safety and Quality Information (Kaiser Family Foundation, AHRQ, and Harvard School of Public Health, 2005). These studies found

that most patients either based their responses simply on personal experience or were not able to recognize systemic quality problems because they had no specific knowledge of hospital administrative policy, clinical expertise, or quality-related skills, especially in relation to rates of hospital associated infection in Taiwan and medical errors in the US. Similarly, “despite the fact that patients are recognized as the ultimate justification for providing collaboration care” (D’Amour et al., 2005, p. 116) patient satisfaction cannot be fully realized as a major performance indicator until there is a methodology for their active participation in the health care team.

In the same manner, regulatory compliance has been positively associated with organizational performance, in terms of interagency coordination of social services in the United Kingdom (Alaszewski & Harrison, 1988) and of interdisciplinary effectiveness in a cross-sectional study of 1,784 community hospitals by Weiner, Alexander, Shortell, et al. (2006). However, Chuang and Inder (2009) believe that existing literature has not generated empirical evidence for the notion that a regulatory hospital accreditation system can improve the quality of care.

However, accreditation agencies like The Joint Commission (2010) have implemented patient-centric core measures that are evidence-based and focus on direct patient conditions such as acute myocardial infarctions and community-acquired pneumonia. Researchers at Stanford Hospitals and Clinics in Stanford, CA have established accountability initiatives through interdisciplinary teams in these academic medical centers that have improved unit performance in four areas (Pardini-Kiely, Greenlee, Hopkins, Szaflarski, & Tabb, 2010). These areas were heart failure, acute myocardial infarction, community-acquired pneumonia, and surgical quality. Pardini-

Kiely et al. (2010) and Sorensen and Iedema (2008) attribute performance improvements to the implementation of unit interdisciplinary teams using communication to consolidate diverse medical perspectives and establish accountability in order to improve patient outcomes.

Recently, Patient Safety Indicators (PSIs) designed by the Agency for Health Care Research and Quality (2008) have been successfully applied. Weiner et al. (2006) used AHRQ PSIs to outline a broad approach extending system capabilities by improving work process. The authors concluded that organizational effectiveness depends on interdepartmental collaboration to "implement across many conditions, disciplines, and departments" (Weiner et al., 2009, p. 309). Researchers at the Mayo Clinic Rochester hospital (Naessens, Campbell, Huddleston et al., 2009) tested several known measures of adverse events, including the AHRQ PSIs, and concluded that multiple methods are necessary to identify the greatest range of them. Analysis of Veterans Administration (VA) medical discharge records for 1997-2005 found that rare adverse events in inpatient care could not be measured using AHRQ PSIs measures. AHRQ PSI may exclude VA or other medical facilities that perform only outpatient surgery without anesthesia, are not classified to perform the major surgeries for which the PSIs are designed (Romano, Mull, Rivard, et al., 2008) or experience other reliability limits on rare adverse events (West, Weeks, & Bagian, 2007). For example, patients at long-term-care facilities are most susceptible to nosocomial infection (Stevenson and Loeb, 2004), but its occurrence there may be overlooked in this facility because it could not be related to a surgical procedure. Patient harm from an adverse event is generally attributed to a combination of individual error and systemic failure (Kohn, Corrigan, & Donaldson, 2000). Therefore, measures

that account for variation in both the medical facility and ancillary services should be considered.

Beckett and Kipnis (2009) suggest TJC NPSG as the basis for healthcare systemic goals such as the reduction of adverse events and the elimination of hospital-acquired infections. Optimal professional achievement through collaboration, communication, and teamwork is essential to quality care and safety (Beckett & Kipnis, 2009), to bridging the gaps in scientific knowledge among the interdependent healthcare professionals (D'Amour et al., 2005). The literature suggests that interdisciplinary dynamics may be an intangible aspect of organizational performance that has not been significantly explored.

This section has demonstrated that the overarching measure of organizational performance premises effectiveness, efficiency, equity and ethical professional relationships to support quality. Consequently, analysis must include multiple factors whose impact in combination with processes on the quality of healthcare can be assessed. The next section establishes a broad spectrum of elements comprising organizational performance and intangible dimensions for measurement drawn from the literature, to develop the conceptual framework and theoretical support for outcome measures of the quality of patient care. The literature review has indicated reservations about the use of patient safety indicators because they do not capture the adverse events in all types of healthcare facilities. Finally, the literature suggests that use of the NPSG can produce effective, efficient and equitable outcomes.

2.2 Organizational Performance Metrics in Clinical Engineering

The literature recounts several applications of the factor of effectiveness and a scant few applications in efficiency in metrics for clinical engineering organizational performance. In the US effectiveness is equated with a health system's quality of clinical care measured by outcomes as opposed to the internationally recognized definition of effectiveness as the completion of system goals (Arah, Klazinga, Delnoij, Ten Asbroek, & Custers, 2003). This section details some specific clinical engineering models, the departmental link to nursing performance, and performance metrics established in the literature.

A clinical engineering effectiveness model was developed by Frize in her 1989 doctoral dissertation which established organizational culture as a causal link to the effectiveness of clinical engineering in Canadian hospitals. The model, which used organizational characteristics, managerial policies and practices, external environment, organizational climate and employee characteristics, was later applied by her protégé (Cao, 2003) in the assessment of Third World clinical engineering departments. Since that time, a few quality models have noted the relevance of medical equipment and/or personnel to the environment of care in a progressive interdepartmental/interdisciplinary approach to quality: Logical Framework Analysis (LFA) to reduce adverse events (Dey & Hariharan, 2006); Critical Success Factors (CSF) captured in "PROCESS" as an effective system to reduce medical errors (McFadden et al., 2004); and diagnostic process optimization framework (DPOF) to increase hospital efficiency (Podgorelec et al., 2009; Podgorelec & Kokol, 2001).

LFA is a project management framework that uses group dynamics to elicit objectives, incremental monitoring and evaluation methods to improve processes. The framework was used by hospital administrators, practitioners, and support staff in a 650-bed tertiary care facility in Barbados to improve service utilization in the operating room and emergency room, and improve perceived poor care in the intensive care unit. The group encounter elicited several consistent factors concerning medical equipment and improper communication structure (both within and between departments) that contributed to adverse patient outcomes. Items were first delineated into Donabedian's Structure-Process-Outcome model. Implementation of the objectives improved the use of services in OR and ER, remarkably reduced overall adverse patient events, and increased patient satisfaction. (Dey & Hariharan, 2006).

PROCESS is an acronym developed by McFadden et al. (2004) that stands for critical success factors in reducing errors: (P)artnership of all stakeholders, (R)eporting errors without blame, (O)pen-ended focus groups, (C)ultural shift, (E)ducation and training programs, (S)tatistical analysis of error data, and (S)ystem redesign (McFadden et al., p. 65). The authors contend that to achieve effectiveness, a system-wide implementation of these suggested practices in the hospital environment of care must include practitioners, physical therapists, and non-clinical personnel such as pharmacists. In their proposition, "a 'system' includes the functioning of equipment and technology, or the procedures that people follow when administering the needs of patients" (McFadden et al., 2004, p. 65). McFadden et al. performed a case analysis of the effectivenss of the PROCESS model in 4 Illinois hospitals (2 teaching, 2 community) and with a total of 8 representatives. Relevant results include the assignment of a high level of importance to

all the PROCESS factors on average, except for ‘open-ended focus groups’ which may be considered a communication factor. This study is one of the few that incorporate multiple structural components (organizational culture, coordination, cooperation, social forces) and processes (communication, partnerships) with the objective of improving the quality of care by reducing errors through the assessment of adverse events.

Though healthcare management has responded to the drive for efficiency by absorbing competitors, such consolidation has not increased efficiency (Podgorelec & Kokol, 2001). These authors instead propose additional efficiency measures identified by a diagnostic process optimization framework (known as DIAPRO, later revised as DPOF) that focused efforts on the “diagnostic-therapeutic cycle” that consists of the traditional clinical methods of observation, diagnosis, and therapy (Podgorelec et al., 2009, p. S56). Together, Podgorelec et al. (2009) formulated a solution that minimized the diagnostic process by optimizing external inputs (regulated by clinicians, laboratory personnel, pharmacists, and equipment technicians) that matched available and qualified personnel with the most reliable equipment, increasing efficiency through knowledge management by maximizing two relevant organizational components—personnel and equipment. Podgorelec et al. (2009) applied the DPOF in a case study of mitral valve prolapse syndrome in a regional hospital presumably in Slovenia where the authors are located. In this instance, translating the tacit knowledge of departmental personnel to explicit (quantitative) data enabled efficient practices incorporating localized and/or individual information (lab turnover time, equipment sanitation schedules, personnel, patient health history) into the diagnostic process. The DPOF methodology is a solid application of the

structure, process, and outcome premise of a system-wide approach to efficiency at multiple levels: individual, departmental, and organizational integration.

Several studies have agreed on the relevance of the BMET department as the primary supplier of medical devices for the EC. Gurses and Carayon (2007) in their survey of 2727 Wisconsin intensive care nurses, cite insufficient or malfunctioning equipment as a major obstacle to nursing performance profession and a factor destructive to the quality of working life. Although greater contributions from other areas were found (e.g. noisy work environment, 46%; family distractions, 42%) problems with equipment availability contributed 32% of perceived performance obstacles and 20% of time was wasted searching for equipment (Gurses & Carayon, p. 189). In another study (Needleman et al., 2009, p. 11S), nursing performance measurement objectives were linked to "workplace practices [that] include organizational culture, interdisciplinary collaboration, equipment failures, and documentation burden".

Researchers in Japan have also considered the use of medical devices in clinical care as a major aspect of patient safety. Matsubara, Hagihara, and Nobutomo (2008) surveyed multiple healthcare professionals, including nurses and physicians, in 9 non-teaching hospitals. Healthcare support personnel, as well as various services, included technical staff and pharmacy staff. Major organizational factors evaluated included equipment availability and the role of social structure in the acquisition of needed equipment. Responses from the 1878 participants in Fukuoka Prefecture indicated that 64.3% of total variance in organizational factors could be attributed to three aspects of safety leadership (supervisors, allied professionals', patient safety committee) and to rules/equipment availability (Matsubara et al., 2008, p. 213).

Organizational performance metrics in clinical engineering have been developed. One of the first practical benchmark indicators was the calculation of value derived from total clinical engineering (CE) expenses/total equipment cost, introduced by Cohen et al. (1995) and validated by statistically significant correlations in Cohen's follow-up study in 1997. The use of ratio relationships to measure effectiveness has been advocated by Andersen (2006). Consequently, this study recognizes additional clinical engineering measurement ratios—Capital Index Planning (Wang, Eliason, Richards, Hertzler, & Koenigshof, 2008) and Global Failure Rate or GFR (Wang, Eliason, & Vanderzee, 2006).

The Capital Planning Index advocated by Wang et al. (2008) is a technology assessment in which the total cost of management and maintenance of medical equipment (AKA Total Clinical Engineering or Total CE Expenses) is divided by the total capital maintenance costs, from continuous financial data provided by study participants. Wang et al. (2006) proposes the GFR: the ratio between the number of completed repair work orders and the number of devices, as having potential for use as a systemic outcome metric. The proposition is based on recognition that properly managed and accessible equipment promotes delivery in healthcare services and can be considered an environmental condition controllable by the BMET department. Early research was conducted by the Association for the Advancement of Medical Instrumentation using this method on a small sample size, did not consider this as a promising metric. However, Wang et al. (2006) assessed data from the Integrated Systems Information System with a larger study sample at 24 sites that were managed by ServiceMaster during 2001-2003. Although independent use of the GFR was not recommended, the tool provided valuable information as a component of a more comprehensive performance tool such as the

balanced-scorecard approach. A potential barrier for use of the GFR is that comparisons between organizations may be difficult due to different data collection methods or to proprietary limits on data sharing among organizations and between departments in the same organization. Wang et al. (2008) offer suggestions for refined analysis, including more "detailed knowledge of operational characteristics and financial analysis" such as "type of equipment supported, values of maintenance contracts, and external Time & Material expenses" (Wang et al., 2008, p. 34).

Wang et al. (2008, p. 25) compiles an extensive list of existing methods to assess effectiveness through measurements of outcome in four critical categories: operational, staffing, financial and staffing. Operational outcomes that measure internal processes include scheduled maintenance completion rate, percentage of repairs completed within 24 hours and within 1 week, full time employees/number of capital devices, and number of scheduled maintenances/number of capital devices. Staffing outcomes that measure learning and growth include staff turnover rate, percentage of CE budget devoted to training, staff qualifications and competency, and employee satisfaction score. Outcome measures of customer satisfaction include customer satisfaction score, Global Failure Rate (GFR) and group failure rate for high-risk equipment, uptime for mission-critical equipment, and percentage of equipment-related patient incidents. Finally, outcome measures for financial indicators include the calculation of total CE expense as a percentage of total acquisition cost or value=total CE expenses/total equipment costs; total CE expense per adjusted patient discharge and/or patient day; total CE expense per staffed patient bed; and total CE expense as a percentage of hospital total operating cost.

This section has demonstrated that research has used the measurement of effectiveness and efficiency to some extent in assessing quality in clinical engineering, which supports the claim that access to operational medical equipment—a function of the biomedical engineer in clinical engineering, is a causal factor in nursing performance. This section provided several examples of outcome measures for organizational performance in operations, staffing, financial, and customer satisfaction. The barriers to organizational study comparisons presented by constrained access and divergent data reporting are acknowledged.

2.3 Summary

This chapter reviewed the literature on empirical evidence supporting the use of performance metrics in model and hypothesis development. Organizational Performance Theory has been successfully applied to studies of hospital units in healthcare (e.g., ICU, ED) and to other industries such as policy analysis and manufacturing, using derivatives from the classic criteria of effectiveness, efficiency, and/or equity. However, healthcare studies have emphasized nurse-physician clinical relationships, and they have often measured only a small number of predictors in relation to one aspect of organizational performance such as financial or other administrative categories. Further, the literature revealed an inability to capture interdependent relationships. The literature does support an inclusive approach to systemic problems that extends research by using multiple predictors in relation to a range of practitioners and non-clinical personnel (e.g., biomedical engineering technicians) on the basis of their indirect impact on patient health. Previous findings have captured a variety of individual predictors and aspects of

organizational performance outcome measures, with some contrasting results. For example, a multidisciplinary approach using communication as a predictor has mixed results for the outcomes of patient safety and job satisfaction. Difficulties with analysis using core measures and patient safety indicators in relation to adverse events were discussed and alternatives introduced. This section also identified the use of critical evaluation criteria in research on clinical engineering performance, the departmental link to nursing performance, and listed current performance metrics as well as the barriers to divergent financial data collection. The next describes the theories used to develop the study's conceptual framework and the hypotheses.

CHAPTER 3: THEORETICAL FRAMEWORK

The preceding chapter's literature review on empirical evidence in healthcare, in other industries, and in clinical engineering supports the use of predictor and outcome metrics for organizational performance predictor for this study's model and hypothesis development. This chapter provides the theoretical framework used to develop the study model, research questions, and hypotheses.

John Brunner, 20th century British science fiction author:

There are two kinds of fools, one that says, "This is old, and therefore good." And one that says, "This is new, and therefore better."

The healthcare industry has seen a paradigm shift in quality management since Donabedian (1970) recognized the organizational limits of physician-only solutions to patient care. That recognition impelled the movement from isolated efforts to improve quality (identified by inpatient service delivery by physicians assessed by management's interpretation of financial indicators) to consideration of personnel, structural characteristics and associated processes in the environment of care (EC). Guided by Donabedian, the nursing profession was the first to move beyond the constraints of traditional patient care, as they stepped into the role of patient advocates to address broad-based community problems such as access to care. Quality initiatives during the late 1980's indicated a widening span of professional concern. As a result, changes in the structural components of the hospital EC in conjunction with the processes of care were recognized as keys to eliminating or at least reducing adverse events that affect patient health. The processes involved in patient monitoring and the administrative oversight of

those tasks were recognized as vital to optimal outcomes. These components—structure, process and outcome of the quality of care, known as the Donabedian Triad, have become standard measures since their introduction by Donabedian (1966) as fundamental constructs of Organizational Performance Theory. However, four decades after Donabedian recognized the need to fully engage nursing in addressing healthcare quality, no notable advances in other healthcare professions and ancillary services have followed. Since health care outcomes are products of multiple health care personnel and characteristics, the continued endeavor to address systemic quality problems by engaging specialized clinical and non-clinical professionals is the next logical application of the Donabedian Triad. The challenge is to identify the systemic clinical and non-clinical practices and the EC conditions that ensure the most effective, efficient, and equitable patient care.

One systemic problem is the pervasiveness of iatrogenic illness which means illness "brought forth by a healer" (Francis, 2008, p. 223). Iatrogenesis includes medical errors (including those related to medical devices and equipment), nosocomial infections (NI), and other hospital associated infections (HAIs) known to increase mortality and morbidity rates and extend hospital stays and thus to increase healthcare costs. The supplemental care required is not associated with the original progression of disease or illness that brought the patient into care (Brady, Redmond, Curtis, Fleming, Keenan, Malone, & Sheerin, 2009; Francis, 2008).

Though ubiquitous hand sanitation campaigns have produced some satisfaction, the overall incidence of iatrogenic rate has continued to rise, and the healthcare industry has struggled to find solutions (Fakuda, Imanaka, Hirose, & Hayashida, 2009; Corrigendum,

2009). However, the dilemma opens the door for efforts to mitigate impact systemic problems by turning to expanded roles for the full range of healthcare professionals, much as Donabedian's work roused nursing to professional standards of patient advocacy. "Infection control programs were among the first organized efforts to improve the quality of healthcare delivered to patients" (Stevenson & Loeb, 2004). Today, infection control and communication among practitioners remain principal targets of National Patient Safety Goals in the United States (JCT NPSG, 2010). Hence, analysis using the Donabedian Triad may shed additional light on the endeavor.

The following sections define the fundamental theoretical premise and distinguish the elements used to develop the study model. In addition, Integrated Empirical Ethics is introduced as a supporting theoretical premise. Respondent and organizational control variables are specified and the hypothesis statements for the study are presented.

3.1 The Structure-Process-Outcome Theory

This section defines the basic components of Donabedian's Triadic Theory: structure, process, and outcome. In accordance with them, specific elements of this study (Structural Complexity, Process Adequacy, and Level of Quality) are detailed.

Donabedian (1989, p.11) found the following:

While the primary reliance in our quest for quality is on the knowledge, skill, motivation, integrity, and dedication of health care practitioners, we cannot expect them to be unflaggingly heroic or self-sacrificing in the service of quality. It is the responsibility of the organization, rather, to create the conditions under which good practice is as effortless and rewarding as it can possibly be.

Donabedian's (1988, 1966) organizational performance theory appropriately begins with assessment measures derived by identifying the multiple conditions that characterize the location where health care is received and those who provide it. Upon this foundation, the elements of the theoretical premise arise: structure (the health care practitioner attributes or organizational features defining material resources that affect performance), process (activities related to caregiver responsibilities and patient responses to care), and outcome (evidence such as health status gathered from the recipients of care).

As guided by Donabedian's (1989) quality approach to systemic issues, process assessment emphasizes system design and performance monitoring. Corporately, this step requires large-scale collaboration among multiple units across the entire operation to achieve large-scale effectiveness, efficiency, and regulatory compliance. The assessment establishes the dimension of systemic change, and performance monitoring gathers information by "(1) systematically collecting information about the process and outcome of care, (2) identifying patterns of practice, (3) explaining these patterns, (4) acting to correct deficiencies, and (5) verifying the effects of remedial actions" (Donabedian, 1989, p. 3).

For example, the documented relationship between infections and medical equipment suggests that existing processes may need revisions that require adding atypical personnel. Support for this conjecture can be found in the systemic approach to the reduction of HAI in England, where outbreaks were generally attributed to deviations in established processes over time that progressed to adverse events (Waterson, 2009). Four of the five factors contributing to outbreaks were controllable within existing

organizational boundaries. They include: 1) organizational management, 2) clinical management in hospital wards, 3) infection control involvement, and 4) specific factors of hygiene and equipment. The significance of the approach is the use of a risk reduction modeling framework to identify "dynamic interaction between levels within large-scale sociotechnical systems" (Rasmussen, 1997 as cited by Waterson, 2009, p. 166). At minimum, this perspective validates Donabedian's call to incorporate diverse elements of care across professional boundaries, which requires a collective understanding of their responsibilities in the EC to be reached through collaborative processes.

Consideration of a controlled, quality-assurance driven Organizational Performance Theory approach to hospital management reflects the industry's move away from rigid hierarchies as the result of several inputs: the rapid rise of merged services across many clinical practices, conflicting regulatory obligations, emergent shared medical record-keeping platforms, and a multitude of additional contextual factors that call for a broad evaluation of the structural, process, and outcome complexities. The premise is based on communication among multiple entities without a consistent level of authority. Consequently, theoretical analysis requires knowledge management that can effectively communicate and incorporate knowledge across professional, departmental, or other cultural barriers. However, the absence of complete systemic information requires the application of Triadic analysis for a better understanding of the 'missing parts' of healthcare delivery. Runciman et al. (2009, p.1) recognized the "physical infrastructure and biomedical engineering support systems, as well as how healthcare services are organized with respect to… the availability of the necessary equipment and supplies" as important elements of structure. Section 2.2 detailed the prevailing focus in research on

physician-nurse relationships and hospital units such as the ER, OR, or ICU. Given the historic emphasis on unit studies as well as the importance of medical equipment for nursing performance and the association of iatrogenesis with medical equipment, processes performed by biomedical engineering technicians in clinical engineering are salient in healthcare. Finally, the commonality of healthcare measured by effectiveness, efficiency, and equity suggests that outcome measures in terms of clinical engineering effectiveness, clinical engineering efficiency and regulatory compliance are appropriate proxy measures of the level of quality. Therefore, Donabedian's (1966) modified Structure, Process, and Outcome Model of Organizational Performance is the basis for this study's use of latent constructs to enhance understanding of the indicators and associated processes that improve the quality of care.

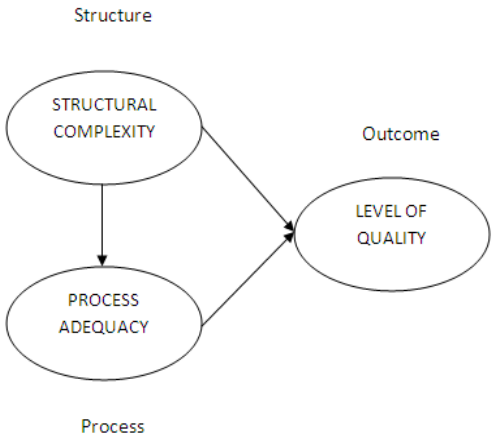

Figure 3.1 Modified Structure-Process-Outcome Model

Figure 3.1 demonstrates the fundamental theoretical components in the temporal sequence that is the basis for further analysis. Structure, process, and outcome components delineate quality of care through methods that ensure the highest level of care at the least cost (Donabedian, 1989). Quality as an outcome should therefore include

factors that represent internal measures of cost efficiency, the span of reach or effectiveness, and the extent to which external factors such as regulatory policy to promote those objectives.

The theoretical premise established three primary latent constructs supported by the literature: Structural Complexity, Process Adequacy, and Level of Quality, which represent the complexity in healthcare composed of multi-management interfaces. Therefore, independent variables were not eliminated until analysis had examined their inter-relationships in detail. Concurrent examination of the variables may reveal important relationships that have not been cumulatively assessed heretofore in this context (Figure 3.2).

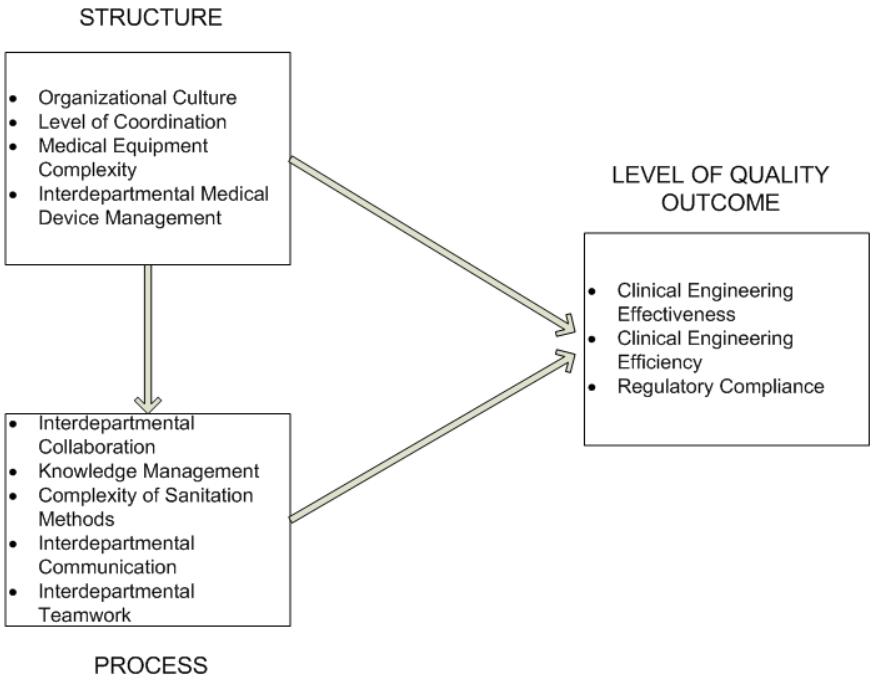

Figure 3.2 Conceptual Model of Structure-Process-Outcome Dimensions of the Biomedical Engineering Technician Healthcare Support Personnel

The following section elaborates on each of the nine content-based categories established from the literature review, which focused on organizational and process determinants in the hospital EC, the personnel integration proposition, and the quality-focused BMET/CE outcomes representing interdependent professional reliance on medical equipment to achieve performance goals. The interrelationships of the study variables should be evident. They represent observable variables of the Structural Components and Process Adequacy latent constructs. Three observable measurement variables for the latent endogenous variable of the Level of Quality also follow. (Appendix A1).

3.1.1 Structural Complexity: Latent Exogenous Construct and Measurement Variables

This section discusses the four observable variables of the latent exogenous construct of structural complexity used in this study. They are organizational culture, level of coordination, medical equipment complexity, and interdepartmental medical device management. Although scholars have concluded that structural changes alone do not automatically become a source of improvement in healthcare quality (Flood et al., 2006), Donabedian's quality assessment and monitoring cycle (2003, p. xxviii) requires an analysis of current conditions to identify variances in resource, capacity and other factors.

3.1.1.1 Organizational Culture

Research on organizational culture has yielded mixed interpretive results for the level of added value (Waterson, 2009; Minvielle, et al., 2008, 2005; Stock et al., 2007; Scott, Mannion, Davies & Marshall, 2003a). The lack of consensus about appropriate models multiplies the subjective interpretations. Despite the divergent views on the very broad notion of organizational culture, scholars generally agree that environmental conditions influence individuals through the social queues in a particular institution. Hence, the role of culture is vital to understanding organizational contexts.

Examining the divergent formulations of organizational culture can yield a more manageable component for analysis. According to Scott et al. (2003a), the problematic definition of organizational culture can be narrowed to two primary approaches: that of a general metaphor or that of an attribute. The authors describe organizational culture as an emergent property related to a social institution's status. They argue that therefore "culture is not assumed a priori to be controllable" and "that its main characteristics can at least be described and assessed in terms of their functional contribution to broaden managerial and organizational objectives" (Scott et al., 2003a, p. 112).

Garnett, Marlowe, & Pandey (2008) distinguish those two perspectives on organizational culture. As an attribute, organizational culture is defined by the physical description of the climate or culture. The metaphorical, or symbolic, perspective interprets organizational culture from stories of events that provide a general understanding of how it functions.

Stock et al., (2007) defines the construct of organizational culture in great detail by using a scale of locus of control that features an x- and y-axis relationship. The x-axis

ranges from ‘internal’ at the left to ‘external’ at the right and the y-axis is central to the x-axis and is represented by ‘control’ below the intersection point and ‘flexibility’ above it. Thus four major quadrants of organizational culture are delineated: Development Culture in the mathematically designated quadrant I, located at 0 to 90°, is characterized by more external indicators such as resource acquisition and more flexible components such as risk taking. Successive quadrants move counter-clockwise. The second quadrant, Group Culture, is characterized by teamwork, as a more flexible characteristic, and by personal relations, as more representative of internal controls. The third major quadrant is Hierarchical Culture, characterized by internal indicators of formal rules and structure, the control being coordination and internal efficiency. The fourth quadrant represents Rational Culture characterized by control indicators of market leadership and competitiveness, showing the results-orientation of the organization.

It has been shown that an organizational culture may hamper efforts to improve the quality of care by enlisting a range of professionals through interdepartmental partnerships facilitating cooperation and coordination (McFadden et al., 2004). Specifically, an organizational culture may or may not support cooperative integration among hospital support personnel as sought with proponents in the BMET profession (Dondelinger, 2008; Fennigkoh, 2005) and/or researchers who recognize the potential contributions to quality of medical equipment technicians (Falagas & Karagerogopoulos, 2009; Dey & Hariharan, 2006). Infection-control measures should focus on limiting transmission by paying attention to the contribution of the “inanimate environment, hospital personnel, and medical equipment” (Falagas & Karagerogopoulos, 2009, p. 345). The findings from studies of cooperation have recognized the contribution of health

support professionals in reducing overall patient risk through corporate participation (McFee, 2009; Mark et al., 2003).

In healthcare, organizational culture has intervening effects on measures of quality policy and procedure through normative processes that improve patient care (Minvielle et al., 2008; Dey & Hariharan, 2006; Scott, Mannion, Davies, & Marshall, 2003b). In addition, Minvielle et al. (2008, 2005) in their study of 26 intensive care units in Paris, France, found a strong relationship between the types of shared cultural values and organizational performance.

Organizational culture has also, however, been considered a substantial barrier to improving organizational performance in the field of healthcare, specifically among BMETs and other professionals. For example, McFadden et al. (2004) showed that quality efforts can be thwarted by administrative and social forces that prohibit the cooperation and coordination necessary to accomplish change. Leading BMET professionals (Dondelinger, 2008; Fennigkoh, 2005) agree that although cooperative integration among hospital support personnel is a fundamental component of systemic change, the professional opposition has been intransigent. However, increasing numbers of non-BMET professionals have recognized the contribution to quality of medical equipment technicians (Falagas & Karagerogopoulos, 2009; Dey & Hariharan, 2006).

These examples of an inclusive approach in healthcare show its traditional operational silos are opening to interdependent efforts on behalf of patient care. (Waterson, 2009; Allegranzi et al., 2007; Connor et al., 2002).

Indicators of organizational culture in this study have been drawn from the multiple sources noted above. Primary items used to measure organizational culture in

this study include whether biomedical engineering technicians value contributions to other staff members' professional development; whether they receive training in their job functions, and whether standards are applied equally across departments.

3.1.1.2 Level of Coordination

The second factor of structural complexity in this study is the level of coordination. Wells et al. (1998, as cited in Fewster-Thuente & Velsor-Friedrich 2008, p. 41) defined the attributes of collaboration as "open communication, cooperation, assertiveness, negotiation, and coordination." D'Amour et al.'s (2005) formulated the conceptual basis for interpersonal collaboration and advocated interdisciplinary collaboration between nurses and physicians. Such efforts have led to successful coordination of admission planning and many clinical improvements including the reduction of adverse events.

Lack of coordination among the various social services in the UK during attempts at reform in the early 1960 and the 1970's were shown to increase healthcare costs (Alaszewski & Harrison, 1988). Cost reductions then appeared when the multiple inputs from administrative and clinical services were focused on patient needs. The authors present a case for the rational model that depicts complex coordination, defined by them as a combination of communication and structure (p. 637), as essential to a comprehensive approach that improves patient outcomes.

Research in the last decade has been dominated by the notion of coordination as an output of collaboration (D'Amour et al., 2005; Wells et al., 1998; Corser, 1998). Other researchers (Alaszewski & Harrison, 1988) chose to view coordination as concurrent with

collaboration in a more inclusive perspective that presumes both are necessary to cover the span of interagency activity. However, whether a subordinate or a lateral position is assigned to coordination with respect to collaboration, understanding the interdependent nature of coordination is vital to advancing quality. “More formally organized professional staffs with well-defined coordination and conflict management processes” and “higher levels of differentiation and coordination of medical staff” are generally associated with better quality of care (Flood et al., 2006, p. 430).

In this study, indicators of the level of coordination have been drawn from the multiple sources noted above. The primary indicators are whether biomedical engineering technicians receive and/or provide inter-departmental input in order to complete work successfully; whether they pursue inter-departmental solutions to systemic problems, and whether any results of inter-departmental coordination are visible.

3.1.1.3 Medical Equipment Complexity

The third structural complexity factor of this study is medical equipment complexity. The introduction of highly complex medical equipment technology together with persistent use of antiquated standard safety measures that do not take this aspect into account means that the criteria needed to reduce adverse events are missing (Hwang & Herndon, 2007; Fennigkoh, 2005; Baker, 2003). The deterrent to taking corrective action has been the cost attributed to doing so. For example, directives that rural providers invest in advanced equipment and personnel to reduce medical errors have been noted by Wakefield (2008). But the existing policy and administrative procedures may block such technology advances that diagnose, treat, and in some cases formulate

evidence-based care. Nevertheless, the rise in adverse events and subsequent financial liabilities has impelled administrators to consider more accurate reporting mechanisms in order to reduce adverse events, to review diagnostic and treatment processes that use medical equipment, and to create new standards of safety for patient care.

Hwang et al. (2007, p. 21) presented this important finding:

Many safe practices and quality enhancing improvements, such as computer provider order entry, proper infection surveillance, telemedicine intensive care, and registered nurse staffing are in fact cost-effective.

The new focus on patient safety has persuaded healthcare managers of the long-term benefits of technology despite their fear of its initial costs. However, the consistent reporting of adverse events that is requisite to improving the quality of care is stalled by cultural taboos and fears of litigation. Moreover, in the absence of information integration, access to the level of information that can sustain, operate, and efficiently manage complex equipment across the EC remains short of what is needed for quality of care.

Medical technologists and other members of the BMET community are aware of such problems, which they know must be addressed to advance industry standards to manage medical equipment's complexity. In particular, Fennigkoh (2005) cited the increased importance of clinical engineers for managing the significant environmental factors presented by high-tech and often dangerous equipment.

The regulatory lag with regard to the maintenance and operation of complex medical equipment ignores the potential contribution to patient safety of the BMET. Current regulations still focus on preventive maintenance comprising electrical safety checks. These checks, though important, are outdated because they are an inadequate

form of preventive maintenance. They do not engage the BMETs broad spectrum of skills for reducing risk through their knowledge of design and high-tech safety engineering (Cram et al., 2004; Baker, 2003).

An emphasis on "equipment complexity… more likely to induce human error" (Baker, p. 185) shifts the focus from fixed electrical safety checks to such professional considerations s “annual performance checks and regular cleaning or visual inspection” (Baker, 2003, p. 184). The BMET and/or clinical engineering role in lowering patient risk should include consultation about selection of standardization and user training that supports successful introduction to equipment (Cram et al., 2004).

As the level of complexity of medical equipment increases, so does the importance of the BMET’s expertise in the overall community of care, to lower the clinical risk factors arising from “technology frustration and inadvertent user error” (Cram et al., 2004). The level of medical equipment complexity should drive not only advances in the BMET profession, but also the identification of internal administrative and external regulatory changes expected that are essential for patient safety and the quality of care in an up-to-date and cost-effective EC.

The study’s indicators of medical equipment complexity have been drawn from the sources noted above. The primary indicators are whether biomedical engineering technicians have adequate knowledge of all of the equipment’s available functions, whether the BMETs believe that excessive operations on the equipment are increasing the difficulty of using it, and whether BMETs need help to understand the equipment’s operation and/or maintenance.

3.1.1.4 Interdepartmental Medical Device Management

The fourth and final structural complexity factor of this study is interdepartmental medical device management. Healthcare risk assessments have noted the highly visible impact of equipment downtime on patient care, but experts do not always agree on the best method to assess or establish the effectiveness of a facility's equipment maintenance (Ridgway, Atles, & Subhan, 2009; Brush, 1994, 1993). A study by Agnew, Komaromy, and Smith (2006) emphasizes relationships between adverse events involving medical devices and the number of settings on a device, use of the same model type across all ECs, and the environment where the equipment is used as factors that affect the "condition, sustainability, and availability of equipment" (Agnew et al., 2006, p. 521).

There is little information about interdepartmental medical device maintenance management beyond the departmental repair orders for service that are stored in management maintenance systems. This data has been used for the ratio of equipment inspected in compliance with JCT regulations and so has been maintained in relative departmental isolation. Data on medical device management is risk relevant, however, since the availability of alternative equipment with the highest operational status must be included in the report of an adverse event involving medical equipment. This information is included in order to determine if the use of another device might have prevented the incident.

An isolated example of coordinated efforts by nurses and BMET staff to respond to a threat to quality is recounted by Robert Stanford, biomedical manager at the University Hospital in Augusta, GA (Williams, 2006). Responding to nursing concerns about dirty, broken, or missing equipment, Stanford orchestrated relocation of his

department near the Central Sterile location where used equipment was returned by hospital staff after patient use. The move placed his department in a position to formally implement new equipment inspection procedures including cleansing and sanitation that improved patient services and reduced complaints. The change increased awareness of the departments' contribution to the hospital EC.

Indicators of interdepartmental medical device management have been drawn from sources noted above. The primary indicators for interdepartmental medical device management in this study are whether medical devices (models and types) are consistent across departments, whether the biomed department is centrally located for easy access, and whether specific training is provided in recognizing medical device failure.

3.1.2 Process Adequacy: Latent Intervening Construct and Measurement Variables

Since structural complexity is expected to affect process adequacy in our modified Donabedian Triad S-P-O model, process adequacy is defined as a latent intervening construct until data analysis determines its moderating or mediating status. This section establishes five key process elements noted in the literature: Interdepartmental Collaboration, Knowledge Management, Complexity of Sanitation Methods, Interdepartmental Communication, and Interdepartmental Teamwork, detailed below.

3.1.2.1 Interdepartmental Collaboration

The first process adequacy factor of this study is interdepartmental collaboration. The complex relationship between coordination and collaboration has been previously noted. But the depth of significance of these factors in terms of their combined organizational impact may not be fully appreciated. "Collaboration is a complex process that requires intentional knowledge sharing and joint responsibility for patient care" (Lindeke & Siecker, 2005 as cited in Fewster-Thuente & Velsor-Friedrich, 2008, p. 41).

A Canadian study by D'Amour et al. (2005) categorized the notion of collaboration in five underlying concepts: 1) sharing, 2) partnership, 3) power, 4) interdependency, and 5) process. The research emphasized the essential contribution to quality of care made by collaborative patient-centered care in the context of teamwork. The authors found little literature examining interdependent relationships in healthcare. Their conclusions note a consolidated version of the definition of collaboration to guide for further understanding.

"The term collaboration conveys the ideas of sharing and implies collective action oriented toward a common goal, in a spirit of harmony and trust, particularly in the context of health professionals." (D'Amour et al., 2005, p. 116).

A limited though relevant focus on nurse-physician collaboration to improve patient outcomes as well as provider satisfaction dominates research on healthcare collaboration (Francis, 2008; Lindeke & Sieckert, 2005; Larson, 1999) For example, proactive nurse-physician collaborations in nursing strategies to reduce HAI have featured consultations about using invasive devices that are linked to infections (e.g., catheters) only when deemed necessary by the physician (Francis, 2008).

The collaborative approach to improving patient outcomes relies on recognition of the specialized contribution of each discipline. The nursing profession is committed to autonomy and accountability as fundamental to successful patient outcomes (Larson, 1999). Collaborations with physicians may have commitment side-effects. For example, without clear role delineation, responsibilities can become grey areas, with deleterious consequences for patient outcomes (Larson, 1999).

Collaborative research by nurses, physicians, and other support groups has led to positive patient outcomes associated with the nursing profession (Mark et al., 2003). However in that study the subject of analysis was not the hospital organization or health support services, but rather the impact of context and structure on the effectiveness of nursing professionals. Unique to this study was the simultaneous measure of support services and patient-related technology. Results indicated a proximate impact on the positive patient outcomes. Support services were represented by laboratory specimen collection, patient transportation, order entries (such as those to fill prescriptions), and internal administrative services like coordination of patient discharge.

The lukewarm interest in collaboration in healthcare may well be a sign that its expected outputs conflict with long-standing hierarchical management objectives. "[A]ttributes of collaboration include shared power based on knowledge, authority of role, and lack of hierarchy" (Kraus, 1980 as cited by Fewster-Thuente & Velsor-Friedrich, 2008). A shift towards those characteristics is a shift away from personal interests that are difficult to deconstruct towards an emphasis on collective interests. Consequently, healthcare's survival-mode has continued to rely on short-term responses in daily operations rather than making the long-term changes that are necessary.

The interaction between clinicians and the biomedical engineering technician department in particular has not been explored in detail. However, one significant extension of the role of the BMET as an intermediary is outlined by Ebben et al. (2008, p. 326), who suggest collaboration to extend their equipment knowledge across what they term "the chasm between technology developers and technology integration." Their suggestion is an example of how inter-professional training can expand to address systemic problems that contribute to medical errors. In their example, medical errors can be reduced through collaboration between the original equipment manufacturers (OEMs) and the end users of health technology, with the BMET as an intermediary. The authors recommend increased visibility in the process of purchasing new medical equipment to develop liaison relationships between OEMs and the clinical staff who use the equipment in patient diagnosis and treatment.

The study's indicators of interdepartmental collaboration have been drawn from the sources noted above. The primary indicators are whether biomedical engineering technicians receive and/or provide advice about new equipment purchases; whether the BMETs trust the equipment/clinical knowledge of other departments; and whether the BMETs recognize other departments as professional equals.

3.1.2.2 Knowledge Management

The second process adequacy factor of this study is knowledge management. Intensive management research in manufacturing and information systems at the end of the last century has established the potential of knowledge management which is equally relevant in health care. Indeed, knowledge management through interactive decision-

support systems, has produced successful patient safety guidelines in the diagnosis and treatment of patients with acute myocardial infarction (Quinn & Mannion, 2005), and has aided in the development of evidenced-based practices embodied in many treatment standards of The Joint Commission and other healthcare agencies.

Historically, knowledge management has been important in understanding fundamental research (Alavi & Leidner, 2001), system capacity (Gold, Malhotra, & Segars, 2001), the impact of cultural barriers (De Long & Fahey, 2000) and organizational performance (Choi, Poon, & Davis, 2008). In the hospital EC, knowledge management has practical application: the ability to translate vital patient information or to determine the availability of emergency personnel or equipment, as demonstrated by Podgorelec et al. (2009) and Podgorelec & Kokol (2001). Ultimately, constraint on information exchange in any system of care is problematic because patient outcomes will reflect any less than optimal information on which diagnosis and treatment decisions were based.

The delicate combination of collaboration, information, and patient care that is inherent in knowledge management can be either an avenue to successful patient outcomes or a significant barrier to solving systemic problems. In the hospital EC, knowledge management is an opportunity for intentional exchange through collaboration in order to elicit patient care among those jointly responsible (Lindeke & Sieckert, 2005). The conceptual approach to improved patient outcomes has roots in a Hage, Aiken & Marrett (1971, p. 860-1) study that traced how various 'linkage mechanisms' promoted a multi-party approach to the "transmission of new information [through] coordination by feedback and mutual adjustment."

Professional data integration that supports knowledge management in the hospital EC requires significant collaboration to incorporate healthcare data that span laboratories, human resources, clinicians, and equipment specialists (Podgorelec et al, 2009). Podgorelec's approach recognizes both the individual and organizational roles of support services in providing cost-effective services while instilling the value of their interdependent role that ensures the availability of complete, professional data.

Hagtvedt et al. (2009) present an interdisciplinary response to the problem of HAI. In their study, a team of experts in engineering, economics, and medicine, gathered from Georgia Tech and Cook County Hospital in Chicago, simulated a model including such typical protocols as hand sanitation and isolation of the patients and/or unit under investigation. However, the model also incorporated economic considerations such as demand and costs. Their findings recognized a "complex interplay of factors" that "suggest that a systems-level approach to infection-control procedures will be required to contain health-care-associated infections" (Hagtvedt et al., p. 256).

However, for an individual to translate tacit knowledge and experience in an interdisciplinary professional realm is not a simple task even in the same EC. A system-level approach thus requires "inclusion of healthcare personnel with specific knowledge required to address systemic issues" (Edmond, 2009, p. 75). Knowledge management may be the key to presenting competencies so that expertise is appropriately sought and can help avoid adverse events. The BMET brings unique understanding of hospital medical equipment and regulatory guidelines—knowledge that is a prerequisite for advanced infection control and for reducing adverse events caused by errors in using equipment (Cram, et al., 2004).

The study's indicators of knowledge management have been drawn from the sources noted above. The primary indicators are whether biomedical engineering technicians share informal knowledge to benefit patient care, whether the BMETs have access to formal knowledge within the department, and whether BMETs have access to cross-functional knowledge through electronic or other methods.

3.1.2.3 Complexity of Sanitation Methods

The third process adequacy factor of this study is complexity of sanitation methods. The advent of complex medical equipment has required more complex disinfection and sanitation methods. Though manual cleansing and disinfection processes are universally required, less complex methods of decontamination have been used in the general EC. For example, the use of hydrogen peroxide or other cleaning agents for pathogenic surface decontamination is prevalent, but these agents have only a limited ability to reduce NIs. Newer decontamination methods extend decontamination parameters to include internal equipment components and apply beyond the hospital EC to other contents of care such as ambulatory transport.

The level of sanitation needed for reusable medical devices and instruments is directly related to the amount of contact with sterile patient tissues during invasive procedures. Consequently, all medical equipment requires cleaning. Minimum instrument contact with unbroken patient skin is categorized as noncritical (e.g., blood pressure cuffs) and requires only low level disinfection. Semi-critical items that invade mucous tissue (endoscopes) or critical items (surgical instruments), require high levels of disinfection and sterilization. (Rutala & Weber, 2004).

Halcomb et al. (2008) conclude that the conventional solutions and materials used in terminal cleaning are not completely effective against HAIs. More intensive systems are required to guarantee sterile equipment (Dubois, 2001). Recognition of the difficulty in eradicating or even reducing NI transmission has markedly spawned international high technology solutions to overcome the deficiencies in manual cleaning methods.

Schabrun and Chipchase (2006, p. 239) analyzed quality documents dating from January 1972 to December 2004 to identify medical equipment's contamination levels and cleaning protocols and found that approximately "one-third of all NIs may be prevented by adequate cleaning of equipment." The authors established an 86.8% equipment contamination rate, which declined to 4.7% after regular cleanings by equipment using 70% alcohol concentrations. Other experimental researchers in the UK seeking ways to reduce HAI transmission rates approximated hospital cleaning environments by using a solution of microbiological agents and adenosine triphosphate (which is common to human muscle tissue and helps to translate stored energy) to simulate human tissue transference residue that may be contaminated with HAI and remain after manual sanitation efforts (Lewis, Griffith, Gallo, & Weinbren, 2008). Both of these studies focused on surface cleaning methods that improve sanitation incrementally, but are not complete systemic solutions. Though the methods employed substantially reduced the risk of NI transmission and were relatively cost effective with simple implementation measures, complete eradication of pathogens did not occur. As a result, alternate methodologies must be considered.

In Norway, Anderson et al. (2006) tested a programmable device developed by Gloster Sante Europe called Sterinis that disburses a dry fume containing 5% hydrogen

peroxide. The Norwegian research team recognized the importance of decontaminating the internal components of medical equipment, which can be reservoirs for HAIs in portable equipment like infusion pumps. In particular, internal fans used to recirculate air to cool motors on equipment in patient environments require more extensive internal decontamination. Consequently, the team introduced alternatives to "manual chemical disinfection (that) is both time and labour consuming" and has inherent defects that may result in inadequate coverage (Anderson, et al, 2006, p. 150). French researchers have introduced agents that meet the special requirements of heat-sensitive medical equipment to aid in the development of systemic solutions to HAI transmission (Lehmann, et al., 2009).

The consequences of the increased complexity of medical equipment and sanitation processes call for the option of BMET integration. A case in point occurred during a recent study of a Maine healthcare facility (Lessa et al., 2008). The study assessed the impact of a lapse in sterilization of the equipment used in prostate biopsies during the period of January 30, 2004 through January 27, 2006. Though there was insufficient evidence of a direct link to transmission of HAIs, analysis of the event revealed that the original equipment manufacturer (OEM) did not provide cleaning brushes for the reusable needle in the product kit. The researchers deemed advanced review of the OEMs reprocessing procedure to be 'critical' in order "to establish appropriate procedures to avert potential pathogen transmission and subsequent patient concerns" (Lessa et al., 2008, p. 289). Integration of a BMET with the nursing and technician staff may have been able to avoid the problem.

The indicators of complexity of sanitation equipment have been drawn from the sources noted above. The primary indicators are whether biomedical engineering technicians use manual sanitation methods on the surface of medical equipment, whether BMETs have introduced new high technology methods that cleanse and sanitize internal parts of medical equipment, and whether high technology methods for internal sanitation have been adopted as a standard at their facility.

3.1.2.4 Interdepartmental Communication

The fourth process adequacy factor of this study is interdepartmental communication. "[C]ommunication is conceptualized as the central social process in the provision of healthcare delivery and the promotion of public health" because information sharing is "essential in guiding strategic health behaviors, treatments, and decisions" (Kreps, 1988 as cited in Nanda et al., p. 4).

The information system age has made the relay of information quicker and more accessible, but has not formulated a universal method of doing so. Sentinel events reported to the Joint Commission indicate that as much as 70% have resulted from gaps in communication and collaboration (Fewster-Thuente & Velsor-Friedrich, 2008, p. 40). Various independent studies are consistent with a 60-85% range of independent contribution from communication (Fewster-Theunte & Velsor-Friedrich, 2008, p. 40; Fennigkoh, 2005, p. 310; Provonost et al., 2003, p. 71).

Other research has also confirmed that communication has tremendous impact in the EC. Ballard and Siebold's (2006) studies on the impact of delayed responses in interdepartmental communication concluded that a breakdown in the relay of information

between units has a negative systemic impact. Specifically, a decline in job satisfaction was attributed to communication gaps that disrupted the linear work patterns of focused responses to patients.

Communication failure has been attributed to several general factors: time-sensitive responses, partial content or accuracy, excluded stakeholders, and unaddressed clinical issues given low priority until a critical situation is reached (Fenningkoh, 2005). Recognition of the impact of "failure to communicate" (Fennigkoh, 2005, p. 310) has moved swiftly throughout the healthcare community. As a result, internal and external improvements and relationships with end users have now been targeted across the hospital EC because researchers have reported that increased levels of communication were related to better patient care (Minvielle et al., 2008, 2005; Ballard & Siebold, 2006; Provonost et al., 2003).

Efforts by the BMET community to keep inter-departmental communication are evident. Fennigkoh (2005), Xu et al. (1997), and Moniz et al. (1995) have recognized the BMET role in the dissemination of vital information to medical staff. Moniz et al. cites the development of equipment safety classes for new nurses as an example of BMETs' consistent effort to reduce adverse events. Xu et al. applied increased intra-departmental communication between the BMET supervisor and technicians in order to promote a top down approach to increasing internal communication and communication external to the department.

Finally, Fennigkoh (2005) applied a human factors approach modeled after Reason's Swiss Cheese Model of Error Management to reduce communication errors (Reason, 2000). Reason, a pioneer in Human Factors Theory, defines system failure from

the viewpoint of hospital adverse events. Recognizing the direct impact of unsafe actions by medical personnel that arose from environmental circumstances, he sought ways to optimize relationships to reduce negative events. Fennigkoh used Reason's recognition of the natural tendencies for errors as an opportunity to proactively introduce an inter-disciplinary systems approach that optimized information through increased communication.

The study's indicators of interdepartmental communication have been drawn from the sources noted above. The primary indicators are whether biomedical engineering technicians can easily discuss equipment issues, whether BMETs receive and/or provide training on the proper operation of equipment, and whether BMETs receive and/or provide clean, operational equipment in a timely fashion.

3.1.2.5 Interdepartmental Teamwork

The fifth and final process adequacy factor of this study is interdepartmental teamwork. D'Amour et al. (2005) pays homage to a plethora of groundbreakers in the area of interdepartmental teamwork and quality healthcare. He effectively consolidates the relationship between collaboration and teamwork that Schmalenberg et al. (2005) propound: that if there is a claim to collaboration, there should be evidence of teamwork. D'Amour et al. (2005, p. 119) found that:

Teamwork has become a sine qua non condition for effective practice in health-related institutions. Indeed, collaboration is essential in order to ensure quality health care and teamwork is the main context in which collaborative patient-ordered care is provided."

Several defining characteristics of teamwork are interspersed with collaboration and are found across the literature described by similar terms for the concept. D'Amour et al. (2005) define inter-professional collaboration five underlying concepts: sharing, partnership, power, interdependency, and process, which suggest teamwork. The term interdisciplinary collaboration occurs in many research vignettes on the roles of gender, safety, and teamwork in high-risk nursing areas that indicate a positive relation between nurse-physician relationships and patient satisfaction (Fewster-Thuente & Velsor-Friedrich, 2008; Yeager, 2005; Corser, 1998). Regardless of the preferred terminology, the goal of reducing the approximately 70% of adverse events attributed to lack of communication and collaboration as reported by the Joint Commission (Fewster-Thuente & Velsor-Friedrich, p. 40), is the same.

Case studies by hospital quality improvement teams may continue to raise awareness of the need to shift measures of systemic quality that embrace teamwork. For example, Docque's (1993) dissertation noted how departmentalization impeded quality efforts to improve the quality of care for multi-discipline input. The experiment produced factions drawn from established departmental and/or professional alliances that were judgmental and lacked the avenues for communication that were needed to achieve innovative and collaborative solutions. Docque concluded, "The facilitators were inhibited from doing team building by the existing administrative structure" (1993, p. iv).

Yeager (2005) emphasizes how higher levels of patient illness and the consequent demands on information management that compete with patient access to an increasing body of knowledge require further inter-discipline collaboration in the EC. The prominent teamwork of nurses and physicians is just one positive step in that direction

(Francis, 2008). Interaction among a range of healthcare professionals is still far from what is required to reduce infections derived from invasive devices and/or preventable errors.

Inter-professional teamwork has been a logical response to the need for multiple inputs to address the complications of long-term care (Xyrichis & Lowton, 2008), the growing need for information management (Yeager, 2005), and the level of cooperation with healthcare support services necessary to meet service requirements (Molleman, Broekhuis, Stoffels, & Jaspers, 2008). Xychris and Lowton review the literature regarding a theoretical basis for an integrated approach to primary care. Molleman et al. (p.329) conclude that "health professionals increasingly face patients with complex health problems and this [pressures] them to cooperate." However, Xychris and Lowton point to evidence that multi-discipline teamwork has not achieved the expected benefits and suggest that the temporary nature of team formations may be problematic. They advocate permanent inter-professional teamwork that recognizes the benefits of persistent interdependent practices, which is a recommendation consistent with this study.

The study's indicators of interdepartmental teamwork have been drawn from the sources noted above. The primary indicators are whether biomedical engineering technicians receive and/or provide detailed information about out-of-service equipment, whether BMETs receive and/or provide training in how to properly clean and sanitize equipment between patient uses, and whether nursing and biomedical engineering conduct regularly scheduled meetings on equipment issues.

3.1.3 Level of Quality: Latent Endogenous Construct and Measurement Variables

This section introduces the endogenous construct of the level of quality. Three positive observable measurement indicators of the Level of Quality are used to quantify outcomes. They are Clinical Engineering Effectiveness, Clinical Engineering Efficiency, and Regulatory Compliance. This selection of outcome measures follows Donabedian's evaluation criteria to assess personnel and their perception of interdepartmental processes and the delivery of professional services to improve patient outcomes (Lohr & Schroeder, 1990; Donabedian, 1988).

The clinical measurements found in AHRQ PSIs and TJC NPSGs (Section 2.1) used in conjunction with financial and other administrative information considers to some extent the combined effects of intangible and tangible measures. However, access to and availability of consistent administrative data is limited by the diversity in hospital care, the variety of reporting parameters, and proprietary concern about liabilities for adverse events and/or nosocomial infections. This study, therefore, uses proxy measures.

3.1.3.1 Clinical Engineering Effectiveness

The first quality measurement in this study is Clinical Engineering Effectiveness. The global definition of organizational effectiveness is the "degree to which organizational goals and objectives are successfully met" (Flood et al., 2006, p. 420). Since daily interaction with some form of medical equipment is necessary in patient care, the ability to tie BMET objectives to such organizational goals as the reduction of systemic adverse events related to medical equipment is critical for organizational

performance. Given that fact, performance outcome measures using only work productivity data based on the calculation of the number of repairs may offer only a tangible but incomplete measure (Section 2.2). Consequently, scholars and biomedical experts agree that intangible elements of productivity, quality, and job satisfaction are important for accurate measurement.

The "decision-making process surrounding acquisition and standardization" and "the facility management process" (Yadin & Rohe, 1986; Mullally, 2008, p. 9, 23) are factors in clinical engineering that influence organizational productivity and the level of quality. Hence, a strategy that integrates biomedical engineering across atypical platforms by increasing the opportunities for communication with other units follows this logic. These events capitalize on educational opportunities to cross-train nurses on equipment, the establishment of both corrective and preventive maintenance of equipment, and user acceptance testing on new equipment.

The literature has not explored the interaction between clinicians and the biomedical engineering technician department in detail. However, several salient outcome measures of clinical engineering effectiveness are cited: “penetration of other fields, incoming inspections, user education, pre-purchase consultation, clinical research, quality assurance, and satisfaction with reporting authority” (Yadin & Rohe, 1986, p. 435). Other researchers concur. For example, Ebben et al. (2008) recommend increased visibility in the process of purchasing new medical equipment, and increased technology development and integration. Mullally’s (2008) study also finds that satisfaction with reporting authorities contributes to CE effectiveness.

The indicators of clinical engineering effectiveness have been drawn from the sources noted above. The primary indicators are the basis for proxy observable variables in the BMET department, including whether the BMET is integrated into the process of purchasing medical equipment, whether the BMET is represented in facility management positions like Central Sterile, Infection Control, and Management Information Systems, whether department goals are derived from organizational objectives, and the BMET perception of job satisfaction with reporting authorities.

3.1.3.2 Clinical Engineering Efficiency

The second measure of the level of quality for this study is Clinical Engineering Efficiency. Hwang and Herndon et al. (2007, p. 23) submit that "healthcare is an enormous sector with tremendous room for improvement in cost efficiency, much of which is closely tied to increased quality." But recognized variations in hospital size, case mix, and the resources available to acquire medical equipment and technology still present continued obstacles to measurement (Wang, Ozcan, Wan, & Harrison, 1999). As a result, four proxy components are used here to determine the conditions conducive to efficiency in the EC and specifically in Clinical Engineering. The proxy components are 1) an existing system for tracking device failure, 2) an existing medical device inventory, 3) implemented cost assessment metrics, and 4) productivity assessment.

"Technology frustration and inadvertent user error" (Cram et al., 2004) contribute to the clinical risk factors generally equated with medical equipment and the consequent mortality and financial loss. Therefore, the contributions from an efficient clinical engineering department can advance safe practices that reduce costs and

minimize adverse events. Hence, a system for tracking medical device equipment failure is advocated for the BMET department since properly managed and accessible equipment is an instance of controllable environmental conditions (Needleman et al., 2007; Wang et al., 2006). Availability of equipment presumes the presence of accurate inventory of medical devices with their costs for acquisition and associated maintenance and repairs. These explain the contribution of the first three proxy measures.

Justification for the use of the final proxy factor—productivity assessments rests on the association between labor costs and the number of hours directly dedicated to medical devices, since organization performance is linked to the costs associated with resource availability and the activities of patient care (Dey, Hariharan, & Clegg, 2006; Donabedian,1988). Thus, clinical engineering efficiency is measured in terms of personnel cost and maintenance costs for devices used in patient care.

The study indicators of clinical engineering efficiency are drawn from the sources noted above. The primary indicators are the basis for proxy observable variables in the BMET department: whether biomedical engineering tracks device failure through a system for repair work orders, whether the BMET maintains an inventory of medical devices, measures cost, and measures labor costs as a function of productivity.

3.1.3.3 Regulatory Compliance

The third measure of the level of quality determines Regulatory Compliance with healthcare directives. The latent construct is derived from “a monumental study of nine large U.S. government bureaus by Kaufman and Couzens (1973) who found that seven of the nine bureaus clearly had enough administrative feedback to detect noncompliance of

agency policy—one indicator of performance" (cited in Garnett et al., 2006, p. 268). In addition, Waterson (2009, p. 170) recently noted, "Poor communication, confusion of responsibilities and accountabilities between and within the various regulatory bodies delayed the time in which they could react to the outbreaks." Even so, the relationship between performance and accreditation has been a topic of debate; some researchers report that accreditation is not statistically related to the hospital EC (Miller, Provonost, Donithan, Zeger, Zhan, Morlock, & Meyer, 2005), others that regulation is a necessary component in clinical engineering quality (Subhan, 2005).

Differences across departments may result from of a simple difference—BMETs are dominated by compliance regulations whereas nursing staff are normally patient or outcome-focused. But this notion has received scant notice in literature. Conflicts between regulatory requirements and practical patient applications present disunity in terms of the overall EC that may be rectified through some unification efforts without jeopardizing the unique contributions of each profession. Consequently, proof of compliance with standard quality criteria will suggest a measure of quality performance, but may also provide insights into each profession's unique perspectives that may suggest points of collaboration to advance systemic quality initiatives.

The study indicators of regulatory compliance are drawn from the sources noted above. The primary indicators provide the basis for proxy observable variables in the BMET department: whether biomedical engineering understands medical equipment regulatory policy, whether biomedical engineering applies medical equipment regulatory policy, whether the department can be decisive when faced with policy conflicts between

compliance with medical equipment regulations and patient-centered outcomes, and whether all departments have access to data on hospital-acquired infections.

In this study the application of standards in clinical engineering can represent the 'equity' component of critical evaluation tools. Though application of standards has mixed findings in the literature, an examination of methods to resolve medical plurality in healthcare performance and evaluation may also require a more direct and combined application of the concept of 'equity' detailed in Section 3.2.

3.2 Integrated Empirical Ethics Theory

Though the phrase "First, do no harm" uttered by Hippocrates (circa 460 B.C.) may be the most recognized prime directive of caregiver medical ethics, the emergent literature on Integrated Empirical Ethics Theory (Molewijk, 2004) is an opportunity to generate active academic response to the divergent healthcare professional mandates that can affect hospital quality. This section introduces the relevance of that perspective as multidisciplinary efforts seek commonalities in order to manage complex, long-term patient care requirements and the moral challenges stemming from advanced health technologies.

As empirical evidence grows about structure and processes that can improve hospital quality outcomes (Section 3.1), the formulation of common goals that consolidate and align the approach to patient care is required for implementation. The concept of "embedded ethics and interactive practice improvement" (Abma, Baur,

Molewijk, & Widdershoven, 2010) in the medical community provides a foundation for professional interdependency advancing hospital quality.

Balancing science and ethics, IEE represents the scientific development and application of policies that recognize the contribution of individual practitioners— or in this case, professional autonomy, in social practice. Interactive cooperation between participating members such as BMETs and the nurses can blend moral with scientific objectives for normative practices that improve patient services by prioritizing diverse healthcare directives (Widdershoven, Abma, & Molewijk, 2009; Widdershoven, Molewijk, & Abma, 2009; Molewijk, Stiggelbout, Otten, Dupuis, & Kievit, 2004; Molewijk, 2004).

The literature has noted the relevance of professional and ethical considerations in the environment of care (EC) that may affect priorities and perceptions of patient care needs among clinicians (physicians and nurses), healthcare administrators, and biomedical engineers (Laxmisan, Malhotra, Keselman, Johnson, & Patel, 2005). The Laxmisan et al. study (2005) found that in simulated scenarios, common medical errors generated anxiety about actionable problems, along with concern with expertise. For example, practitioners were highly focused on human errors in clinical environments whereas administrators emphasized clinical documentation and the need for skills development. Not surprisingly, the BMETs focused on device function errors. But, awareness of the interpretive differences among professionals is only the beginning of the resolution debate. The overarching premise of Integrated Empirical Ethics (IEE) supports management resolution of the divergent internal and external controls that can reduce hospital level of quality in such scenarios.

An example of a normative practice solution may be the emphasis on achieving patient safety concerns through an interdisciplinary approach to reduce adverse medical events. The interdisciplinary approach to systemic errors is noted in National Patient Safety Goals, Joint Commission Infection Control recommendations and other efforts that overcome diverse regulation and control problems through multidisciplinary involvement that focuses on universal objectives. In that respect, IEE can be a necessary component in translating analysis results from Donabedian's Triad into actionable items while respecting the individual responsibilities of professions within the healthcare EC.

Despite a lack of cohesive healthcare ethics, many healthcare professionals are guided by a code of ethics such as the American Medical Association (AMA, 2004) physicians' principles of medical ethics. Though no professional hospital BMET code of ethics is in place, biomedical organizations such as the Biomedical Engineering Society (BES) and the American College of Clinical Engineering (ACCE) provide guidelines that emphasize patient safety. In particular, the BES ethics statement notes BMET responsibilities in health care including honoring patient privacy rights and cost containment (Christe, 2009, p. 41). The ACCE provides the Clinical Engineer with specific guidelines for their role in patient safety, technology application and knowledge management, and implicitly restricts services to those within their area of medical equipment expertise (Christe, p. 42). In contrast, the revised 2001 American Nurses Association professional code of ethics (Mappes & DeGrazia, 2006) is patient-centered with specific quality objectives that stress collaboration with direct application to the hospital EC. Given this dichotomy, IEE is an opportunity to open communication channels (Widdershoven et al., 2009) about appropriate quality efforts to address systemic problems through empirical efforts designed to minimize professional bias.

As other health support professionals extend the principles of medical ethics like those of the American Medical Association (2004) for physicians, professional and ethical roles in the hospital EC can be strongly delineated to ensure clearly defined service expertise. Such an approach can secure the inclusion of the unique expert knowledge in each profession and overcome the potential for harm to patient outcomes from collaborations where too much crossover of roles can lead to accountability 'grey areas' (Larson, 1999).

That approach has some methodological difficulties, since the theoretical premise is in its infancy there is scant, if any, empirical evidence relevant to IEE. IEE also has encountered criticism. Musschenga (2005) contends that identification of moral issues in the hospital EC is affected by context sensitivities (cultural or institutional) that may blur the distinction between philosophical ethics and medical ethics. Abma, Molewijk, and Widdershoven (2009) and Molewijk, Abma, Stolper, and Widdershoven (2008) argue that clinical morality does not arise from moral experience in the clinical environment, but instead from ethics instilled during education, by theoretical 'moral case deliberation'. Moral case deliberation inserts a moral question into an actual clinical case and invites practitioners to consider alternative actions (Abma et al., 2009; Verkerk et al., 2004).

Others imply that to extract relevant data, the type of study datum, analysis methods, and study population must first be defined (Holm, Soren, & Jones, 2004). A common barrier in ethical discussion is the lack of crossover in the analytical methods used by practitioners, ethicists, and health support services not attuned to statistical evaluation. However, such general issues are associated with the preliminary research required to perform any project.

In summation, integrated empirical ethics is a basis for research that attempts to identify and resolve potential professional conflicts and the associated priorities in the clinical environment known as medical plurality. Once supported by research, IEE is a

methodology that can mesh divergent professional inputs and accountabilities in order to benefit patient outcomes through the collaborative dialogue of multidisciplinary teams. At present, the concept of IEE can support the development of a code of ethics that establishes clear professional responsibilities for hospital healthcare support services (Davis, 1992). The expected benefits of doing so are a more inclusive professional participation, expanded efforts for systemic quality, and clarity about the respective duties in multidisciplinary teamwork, and the possibility of solving problems objectively through open dialogue across professions. Future research is required to examine these expected outcomes.

3.3 Control Variables

A multitude of confounding factors influence the context of a health care environment, so research must obtain some facility and respondent characteristics so that conclusions are accurate. The following items are basic individual and organizational differences to be taken into consideration when evaluating study results.

3.3.1 Respondent Information

Individual control variables are respondent's profession, years of experience and education. Professional identification helps to establish perspective and can be used in future analysis of variance among nursing and other professionals responsible for quality of care. The level of education is included because of its association in the literature with improved productivity and influence on "organizational efficiency and effectiveness" (Carmeli & Tishler, 2004). Finally, respondent's years of experience indicates the

applicant's capacity to respond to survey questions based on prolonged exposure to their work environment.

3.3.2 Organizational or Facility Information

Hospital organization information comprises state, The Joint Commission accreditation, number of operational beds, facility type, and general location designation. These organizational control variables as recommended by scholars include system design elements. Differences in organizations are measured by physical characteristics: hospital size in terms of number of beds and location of facilities such as urban or rural; accreditation status; state, and facility type (public, private, non-profit, university affiliated) (Donabedian, 1989; Mark, et al., 2003; Flood et al., 2006).

3.4 Hypothesis Statements

The objective of this research is to determine the efficacy of applying Donabedian's Triad to the function of biomedical engineering technician in clinical engineering. To examine the potential effects of the BMET profession on quality of care, the study develops a measureable SEM model within the context of a medical environment of care. The hypothesis statements derived from the theoretical premise of Organizational Performance Theory and the existing literature follow.

Hypothesis$_1$: Structural complexity positively affects process adequacy in the hospital environment of care.

Hypothesis$_2$: Structural complexity positively affects level of quality in the hospital environment of care.

Hypothesis$_3$: Process adequacy positively affects level of quality in the hospital environment of care.

Figure 3.3 illustrates the analytic model of the proposed relationships among Structural Complexity, Process Adequacy, and Level of Quality. No control variables appear in this model.

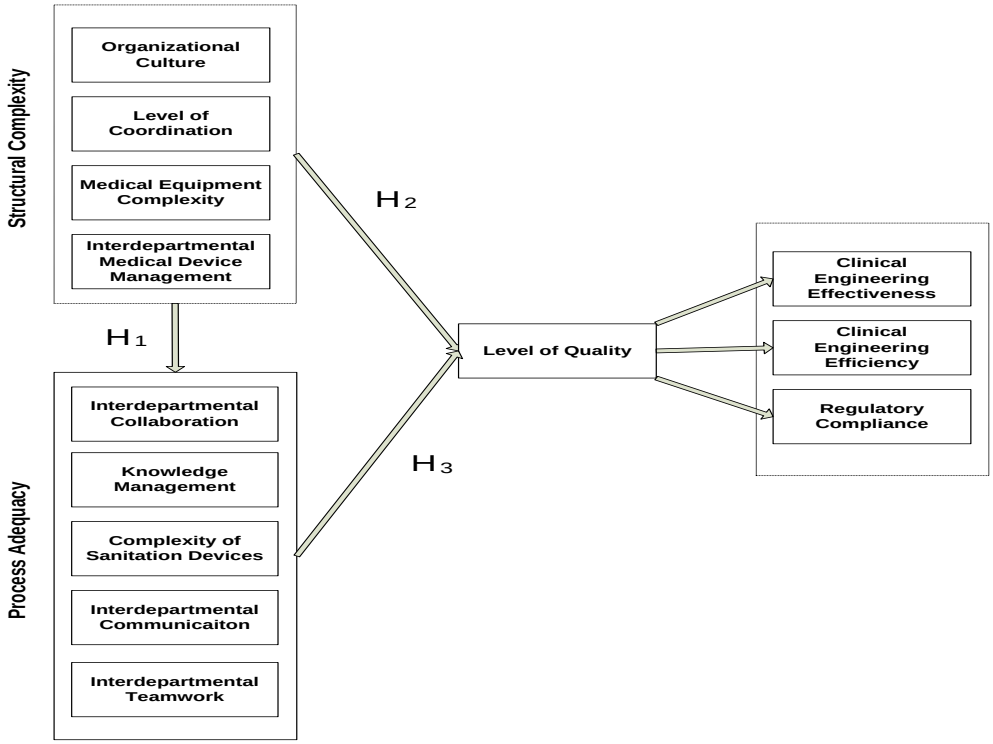

Figure 3.3 Unconditioned Analytical Model with Three Latent Variables Indicating Hypothesized Relationships Between Predictor Variables and the Level of Quality in Clinical Engineering as Measured by the Contributions of the Biomedical Engineering Technician

3.5 Theoretical Summary

This section provides the theoretical principles of Organizational Performance Theory, applying the Donabedian Triadic approach of structure, process and outcome to biomedical engineering technicians in clinical engineering. Details of the translation of the critical aspects of clinical engineering effectiveness, clinical engineering efficiency,

and regulatory compliance yield outcome measures of the quality of care. Predictor variables of structural complexity and process adequacy are derived as potential explanatory factors of quality performance. The study variables and hypothesis statements are presented in an unconditioned analytical model with three latent variables indicating the hypothesized relationships between predictor variables and the level of quality in clinical engineering that is measured by the contributions of the biomedical engineering technician. The next chapter presents the methodology used in this study.

CHAPTER 4: METHODOLOGY

Structural Equation Modeling (SEM) with Confirmatory Factor and Path Analysis, a versatile multivariate approach to the measurement of latent variables and the structural relationships among the study variables (Wan, 2002), is used to determine whether the exogenous (independent) variables are causally related to the endogenous (dependent) variables. This research method is a form of multivariate correlational statistics that tests the hypothesized relationships among three component factors of the theoretical S-P-O model.

This technique uses two statistical analyses. First, Confirmatory Factor Analysis evaluates the validity of the indicators associated with the underlying theoretical constructs. Second, multivariate analysis of the structural relationships among the study variables provides support of a theoretically specified framework and conclusions for improving the quality of care.

4.1 Participants and Data Cleansing

Participants in the BEI Survey were sought from 1307 Biomedical Engineering Technicians in a professional contact database provided by Mr. Patrick Lynch, Biomedical Support Specialist at Global Medical Imaging, in Charlotte, NC. The contact list spans 49 states except for Wyoming and the District of Columbia in the United States, Puerto Rico, and the US Virgin Islands. The BMET professional was selected as the unit of analysis because of the reliance by nursing staff on medical equipment as an element of nursing performance. Review of the contact list revealed instances of the same person listed twice or duplication of email addresses. About five items were removed because of duplication and several more because they listed non-US regions. About another 300 email addresses were not current. Finally, close to 50 individuals indicated that they were either not interested or not biomedical engineering technicians. The final population sample is 953 of whom 395 from 736 hospitals responded to the survey.

The study's inclusion parameters require input from the BMET profession for initial interdepartmental comparisons. Participants were asked to complete a questionnaire intended to gauge their perception of the current status of several factors under analysis.

The Tailored Design Method (TDM) for surveys was implemented to help reduce non-response, beginning with correspondence to introduce the topic to participants (Dillman et al., 2009). Potential participants were contacted on January 7, 2011 via an e-mail that notified them of the Biomedical Engineering Interdepartmental Survey

availability on January 15th, requested informed consent, and offered the option to remove their names from the actual e-mail notification. The UCF Institutional Review Board approved the survey before its distribution (Appendix B).

Next, the survey population received a second notice thanking them for their participation, providing specific instructions and the survey link designation. (Please note that limits in the number of emails sent daily in Hotmail required delivery in batches over a period of 3-5 days.) On January 15, 2011, 950 potential respondents were notified that the survey was available at URL link: http://www.surveymonkey.com/s/KWCKSCK, In the event that participants required clarification or a channel for concerns about the study, relevant instructions and contact information were provided. Finally, three days before the conclusion of the study, participants were reminded that the survey would close at midnight, January 31, 2011.

4.2 Sampling

To ensure sample size, all eligible BMET contact persons were e-mailed with an invitation. Criteria that led to the use of the convenience sampling in lieu of simple random selection were threefold: 1) existing diversity and national representation in the contact list, 2) the statistical software requirements to achieve a minimum sample of 200, and 3) the historical low response rate within the medical community.

The primary consideration for sampling is to achieve minimum levels of participants through the use of power analysis, effect size, and statistical units such as mean and standard deviation. Power analysis is used to offset the impact of Type I and Type II measurement errors.

-Type I errors appear in the form of hypothesis statements that have been falsely rejected when they are true. A method to reduce Type 1 error is to set the level of significance, or the alpha level, $\alpha < .05$.

-A Type II error occurs when the hypothesis is accepted when it is false. This error can be reduced by setting the Beta (β) to $> .80$.

Table 4.1 Minimum Sample Size Calculation

Boundary B	Margin of Error D	Minimum Sample Size n
±.05 [2.95,3.05]	.000625	597
±.1 [2.90, 3.10]	.0025	282
±.2 [2.80,3.20]	.01	91
±.5 [2.95,3.50]	0.625	16
±1 [2,3]	.25	4

The minimum sample size of 282 was selected to meet the required size for performing Structural Equation Modeling, statistical software requirements are n=200 for accurate data analysis. The acceptable variance has been set very small on a 5 point Likert Scale, allowing boundaries to be identified at [2.90, 3.10]. The margin of error, or $D=B^2/4$ is therefore .0025. Tchebycheff's worst case scenario default of $\sigma^2=1$ is expected to account for the incomplete forms and non-response typical of healthcare surveys. The simple sample size calculation formula is:

$$N(\sigma^2) / (n-1) D +1 \qquad (4.1)$$

4.3 Materials, Instrumentation Reliability, and General Procedure

A cross-sectional survey questionnaire was designed to assess the level of quality in clinical engineering from the perspective of the biomedical engineering technician, an emerging area of research with sparse information. The method is "recommended for the collection of data that are descriptive of a situation at a given time" (Schneider, Whitehead, and Elliott, 2007). Specific instrumentation methods are based on DeVellis (2003); Flynn et al. (1994); and Dillman's Tailor Designed Method for survey research.

The questions pertaining to structural complexity in the Biomedical Engineering Interdepartmental Survey were used to form the indicators or measures of that exogenous latent variable. Process Adequacy, an intervening and theoretical construct, is posited to be affected by structural complexity and to directly influence the quality of care. Process Adequacy, in this capacity, serves the role of both an endogenous and exogenous study variable relative to the other constructs.

The 39 questionnaire items associated with the three latent variables or constructs are based on a 5-point Likert scale. The response ranges from 1- (strongly agree) to 5 (strongly disagree) on three questions for each initial indicator of Structural Complexity and of Process Adequacy. Structural Complexity comprises four scale factors (Organizational Culture, Level of Coordination, Medical Equipment Complexity, and Interdepartmental Medical Device Management) that contribute 12 indicators or variables. Process Adequacy comprises five scale factors (Interdepartmental Collaboration, Knowledge Management, Complexity of Sanitation Methods, Interdepartmental Communication, and Interdepartmental Teamwork) that contribute 15 indicators or variables. The Level of Quality contains three subscales: Clinical Engineering Effectiveness, Clinical Engineering Efficiency, and Regulatory Compliance, each having 4 questions.

Three questions about Respondent Information and five questions about Facility Information are measured on the questionnaire, for a total of eight control variables. Those variables were added to reduce the effects of extraneous confounding factors in the sample.

Reliability Analysis of the Measurements

The initial application of the Biomedical Engineering Interdepartmental Survey to the sample population of biomedical engineering technicians has undergone reliability analysis (Appendix Tables C.1 Reliability Item Descriptive Statistics and C.2 Reliability Item-Total Statistics) to determine internal consistencies of the scales derived through the calculation of the Cronbach alpha (α) coefficient on the overall measurement. PASW (version 18.0.0) statistical software reported a range of initial respondent ratings for each latent construct of Structural Complexity, Process Adequacy, and Level of Quality from Cronbach α coefficients 0.774 to 0.833, expressing good internal consistency of >0.7 (DeVellis, 2003). (Table 4.2). This data revealed that all items had some contribution, since no values were reported at zero. The case processing summary indicated that 78/395 or 19.7% of the surveys were excluded from analysis due to missing values.

Table 4.2 Initial Cronbach Alpha Reliability Coefficient for Latent Constructs from Biomedical Engineering Interdepartmental Survey Results

Latent Constructs and Factors	Initial Cronbach's α N=395	Final Cronbach's α N=317
Structural Complexity Construct All	**0.774**	**0.826**
Organizational Culture	0.771	0.771
Level of Coordination	0.833	0.833
Medical Equipment Complexity	-0.177	-----
Interdepartmental Medical Device Management	0.469	0.469
Process Adequacy Constructs All	**0.833**	**0.833**
Interdepartmental Collaboration	0.644	0.644
Knowledge Management	0.748	0.748
Complexity of Sanitation Methods	0.639	0.639
Interdepartmental Communication	0.688	0.688
Interdepartmental Teamwork	0.568	0.568
Level of Quality Constructs All	**0.791**	**0.825**
Clinical Engineering Effectiveness	0.782	0.782
Clinical Engineering Efficiency	0.695	0.695
Regulatory Compliance	0.444	0.607

Subscale items in the main constructs had a range of initial Cronbach α coefficient from –0.177 to .833. The negative Cronbach Alpha in the subscale for Medical Equipment Complexity (MEC) was -0.177, containing three scales: Knowledge Limits (MEC1), “I have limited knowledge of all of the equipment functions available to me”; Excessive Options (MEC2), “There are excessive operations on equipment that increase the difficulty of use”; and Expert Knowledge Requirements (MEC3), “I require outside assistance to understand operation and/or maintenance”. The Structural Complexity constructs Cronbach Alpha improved from 0.774 to 0.826. No additional records were included from this change.

Six subscale constructs rated the highest on the scales, expressing good internal consistency near or greater than .7 (DeVellis, 2003). They were 1) Organizational Culture (0.771), 2) Level of Coordination (0.833), 3) Knowledge Management (0.748), 4) Interdepartmental Communication (0.688), 5) Clinical Effectiveness (0.782), and 6) Clinical Efficiency (.695). The reliability item analysis was then performed.

Reliability Item Analysis

A new baseline Cronbach α was established for N=9 items of Structural Complexity (0.826) with the removal of Medical Equipment Complexity; for N=15 items of Process Adequacy (0.833), and for N=12 items Level of Quality (0.791). Subsequent reliability item analysis within the subscales began with a review of the Inter-Item Correlation Matrix and the Item-Total Correlations for negative correlations, specifically those items reporting Cronbach $\alpha < 0.5$. Each negative corrected item total correlation scale question was reviewed for miscoding and response options with opposite scales. However, none were found to need this potential adjustment to scale criterion.

Regulatory Compliance, a factor in the main construct of Level of Quality, showed a relatively low Cronbach Alpha of 0.444 and a negative correlation. Hence, the variable of Regulatory Compliance—Competing Regulatory Application (RC3), was removed from further analysis. The change improved Cronbach Alpha from 0.444 to 0.607, and the Level of Quality latent construct from 0.791 to 0.825.

Reliability Results

Reliability analysis that included corrected item-total correlation and a review of item analysis resulted in a final latent construct Cronbach α for Structural Complexity of 0.826, for Process Adequacy of 0.833, and for Level of Quality of 0.825 with a reduction in the total number of questions from 39 to 35 items.

Reliability Results Confirmation

Reliability results were confirmed by the Mean Inter-Item Correlation, used when scales have less than ten items (Briggs & Cheek, 1986). Briggs and Cheek (1986) recommend the mean inter-item correlation value reported in SPSS as the Summary Item Statistics table values for a short scale range between .2 and .4 (Pallant, p. 95-98). The individual constructs are within an acceptable range, indicating that they measured what they intended to measure (Table 4.3). However, the balance of variables in the Level of Quality measure of Regulatory Compliance showed a slightly high correlation coefficient of .412, indicating that some small, unspecified measure may contribute to the score.

Table 4.3 Reliability Summary Item Statistics

	Mean	Minimum	Maximum	Range	Maximum / Minimum	Variance	N of Items
Level of Quality All*							
Item Means	2.000	1.281	2.634	1.353	2.057	.197	11
Inter-Item Correlations	.328	.089	.743	.654	8.340	.017	11
Clinical Engineering Effectiveness							
Item Means	2.379	2.041	2.639	.599	1.293	.062	4
Inter-Item Correlations	.477	.405	.579	.174	1.429	.004	4
Clinical Engineering Efficiency							
Item Means	1.735	1.282	2.235	.953	1.743	.231	4
Inter-Item Correlations	.403	.244	.616	.372	2.523	.023	4
Regulatory Compliance							
Item Means	1.855	1.625	2.205	.580	1.357	.095	3
Inter-Item Correlations	.412	.237	.743	.507	3.138	.066	3
Structural Complexity All							
Item Means	2.361	1.918	3.249	1.331	1.694	.215	9
Inter-Item Correlations	.377	.109	.711	.602	6.524	.023	9
Process Adequacy All*							
Item Means	2.335	1.606	3.484	1.878	2.169	.385	15
Inter-Item Correlations	.262	-.019	.838	.857	-43.232	.018	15

Note*: Summary Item Statistics was performed on items N>10 for complete data view. However, this method is typically utilized for N<10. Please see Table 4.2 for complete Cronbach α reliability results.

Table 4.4 Reliability Descriptive Statistics

Indicators	Mean	Standard Deviation	Analysis N
Inter-professional Training	1.98	.910	317
Appropriate Professional Job Training	2.13	.903	317
Uniform Standards	2.71	1.231	317
Inter-Departmental Work	1.89	.794	317
Coordination Efforts	2.16	.952	317
Coordination Evidence	2.01	.877	317
Device Consistency	2.81	1.196	317
Centrally Located Equipment Access	3.24	1.280	317
Device Failure Recognition	2.17	.863	317
Equipment Purchasing Involvement	2.26	1.122	317
Trust in Clinical Expertise	2.56	.961	317
Professional Equity	1.77	.731	317
Informal Exchange	1.60	.693	317
Formal Department Information	1.90	.787	317
Formal System Knowledge	1.88	.756	317
Manual Sanitation	1.90	.683	317
Internal Sanitation	3.41	1.041	317
Internal Standard	3.49	1.042	317
Equipment Discussion Ease	1.77	.811	317
Formal Equipment Training	2.07	.871	317
Available Operational Equipment	2.12	.846	317
Equipment Reporting Standards	2.20	.924	317
Between-Patients Sanitation Training	2.92	1.030	317
Regularly Scheduled Meetings	3.14	1.245	317
Acquisition Integration	2.40	1.175	317
Management Integration	2.63	1.127	317
Department Measures Tied to Organizational Goals	2.04	.872	317
Job Reporting Satisfaction	2.42	.999	317
Device Failure Tracking System	1.37	.538	317
Medical Device Inventory	1.28	.522	317
Implement Cost Assessment	2.05	1.043	317
Implemented Productivity Assessment	2.23	1.004	317
Regulatory Comprehension	1.62	.607	317
Regulatory Application	1.74	.670	317
Regulatory Reporting	2.21	.999	317

The descriptive statistics in Table 4.4 indicate that the standard deviations are less than their respective means, as expected. The sample size of 317 cases is valid.

4.4 Design of the Study

The unit of analysis in this study is the biomedical engineering technician in a hospital support services role for patient safety and quality assurance. A cross-sectional and correlation-based design was formulated. Multivariate analysis was performed to show the relationship between the multiple predictor variables (X_n) and the endogenous variable (Y). A residual term or error (ε) depicts the difference in the actual results from the predicted values. The following linear equation represents the generic form of multiple linear regressions calculated through statistical software:

$$Y_i = \beta_0 + \beta_1 X_1 + \beta_2 X_2 \ldots + \beta_n X_n + \varepsilon_i \quad (4.2)$$

where Y = the endogenous (dependent) variable;

β = the regression coefficient;

X = the exogenous (independent) variable; and

ε = a random error or residual term.

This formal equation is translated into this study by examining the structural relationships among the three latent variables, as follows:

Structural complexity positively affects process adequacy.

$$\text{Process Adequacy} = \beta_0 + \beta_1 \text{Structural Complexity} + \varepsilon_i \quad (4.3)$$

The level of quality is influenced directly by structural complexity and process adequacy:

$$\text{Level of Quality} = \beta_0 + \beta_1 \text{Structural Complexity} + \beta_2 \text{Process Adequacy} + \varepsilon_i \quad (4.4)$$

The analysis is based on a covariance structural mode. The goodness of fit (GOF) statistics (detailed in Section 4.6) show the adequacy of the hypothesized model, using Analysis of Moment Structures (AMOS) and SPSS, Inc. v.18 statistical software. The overall model fit is judged by several statistical estimates: $\chi 2$/degrees of freedom should be less than 4, Goodness of Fit Index (GFI) >0.90; Root Mean Square Error of Approximation (RMSEA) <0.05 or between 0.05 and 0.08; and Hoelter's Critical N index >200. This methodology determines what organizational factors affecting the level of quality (LOQ) from the perspective of the Biomedical Engineering Technician's function in the hospital environment of care (EC).

4.4.1 Multi-Normal Distribution Assumptions

The generic model assumes that there are no correlated errors, that the factors associated with the construct are relevant, and that the constructs of Structural Complexity, Process Adequacy, and Level of Quality are not independent of one another.

The use of SEM with latent variables requires that the study variables with the same construct meet all conditions of multi-normal distribution. Pallant (2007) names those conditions: 1) sufficient sample size, 2) no multicollinearity or singularity present in the independent variables, 3) no extreme outliers in data, 4) normality, linearity, homoscedasticity, and independence of residuals in the distribution of scores and of the underlying relationship between the variables, and 5) no collinearity. The sample size of 317 respondents meets the size criterion. If data assumptions were violated, the AMOS statistical software would not calculate estimates (Arbuckle, 2009; Pallant, 2007).

As with the multiple linear regression assumptions (Azen & Budescu, 2009; Daniel, 2009), SEM with latent variables has to meet certain conditions. Accepted statistical methodologies and constraints are as follows (Pallant, 2007):

1. Linearity – the condition in which predictors and response variables indicate a linear relationship when a straight, diagonal line is visualized from uniformly distributed points observed on a scatterplot diagram.
2. Normality – the condition in which the error score terms are normally distributed. Statistical methods to satisfy this criteria include the creation of Normal Q-Q plots having a straight line derived from plots that calculate observed scores against the expected value within ±3 standard deviation; the Shapiro-Wilk W test that indicates a value close to 1; or interpretation of the values for skewness (distribution symmetry) and kurtosis (peaked distribution) values between approximately ±2 (based on 95% Confidence Interval of 1.96). This study interprets skewness and kurtosis values.
3. Homoscedasticity (constant variance) – the condition in which the underlying relationships between the observed and the predicted dependent variable produce residuals (error terms) that output a residual scatterplot. The output should have a homogenous variance indicated by a concentration of scores in the centerpoint of zero that generally form a rectangular shape. Deviations from this shape indicate a lack of homoscedasticity.
4. Multicollinearity – the condition in which independent variables are highly correlated with each other, which would violate the concept of one measure for each concept. This study follows Kaplan's (1994) and Meyers, Gamst, and

Guarino's (2006) recommendations that correlation coefficient >0.70 be considered for elimination from the measurement model. Other research conditions, such as high reliability and adequate sample size, may tolerate variables that slightly exceed this measure (Grewal, Cote, & Baumgartner, 2004). Tolerance and Variance Inflation Factor (VIF) tests are also acceptable assumption tests used to determine multicollinearity.

5. Independence of residual (error terms) – the condition in which the error terms of the predictor variables are not autocorrelated, having values between 1.5 and 2.5 of the Durbin-Watson W test. Results in this range indicate the independence of the error terms. This study allows common variables and error terms to correlate in order to contain measurement errors (delta or d_i for unique factors on exogenous variables; epsilon or e_i for unique factors on endogenous variables). On the measurement models and/or the structural equation models, this correlation relationship appears in the form of a double arrow between two variables

4.5 Variables

The study variables are summarized in Table 4.5.

Table 4.5 Table of Study Variables

Variable	Role	Operational Measurement
Structural Complexity	Exogenous Latent	12 factors (4 Items each with 3 scales)
Process Adequacy	Intervening Latent	15 factors (5 Items each with 3 scales)
Level of Quality	Endogenous Latent	12 factors (3 Items each with 4 scales)
Profession, Years of Experience, Education	Control	3 Respondent Variables
Number of Beds, State, Accreditation, Urban/Rural, Facility Type, Size, Region	Control	7 Organization/Facility Variables

4.5.1 Endogenous Variable: The Level of Quality

In the Biomedical Engineering Interdepartmental (BEI) Survey, the endogenous response variable of Level of Quality contains three major indicators of quality. They are Clinical Engineering Effectiveness (CEEft), Clinical Engineering Efficiency (CEEfc), and Regulatory Compliance (RC). Each construct comprises four observable items to yield the primary measurement of the latent construct. For example, CEEft consists of Acquisition Integration, Management Integration, Department Contribution to Organization Objectives, and Job Reporting Satisfaction. CEEfc consists of Device Failure Tracking Systems, Medical Device Inventory, Implemented Cost Assessment,

and Productivity Assessment. RC consists of Regulatory Comprehension, Regulatory Application, Conflicting Regulatory Application, and Regulatory Reporting.

4.5.2 Exogenous Variable: Structural Complexity

The BEI Survey contains four major indicators of Structural Complexity. They are Organizational Culture (OC), Level of Coordination (LCR), Medical Equipment Complexity (MEC), and Interdepartmental Medical Device Management (IMDM). OC consists of Inter-Professional Training, Appropriate Professional Job Training, and Uniform Standards. LCR consists of Interdepartmental Work, Coordination Efforts and Coordination Evidence. MEC consists of Knowledge Limits, Excessive Option, and Expert Knowledge Requirements. IMDM consists of Device Consistency, Centrally Located Equipment Access, and Device Failure Recognition.

4.5.3 Process Adequacy: An Endogenous Intervening Variable

The BEI Survey contains five major indicators of Process Adequacy. They are Interdepartmental Collaboration (ICB), Knowledge Management (KM), Complexity of Sanitation Methods (CSM), Interdepartmental Communication (ICOM), and Interdepartmental Teamwork (ITM). ICB consists of Equipment Purchasing Involvement, Expertise Trust, and Professional Equity. KM consists of Information Exchange, Formal Department Information, and Formal System Knowledge. CSM consists of Manual Sanitation, Internal Sanitation, and Internal Standard. ICOM consists of Equipment Discussion Ease, Formal Equipment Training, and Available Operational Equipment.

ITM consists of Equipment Reporting Standards, Between-Patients Sanitation Training, and Regular Meetings.

4.5.4 Operational Definitions

Table 4.6 below depicts the specific indicators and scales from the Biomedical Engineering Interdepartmental Survey used to analyze the biomedical engineering technician profession. Specific indicators are provided for the three major latent constructs of Structural Complexity, Process Adequacy, and Level of Quality.

Table 4.6 Biomedical Engineering Interdepartmental Survey Three Major Latent Constructs, Scales, and Ordinal Response Indicators

Endogenous Latent Construct: Level of Quality		
Indicator	**Equivalent**	**Scales**
Clinical Engineering Effectiveness	CEEft	
Acquisition Integration	CEEft1	Biomedical engineers are integrated in the medical equipment purchasing process.
Management Integration	CEEft2	Biomedical engineers are integrated into facility management (e.g., Central Sterile, Infection Control, Management Information Systems).
Department Contribution to Organization Objectives	CEEft3	Biomedical engineers set and achieve department goals based on organizational objectives.
Job Reporting Satisfaction	CEEft4	Biomedical engineers are satisfied with reporting authorities.
Clinical Engineering Efficiency	CEEfc	
Device Failure Tracking System	CEEfc1	Biomedical engineering tracks device failure through a repair work order system.
Medical Device Inventory	CEEfc2	Biomedical engineering maintains an inventory of medical devices.
Implemented Cost Assessment	CEEfc3	Biomedical engineering measures cost using generally accepted metrics (e.g., labor cost/hour; labor cost/repair; total cost/repair; cost/bed supported; number of medical devices/bed supported; or cost of support as a percentage of the Acquisition Value of Capital Inventory.
Productivity Assessment	CEEfc4	Biomedical engineering measures labor costs as a function of productivity (number of hours worked on completed or uncompleted jobs/total available hours.
Regulatory Compliance	RC	
Regulatory Comprehension	RC1	Biomedical engineering understands medical equipment regulatory policy.
Regulatory Application	RC2	Biomedical engineering is able to apply medical equipment regulatory policy.
Conflicting Regulatory Application	RC3	Biomedical engineers must sometimes choose between medical equipment regulation compliance and patient-centered outcomes.
Regulatory Reporting	RC4	All departments have access to hospital acquired infection data.

Exogenous Latent: Construct Structural Complexity		
Indicators	**Equivalent**	**Scales**
Organizational Culture	OC	
Inter-professional Training	OC1	The organization values contributions to other staff members' professional development.
Appropriate Professional Job Training	OC2	I have been provided clear training to perform my job function.
Uniform Standards	OC3	Standards are applied equally across all departments
Level of Coordination	LCR	
Interdepartmental Work	LCR1	I receive and/or provide inter-departmental input in order to successfully complete work.
Coordination Efforts	LCR2	Efforts have been made to value inter-departmental solutions to systemic issues.
Coordination Evidence	LCR3	Inter-departmental coordination has resulted in visible positive benefits.
Medical Equipment Complexity	MEC	
Knowledge Limits	MEC1	I have limited knowledge of all of the equipment functions available to me.
Excessive Options	MEC2	There are excessive operations on equipment that increase the difficulty of use.
Expert Knowledge Requirements	MEC3	I require outside assistance to understand operation and/or maintenance.
Interdepartmental Medical Device Management	IMDM	
Device Consistency	IMDM1	Medical devices (models and types) are consistent across departments.
Centrally Located Equipment Access	IMDM2	The biomed department is centrally located for easy access.
Device Failure Recognition	IMDM3	I receive and/or provide training to recognize medical device failure.

Intervening Variable (Latent Construct): Process Adequacy		
Indicators	**Equivalent**	**Scales**
Interdepartmental Collaboration	ICB	
Equipment Purchasing Involvement	ICB1	I receive and/or provide advice on new equipment purchases.
Expertise Trust	ICB2	I trust the equipment/clinical knowledge of other departments.
Professional Equity	ICB3	I recognize other departments as professional equals.
Knowledge Management	KM	
Informal Exchange	KM1	I share informal knowledge to benefit patient care.
Formal Department Information	KM2	I have access to formal knowledge within the department.
Formal System Knowledge	KM3	I have access to cross-functional knowledge through electronic or other methods.
Complexity of Sanitation Methods	CSM	
Manual Sanitation	CSM1	We utilize manual sanitation methods on the surface of medical equipment.
Internal Sanitation	CSM2	New high technology internal sanitation methods that cleanse and sanitize internal parts of medical equipment have been introduced to the facility.
Internal Standard	CSM3	High technology internal sanitation methods have been adopted as standard.
Interdepartmental Communication	ICOM	
Equipment Discussion Ease	ICOM1	I can easily discuss equipment issues.
Formal Equipment Training	ICOM2	I receive and/or provide training on the proper way to operate equipment.
Available Operational Equipment	ICOM3	I receive and/or provide clean, operational equipment in a timely fashion.
Interdepartmental Teamwork	ITM	
Equipment Reporting Standards	ITM1	I receive and/or provide detailed information regarding out of service equipment.
Between-Patients Sanitation Training	ITM2	I receive and/or provide training to properly clean and sanitize equipment between patient uses.
Regular Meetings	ITM3	Nursing and biomedical engineering conduct regularly scheduled meetings on equipment issues.

Ordinal Response Options[1]		
Indicators	**Equivalent**	**Scales**
1	1	Strongly Agree
2	2	Agree
3	3	Neither Agree or Disagree
4	4	Disagree
5	5	Strongly Disagree

Note [1]: Response options are consistent for all latent variables.

4.5.5 Control Variables

The BEI Survey incorporated several control variables in consideration of the differences among respondents and facilities. Three control variables were used to distinguish respondent characteristics with regard to profession, years of experience and highest level of education. Note that the unit of analysis in this study is the biomedical engineering technician in hospital support services. Five control variables were used to distinguish facility characteristics with regard to state, Joint Commission accreditation status, the number of operational beds, facility type, and general facility location (Table 4.7). Two additional facility variables were created from the survey responses: hospital bed size and regional location. Complex hospital size indicators derived by the Agency for Healthcare Research and Quality are based on four factors: number of beds, location, region, and teaching status. This study did not obtain teaching status information, and regional distributions by states also varied from AHRQ study samples. For example, AHRQ considered the District of Columbia a Southern entity, whereas this study categorizes DC as in the Northeast. (This method resulted in a relatively equal regional distribution and will add future statistical value because of the ability to perform ANOVA on regional categories.) The AHRQ generic hospital size categories were

derived using location, and number of operational beds designated in three categories 1) small 0-25, 2) medium 26-150, and large >150 (AHRQ, 2010).

Table 4.7 Biomedical Engineering Interdepartmental Survey Respondent and Facility Control Variables and Their Attributes

Control Variables	Variable Attribute and Response Options
Respondent	
Profession	Categorical: Biomedical Engineering Technician, Nurse, Quality
Years of Experience	Categorical: 0-2 years, 3-4 years, 5+ years
Highest Level of Education	Categorical: High School Graduate/GED; Associate of Arts, Associate of Science; Bachelor of Arts, Bachelor of Science; Graduate (Master or Doctorate).
Facility	
State	Categorical: 50 United States and D.C.
Joint Commission Accreditation	Categorical: Yes, No, Other.
Operational Beds	Continuous
Facility Type	Categorical: Public, Private, Non-Profit, University Affiliated
General Facility Location	Categorical: Rural, Urban*
Zip Code if Urban	Categorical/Continuous
Size*	Categorical: Small 0-25, Medium 26-150, Large >150
Region*	Categorical: **Northeast** (Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and Washington, DC.); **Midwest** (Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin); **Southern** (Alabama, Arkansas, Kentucky, Louisiana, Mississippi, Oklahoma, Tennessee, and Texas); **Southeast** (Florida, Georgia, North Carolina, South Carolina, Virginia, and West Virginia); and **Western** (Alaska, Idaho, Montana, Oregon, Washington, Wyoming, Arizona, California, Colorado, Hawaii, Nevada, New Mexico, and Utah).

Note*: Size and Region were created using Number of Operational Beds and State data, respectively.

A multivariate correlation statistical procedure interpreted data from responses to the BEI survey, to measure and analyze the relationships between the predictor variables and the Level of Quality (LOQ), and the LOQ using selected healthcare outcomes

recognized in the BMET field. The unit of analysis was the biomedical engineering technician (BMET) hospital support service. Minimal data cleansing was necessary to enhance the quality of the data sample, primarily by removing surveys that were initiated but only viewed. Reliability testing was conducted to ensure the internal reliability of the data. Threats to external validity appear minimal because of the representation of respondents from across the United States.

4.6 Structural Equation Modeling and Goodness of Fit Metrics

SEM relies on a graphic depiction of data elements and Confirmatory Factor Analysis (CFA) to validate components for significance. A generic model of the aggregated factors of Structural Complexity and Process Adequacy is created in order to study their impact on the potential of biomedical engineering technician hospital support services to reduce systemic adverse events and compliance problems that reduce the quality of patient care.

The determinants of Structural Complexity, Process Adequacy and the Level of Quality were derived from Donabedian's theoretical premise, the literature and preliminary statistical analysis, to ensure that data met assumptions such as normal distribution discussed in 4.4.1. The regression weight or lambda factor loadings were set to 1 in order to allow each construct to vary, because they are independent constructs.

Using the Analysis of Moment Structures (AMOS) computer program, a generic measurement model was created for each construct: Structural Complexity, Process Adequacy, and Level of Quality. Confirmatory Factor Analysis (CFA) was applied to each model to assess how well the common variables (X_1-$X_{9;}$ Y_1-Y_{20}) obtained from the BEI Survey represent the three latent constructs in the study population.

CFA is based on the premise that the researcher has formulated the study constructs and variables on the basis of "knowledge of the theory, empirical research, or both, [postulating] relations between the observed measures and the underlying factors a priori and then testing this hypothesized structure statistically" (Byrne, 2001, p.6). The relationship of the underlying latent constructs with the observed variables is an important metric called factor loading. Normally, a factor loading contribution of .50, or 50% contribution, is generally accepted (Sahin, Yilmaz, & Lee, 2007; Lin, Chow, Madu, Kuei, & Yu, 2005) as a preliminary indication that the models fits the data in the population. Elimination of variables with <0.50 factor loadings helps to produce a parsimonious model from which to generate an overall congeneric model combining all measurement model components. Schumacker and Lomax (2004, p. 212) argue that preferred indicators should have loadings of .7 or higher on the latent variables. For the purposes of this survey study, 0.50 factor loadings are acceptable. Subsequent statistical analysis to determine a goodness of fit is required for a final assessment of the strength and direction of the relationships between the hypothesized constructs and the observable variables (Gallagher, Ting, & Palmer, 2008; Hu & Bentler, 1999; Hair, Anderson, Tatham, & Black, 1998; Bollen, 1989; Browne & Cudek, 1989).

Table 4.8 lists acceptable parameters from which to determine the adequacy of the measurement model in relation to the data. Although there are instances where exact criteria are debated, most statisticians agree on the need to assess the model from more than one criterion. (Byrne, 2001, p. 79-88 defines Goodness of Fit indicators and provides a detailed comparison of alternatives.)

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Table 4.8 Goodness of Fit According to Established Statistical Criteria

Index	Criterion	Citation
Chi-square ($\chi 2$)	Low	Wan, 2002; Garson, 2009
Degrees Of Freedom (df)	≥ 0	Wan, 2002; Garson, 2009
Satorra-Bentler Ratio (aka Likelihood)	<3	Bollen, 1989; Hair et al., 1998; Gallagher et al., 2008
Likelihood Ratio ($\chi 2$ /df)	<4	Wan, 2002; Kline, 2005
Probability	>0.05	Garson, 2009
Goodness of Fit Index (GFI)	>90. x <1.0	Joreskog & Sorbom, 1984
Adjusted GFI (AGFI)	>.85 x <1.0	Bollen, 1989; Gallagher et al., 2008
Normative Fit Index (NFI)	>.90	Hair et al., 1998; Bentler, 1990; Bentler & Bonnet, 1980
Tucker Lewis Index (TLI)	>.90	Hair et al., 1998
Comparative Fit Index (CFI)	>.90	Schermelleh-Engel, Moosbrugger, & Müller, 2003 ; Hair et al., 1998; Bentler & Bonnet, 1980
Root Mean Square Error of Approximation (RMSEA)	.05< value <.08 reasonable	Wan, 2002; Schermelleh-Engel, Moosbrugger, & Müller, 2003; MacCullum et al., 1996
Hoelter's Critical N (CN) (.05)	$75 \leq$ value < 200; acceptable > 200, good	Wan, 2002; Garson, 2009 Garson, 2009

Common latent variables may correlate with each other and contain measurement errors (delta or d_i for unique factors on exogenous variables; epsilon or e_i for unique factors on endogenous variables) that may also be correlated. Correlations are indicated by double arrow relationships between two variables.

CHAPTER 5: FINDINGS

The preceding chapter provided a detailed account of the study variables, the data source, data cleansing procedure, materials, instrumentation, reliability and general procedures. The Biomedical Engineering Interdepartmental Survey was the data source

for the measurements of Structural Complexity, Process Adequacy, and the Level of Quality latent variables. The SEM model was formulated based on the multivariate structural relationship among the three latent constructs. This chapter provides findings from the descriptive analyses of the BEI survey data.

5.1 Descriptive Statistics

Table 5.1 presents the descriptive statistics for the final dataset (N=317). (Appendix Tables D 1 and D 2 contain original pre-cleansing Descriptive Statistics of N=395. No significant statistical differences in data were found). Descriptive statistics—mean, standard deviation, variance, range of scores, kurtosis and skewness verify the normal distribution of the data.

The reported mean for the first variable in Organizational Culture (OC1), which is how the biomedical engineering technician believes the organization values contributions to other staff members' professional development, is 1.98%. The highest mean statistic is in the category of Process Adequacy-Regularly Scheduled Meetings (ITM3), at 3.14%, rating the BMET perception of whether nurses and BMETs conduct regularly scheduled meetings on equipment issues. The lowest mean statistic is in the category of Regulatory Compliance-Regulatory Application (RC2), at 1.74%. All items for the final study sample show a full range of options selected from 1 to 5. Further, mean standard errors are less than the mean statistic, as expected in normally distributed data. Finally, the lowest standard deviation (0.787) is in the category of Process Adequacy-Formal Department Information.

Of the original 395 records, 43 blank records were removed from the dataset. An additional 35 were removed due to incomplete data. Several observed variables from each latent construct were removed from the final dataset due to nonparametric data. Variables removed from Level of Quality are Clinical Engineering Effectiveness-Management Integration (CEEft2); Clinical Engineering Efficiency-Device Failure Tracking (CEEfc1), Medical Device Inventory (CEEfc2) and Productivity Assessment (CEEfc4). Variables removed from Process Adequacy are Interdepartmental Collaboration observed variables of Expertise Trust (ICB2) and Professional Equity (ICB3), Knowledge Management-Informal Exchange (KM1) and Formal System Knowledge (IKM3), and the Interdepartmental Communication variable of Equipment Discussion Ease (ICOM1). All variables of Process Adequacy-Complexity of Sanitation Methods were excluded from the final dataset. Those items are Manual Sanitation (CSM1), Internal Sanitation (CSM2), and Internal Standard (CSM3).

Table 5.1 Descriptive Statistics: N=317 BEI Survey

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
				Structural Complexity				
1 Inter-professional Training	317	4	1	5	1.98	.051	.910	.829
2 Appropriate Professional Job Training	317	4	1	5	2.13	.051	.903	.815
3 Uniform Standards	317	4	1	5	2.71	.069	1.231	1.515
4 Inter-Departmental Work	317	4	1	5	1.89	.045	.794	.630
5 Coordination Evidence	317	4	1	5	2.01	.049	.877	.769
6 Device Failure Recognition	317	4	1	5	2.17	.048	.863	.745
				Process Adequacy				
7 Equipment Purchasing Involvement	317	4	1	5	2.26	.063	1.122	1.259
8 Formal Department Information	317	4	1	5	1.90	.044	.787	.620
9 Formal Equipment Training	317	4	1	5	2.07	.049	.871	.758
10 Available Operational Equipment	317	4	1	5	2.12	.048	.846	.716
11 Regularly Scheduled Meetings	317	4	1	5	3.14	.070	1.245	1.550
				Level of Quality				
12 Acquisition Integration	317	4	1	5	2.40	.066	1.175	1.380
13 Department Measures Tied to Organizational Goals	317	4	1	5	2.04	.049	.872	.761
14 Job Reporting Satisfaction	317	4	1	5	2.42	.056	.999	.998
15 Implement Cost Assessment	317	4	1	5	2.05	.059	1.043	1.089
16 Regulatory Application	317	4	1	5	1.74	.038	.670	.449
17 Regulatory Reporting	317	4	1	5	2.21	.056	.999	.999
Valid N (listwise)	317							

The symmetry of distribution (skewness) and the peakedness of the distribution are confirmed in Table 5.2, with a reported range of standard error from .137 to.273 approximating 0, which indicates normal distribution. Reported ranges in the distribution that approximate 0 and are within ±2 also indicate normal distribution within each variable, based on the 95% Confidence Interval of ±1.96. Range of skewness -.077 to 1.117; range of kurtosis -1.197 to 1.859. Negative skews and kurtosis indicate a shift of data to the right.

Table 5.2 Additional Descriptive Statistics: N=317 BEI Survey Descriptive Statistics

	N	Skewness		Kurtosis	
	Statistic	Statistic	Std. Error	Statistic	Std. Error
Inter-professional Training	317	1.177	.137	1.623	.273
Appropriate Professional Job Training	317	.832	.137	.432	.273
Uniform Standards	317	.234	.137	-1.120	.273
Inter-Departmental Work	317	1.117	.137	1.859	.273
Coordination Evidence	317	.775	.137	.357	.273
Device Failure Recognition	317	.994	.137	1.170	.273
Equipment Purchasing Involvement	317	.897	.137	.044	.273
Formal Department Information	317	.996	.137	1.764	.273
Formal Equipment Training	317	1.087	.137	1.588	.273
Available Operational Equipment	317	.930	.137	1.146	.273
Regularly Scheduled Meetings	317	-.077	.137	-1.197	.273
Acquisition Integration	317	.629	.137	-.487	.273
Department Measures Tied to Organizational Goals	317	1.043	.137	1.243	.273
Job Reporting Satisfaction	317	.627	.137	.132	.273
Implement Cost Assessment	317	.834	.137	-.126	.273
Regulatory Application	317	.748	.137	1.356	.273
Regulatory Reporting	317	.536	.137	-.266	.273
Valid N (listwise)	317				

5.2 Correlation Statistics

The Spearman rho results confirm that multicollinearity, or high similarity in measurement, does not exist in variable relationships characterized by correlation coefficients >.70 (Kaplan, 1994; Meyers et al., 2006). Exceptions are noted.

Spearman rho results on the individual latent constructs of Structural Complexity, Process Adequacy and Level of Control indicate a positive correlation with statistical significance achieved at .01 (2-tailed). (Appendix Tables D3-D5). The highest/lowest correlation for Structural Complexity is Inter-Professional Training and Appropriate Professional Behavior (.554) with Inter-Professional Training and Uniform Standards (.345). The balance of variables ranged from .375 to .496. The highest/lowest correlations for Process Adequacy are Formal Department Information with Formal Equipment Training (.461), and Available Operational Equipment with Equipment Purchasing Involvement (.152). The balance of variables ranged from .215 to .432. Finally, the highest/lowest correlations for Level of Quality are Department Measures Tied to Organizational Goals with Job Reporting Satisfaction (.523) and Implement Cost Assessment with Regulatory Reporting (.208).

In addition to correlations between latent constructs, control variables were also analyzed against each construct. Although multicollinearity was established in the control variables since two variables were constructed from existing measures, no significant relationships were found. (Extended correlation analysis results are available upon request.)

5.2.1 Correlation Between Structural Complexity and Process Adequacy

Normally, performing a correlation matrix analysis on latent constructs is

prohibitive due to large numbers of variables being tested. In this study, the observed variables were significantly reduced, which allowed presentation of the information.

Table 5.3 Spearman Correlation Coefficients of Structural Complexity and Process Adequacy, N=317

Process Adequacy	Equipment Purchasing Involvement	Formal Department Information	Formal Equipment Training	Available Operational Equipment	Regularly Scheduled Meetings
Structural Complexity					
Inter-professional Training	.379**	.336**	.393**	.217**	.332**
Appropriate Professional Job Training	.351**	.375**	.406**	.225**	.316**
Uniform Standards	.262**	.295**	.342**	.231**	.394**
Inter-Departmental Work	.367**	.331**	.445**	.264**	.331**
Coordination Evidence	.397**	.375**	.424**	.329**	.324**
Device Failure Recognition	.273**	.362**	.461**	.335**	.394**

**. Correlation is significant at the 0.01 level (2-tailed).

Table 5.3 shows many positive statistically significant relationships at p=.01 (2-tailed) between Structural Complexity and Process Adequacy, ranging from .217 to .461. The largest relationship is between Formal Equipment Training and Device Failure Recognition. The smallest relationship is between Available Operational Equipment and Inter-Professional Training. Formal Equipment Training also correlates with three other variables >.4. They are Appropriate Professional Job Training (.406), Inter-Departmental Work (.445), and Coordination Evidence (.424).

5.2.2 Correlation Analysis of Structural Complexity and Level of Quality

The correlated coefficients of these latent constructs are particularly interesting because they represent the relationship between the predictor (Structural Complexity) and the outcome variables (Level of Quality).

Table 5.4 Spearman Correlation Coefficient Table of Structural Complexity and Level of Quality, N=317

Level of Quality	Acquisition Integration	Department Measures Tied to Organizational Goals	Job Reporting Satisfaction	Implement Cost Assessment	Regulatory Application	Regulatory Reporting
Structural Complexity						
Inter-Professional Training	.348**	.432**	.467**	.232**	.319**	.222**
Appropriate Professional Job Training	.373**	.361**	.417**	.214**	.232**	.147**
Uniform Standards	.290**	.370**	.464**	.252**	.272**	.183**
Inter-Departmental Work	.405**	.493**	.379**	.254**	.347**	.208**
Coordination Evidence	.430**	.385**	.432**	.295**	.362**	.315**
Device Failure Recognition	.322**	.331**	.401**	.206**	.318**	.263**

**. Correlation is significant at the 0.01 level (2-tailed).

Table 5.4 indicates the relationships between Structural Complexity and Level of Quality indicators; they range from .147 to .493. The largest relationship is between Inter-Department Work and Department Measures Tied to Organizational Goals. The smallest relationship is between Appropriate Professional Job Training and Regulatory Reporting. Job Reporting Satisfaction also correlates with five other variables >.4: Inter-Professional Training (.467), Uniform Standards (.464), Coordination Evidence (.432), Appropriate Professional Job Training (.417) and Device Failure Recognition (.401).

5.2.3 Correlation Analysis of Process Adequacy and Level of Quality

Correlation coefficients were calculated for the intervening variable Process Adequacy and the endogenous variable Level of Quality. The results shown in Table 5.5

indicate that Process Adequacy and Level of Quality indicators are positively associated, ranging from .155 to .688. The largest relationship is between Acquisition Integration and Equipment Purchasing Involvement. The least relationship occurred between Available Operational Equipment and Acquisition Integration.

Table 5.5 Spearman Correlation Coefficient Table of Process Adequacy and Level of Quality, N=317

Level of Quality	Acquisition Integration	Department Measures Tied to Organizational Goals	Job Reporting Satisfaction	Implement Cost Assessment	Regulatory Application	Regulatory Reporting
Process Adequacy						
Equipment Purchasing Involvement	.688**	.389**	.440**	.305**	.313**	.277**
Formal Department Information	.331**	.363**	.385**	.169**	.283**	.219**
Formal Equipment Training	.433**	.428**	.416**	.356**	.378**	.230**
Available Operational Equipment	.155**	.247**	.281**	.172**	.289**	.219**
Regularly Scheduled Meetings	.459**	.349**	.421**	.346**	.239**	.184**

**. Correlation is significant at the 0.01 level (2-tailed).

5.2.4 Correlation Analysis of Control Variables

Several control variables in the BEI Survey reached statistical significance at p=.01 or p=.05. However, the strength of the correlations is relatively low or expected.

The highest positive correlation among control variables is Size and the Operational Number of Beds (.620, p<.01) (Appendix Table D 6). The fact that Bed Size

(Small 0-25, Medium 26-150, and Large > 150) is strongly correlated with the Number of Operational Beds is expected.

The highest negative correlation among control variables in the BEI Survey is between Location Type (Rural or Urban) and the Number of Operational Beds reporting -0.344, $p<.01$. This result is also expected, since many rural hospitals have small numbers of beds.

Many negative correlations between the control variables were noted; the least correlated indicators are Region (Northeast, Midwest, Southern, Southeast, and Western) and whether or not the facility had Joint Commission Accreditation (-0.132, $p<.05$). Though Joint Commission Accreditation has some statistical significance with Regional location, the relationship is not strong.

The lowest positive correlation is Bed Size (Small 0-25, Medium 26-150, Large >150) with Facility Type (Public, Private, Non-Profit, University Affiliated) (.163, $p<.01$). In this instance, facility type is statistically significant in relation to bed size, but the relationship is very small. Cumulatively, the control variables do not contribute to any additional, significant explanation of the latent variables.

5.3 Measurement Models

A generic measurement model was developed and validated for each of the latent constructs derived from Donabedian's Triad in order to achieve the best fit of the model to the data. The analysis and final measurement models of the three latent variables are detailed below.

5.3.1 Structural Complexity Measurement Model

A generic model of the factors of Structural Complexity (X_1-X_9) for the organizational determinants of level of quality was derived from the structure component of Donabedian's Triad theoretical premise and supporting literature (Appendix Figure E 1). Each variable reached 2-tailed statistical significance at .001. The generic model with Chi-square Likelihood Ratio ($\chi 2/df$) of 4.68, exceeds the recommended condition of < 4. The Root Mean Square Error of Approximation (RMSEA) is .108, which exceeds the recommended value of <.05, good measure of precision with a lower/upper boundary of .089/.127 of a two-sided 90% confidence interval for the population, with pClose=.000. Goodness of Fit Index (GFI) = .900 < .912 < 1 as recommended, with Adjusted GFI (AGFI) = .9 < .854 <1 in the acceptable range. (Appendix Table E 1).

Unstandardized regression weights were analyzed for statistical significance for p<.05. All inputs exceeded the recommended criteria at .001 (2-tailed), indicating a statistically significant difference from zero. For example, the probability of getting a critical ratio (the estimate divided by the standard error) as large as |12.590| for the survey question equivalent of LCR2 regarding Coordination Efforts is .001.

As part of CFA, AMOS yields Modification Indices (MI) to suggest that relationships between listed variables can be added to the generic model to increase the goodness of fit and other statistical parameters (Kaplan, 1989; Saris, Satorra, & Sorbom, 1987). In this instance, AMOS reported MI on the covariance between the error measurements in d_5 (LCR2 Coordination Efforts) and d_6 (LCR3 Coordination Evidence), indicating a drop in Chi-Square statistic by 24.165 if allowed to assume an independent value. AMOS reported measurement errors at "d_1" (OC1 Inter-Professional Training) and

"d_2" (OC2 Appropriate Professional Job Training) with MI of 22.788; and d_2 (OC2 Appropriate Professional Job Training) and d_5 (LCR2 Coordination Efforts), with MI of 17.545. Intermittent modifications to the generic model resulted in a -.15 correlation at d_2 (OC2) and d_5 (LCR2). Ultimately, d_5 was removed as the common component. The d_8 (IMDM2 Centrally Located Equipment Access) was also removed because of its low contribution to the variance at .07, resulting in the final and revised measurement model of Structural Complexity.

The researcher retained the factors at d_7 (IMDM1 Device Consistency) despite a .36 factor loading and low variance contribution of 13% to Structural Complexity due to their potential relevance to Process Adequacy. All other factor loadings achieved greater >.50. However, the delta measurement errors and d_1 (OC1 Inter-Professional Training and d_2 OC2 Appropriate Professional Job Training) reduced the factor loading impact by .17. Despite the reduction in factor loading due to the measurement error, the contribution is greater than .50. For example, for OC1 (.72 - .17 = .55).

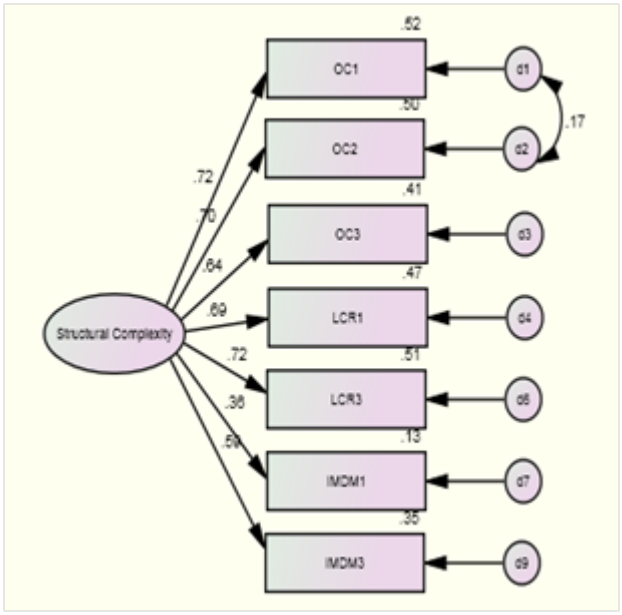


Figure 5.1 Final Revised Measurement Model of Structural Complexity

A final revised measurement model of Structural Complexity (Figure 5.1) maintained the covariance between d1 and d2. This model achieved a significant difference from zero at <.001 level (2-tailed) between all categories. Finally, the revised covariances in the overall model greatly improved the goodness of fit statistics detailed below.

Unstandardized regression weights were analyzed for statistical significance for $p < .05$ from the revised final model. Statistical significance is verified at $p < .001$ (Table 5.6) A comparison between the standardized regression weights from the generic model and those from the final revised Structural Complexity model reveals similarities. However, the largest difference in standardized regression weights is in LCR3 (Coordination Evidence), with a difference of 0.058 (.716 - .774). Finally, all variance terms for Structural Complexity (d_1-d_4, d_6-$_7$, d_9) reach statistical significance at $p<.001$. No further reasonable modifications were recommended by AMOS's MI.

Table 5.6 Final Revised Measurement Model of Structural Complexity

Indicators of Structural Complexity	URW Estimate	SRW Revised	SRW Generic	Standard Error	Critical Ratio	P value
Inter-Professional Training	1.000	.719	.695			
Appropriate Professional Job Training	.973	.705	.664	.079	12.274	***
Uniform Standards	1.206	.641	.621	.121	9.951	***
Interdepartmental Work	.832	.686	.715	.079	10.546	***
Coordination Evidence	.960	.716	.774	.088	10.919	***
Device Consistency	.657	.359	.378	.114	5.765	***
Device Failure Recognition	.783	.593	.577	.084	9.289	***

***<.001 (2-tailed) significance
Abbreviation Notes: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

The largest error variance in Structural Complexity can be attributed to OC1 (Inter-Professional Training), at .516. The least contribution to variance in this construct is IMDM1 (Device Consistency), as anticipated.

The final revised Structural Complexity model Chi-square Likelihood Ratio ($\chi 2/df$) or 2.91 meets the recommended condition for results <4 (Table 5.7). The RMSEA, .078, is an acceptable value. The model retains good precision indicated by a lower/upper boundary of .052/.107 of a two-sided 90% confidence interval for the population, with pClose=.052. Goodness of Fit Index (GFI) = .900 < .965 < 1, as recommended with Adjusted GFI (AGFI) =.9 < .926<1.

Table 5.7 Goodness of Fit Statistics: Structural Complexity Measurement Model

Index	Criterion	Initial	Final
Chi-square ($\chi 2$)	Low	126.462	37.863
Degrees Of Freedom (df)	$\geq .0$	27	13
Likelihood Ratio ($\chi 2$ /df)	<4	4.68	2.91
Probability	>0.05	0.000	0.000
Goodness of Fit Index (GFI)	>.90 x <1.0	0.912	0.965
Adjusted GFI (AGFI)	>.90 x <1.0	0.854	0.926
Normative Fit Index (NFI)	>.90	0.877	0.946
Tucker Lewis Index (TLI)	>.90	0.867	0.941
Comparative Fit Index (CFI)	>.90	0.900	0.963
Root Mean Square Error of Approximation (RMSEA)	$\leq .05$ optimum or .05< value <.08 acceptable	0.108	0.078
Hoelter's Critical N (CN) (.05)	> 200	101	187

5.3.2 Process Adequacy Measurement Model

A generic model of the indicators of Process Adequacy (Y_1-Y_{11}) for the organizational determinants of level of quality was derived from the process component of Donabedian's Triad theoretical premise and the supporting literature (Appendix Figure E 2). Each variable reached 2-tailed statistical significance at .001. The generic models' Chi-square Likelihood Ratio ($\chi 2$/df) of 3.139 meets the recommended condition for results <4. The RMSEA is .110 which exceeds the recommended value of <.05, with a good indication of precision with a lower/upper boundary of .095/.125 of a two-sided 90% confidence interval for the population, with pClose=.000. Goodness of Fit Index (GFI)=.900 < .892< 1 is slightly less than the recommended range and the Adjusted GFI (AGFI)=.9 < .837 <1 also is less than the acceptable range. (Appendix Table E 2).

Unstandardized regression weights were analyzed for statistical significance at

$p<.05$. All inputs exceeded recommended criteria at $p< .001$ (2-tailed) significance, a significant difference from zero. For example, the probability of getting a critical ratio as large as |7.737| for the survey question equivalent of ITM3 regarding Regular Meetings is .001.

AMOS yielded Modification Indices (MI) for the covariance between the epsilon error measurements in e_4 (KM2 Formal Department Information) and e_5 (KM3 Formal System Knowledge), indicating a drop in the Chi-Square statistic by 34.133 if allowed to assume an independent value; also for e_2 (ICB2 Equipment Purchasing Involvement) and e_3 (ICB3 Professional Equity), with an MI of 38.467. CSM2 Internal Sanitation was also removed because of its low contribution to error variance at .08 or 8%, resulting in the final measurement model of Process Adequacy. However, the researcher retained the factor at e_{10} (ITM2 Between-Patients Sanitation Training) despite a low variance contribution of .16 or 16% to Process Adequacy because of the potential relevance to the dependent variable of Level of Quality.

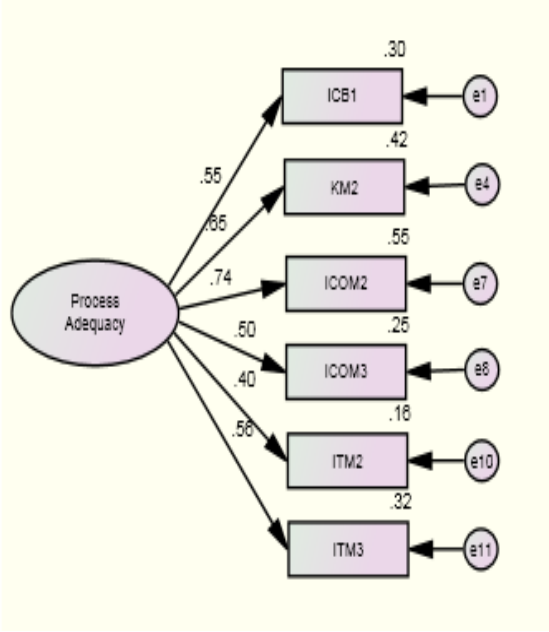


Figure 5.2 Final Revised Measurement Model of Process Adequacy

A final revised measurement model of Process Adequacy (Figure 5.2) shows a significant difference from zero at <.001 level (2-tailed) between all categories (Table 5.8). Finally, the revised covariance in the overall model greatly improved the goodness of fit statistics detailed below (Table 5.9).

Table 5.8 Final Revised Measurement Model of Process Adequacy

Indicators of Process Adequacy	URW Estimate	SRW Revised	SRW Generic	Standard Error	Critical Ratio	P value
Equipment Purchasing Involvement	1.000	.551	0.586		1.000	
Formal Department Information	.827	.649	0.689	.107	7.733	***
Formal Equipment Training	1.046	.743	0.659	.128	8.156	***
Available Operational Equipment	.690	.504	0.511	.104	6.617	***
Between-Patients Sanitation	.662	.397	0.372	.120	5.537	***
Regular Meetings	1.135	.563	0.551	.159	7.122	***

***<.001 (2-tailed) significance level
Abbreviation Notes: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

Unstandardized regression weights were analyzed for statistical significance for p < .05 for the revised final model. Statistical significance was verified at p < .001. A

comparison of the standardized regression weights from the generic model and those from the final revised Process Adequacy model reveals similarities. However, the largest difference in standardized regression weights is found in ICOM2 (Formal Equipment Training), with a difference of 0.084 (.659 - .743). All measurement errors for Process Adequacy ($e_{1,}$ e_4, $e_{7\text{-}8}$, $e_{10\text{-}11}$) reached statistical significance at p<.001. No major MI were recommended by AMOS.

The largest variance in Process Adequacy is in ICOM2 (Formal Equipment Training), at .552. The least contribution to variance in this construct is ITM2 (Between-Patients Sanitation Training), as anticipated from Generic model.

Table 5.9 Goodness of Fit Statistics: Process Adequacy Measurement Model

Index	**Criterion**	**Initial**	**Final**
Chi-square (χ2)	Low	211.646	29.912
Degrees Of Freedom (df)	≥.0	44	9
Likelihood Ratio (χ2 /df)	<4	4.810	3.323
Probability	>0.05	0.000	0.000
Goodness of Fit Index (GFI)	>.90 x <1.0	0.892	0.971
Adjusted GFI (AGFI)	>.90 x <1.0	0.837	0.932
Normative Fit Index (NFI)	>.90	0.757	0.919
Tucker Lewis Index (TLI)	>.90	0.743	0.902
Comparative Fit Index (CFI)	>.90	0.795	0.941
Root Mean Square Error of Approximation (RMSEA)	≤.05 optimum or .05< value <.08 acceptable	0.110	0.086
Hoelter's Critical N (CN) (.05)	> 200	91	179

The final revised Structural Complexity model's Chi-square Likelihood Ratio, (χ2/df) of 3.323, meets the recommended condition for result <4. The RMSEA of .086 is slightly higher than the acceptable range; there is good precision with a lower/upper boundary of .053/.121 of a two-sided 90% confidence interval for the population, with

pClose=.038. Goodness of Fit Index (GFI)=.900 < .971 < 1, and Adjusted GFI (AGFI)=.9 < .932<1, as recommended (Table 5.9).

5.3.3 Measurement Model for Level of Quality

A generic model of the endogenous latent variable, Level of Quality (Y_{12}-Y_{20}) was derived from the outcome component of Donabedian's Triad theoretical premise and supporting literature (Appendix Figure E 3). Each variable reached 2-tailed statistical significance at .001 (Appendix Table E 3). The generic model's Chi-square Likelihood Ratio (χ2/df) of 11.49 exceeds the recommended condition for results <4. The RMSEA is .182, which exceeds the recommended value of <.05, indicating a good measure of precision with a lower/upper boundary of .164/.201 of a two-sided 90% confidence interval for the population, with pClose=.000. GFI=.900 < .814< 1, which is out of the recommended range, and AGFI=.9 < .690 <1, is further from the acceptable range.

Unstandardized regression weights on the generic model were analyzed for statistical significance for p<.05. All inputs exceeded the recommended criteria where p<0 .001 (2-tailed) significance, indicating a significant difference from zero. For example, the probability of getting a critical ratio as large as |9.735| for the survey question of CEEft3 regarding Implemented Cost Assessment is .001. In addition, an example of the interpretation of the estimate of .824 is that when the recorded rating of the overall Implemented Cost Assessment (CEEft3) increases by 1.000, Level of Quality will increase by .824.

AMOS yielded Modification Indices (MI) on the covariance between the epsilon error measurements in e_{18} (RC1 Regulatory Comprehension) and e_{19} (RC2 Regulatory

Application), indicating a drop in Chi-Square statistic by 123.648 if allowed to assume an independent value. Also, e_{12} (CEEft1 Acquisition Integration) and e_{13} (CEEft2 Management Integration) with an MI of 48.505. RC4 (Regulatory Reporting) were noted for a low contribution at .17 or 17% to variance of Level of Quality, but was retained for comparison purposes in the congeneric model. The intermittent model revealed high correlation error rates greater than or at approximately the same factor contribution on e_{18} (RC1 Regulatory Comprehension) and e_{19} (RC2 Regulatory Application), at .64 or 64%; on e_{12} (CEEft1 Acquisition Integration) and e_{13} (CEEft2 Management Integration), .37 or 37%. RC1 and CEEft2 were removed from the model, since each had a poor relationship with the latent construct.

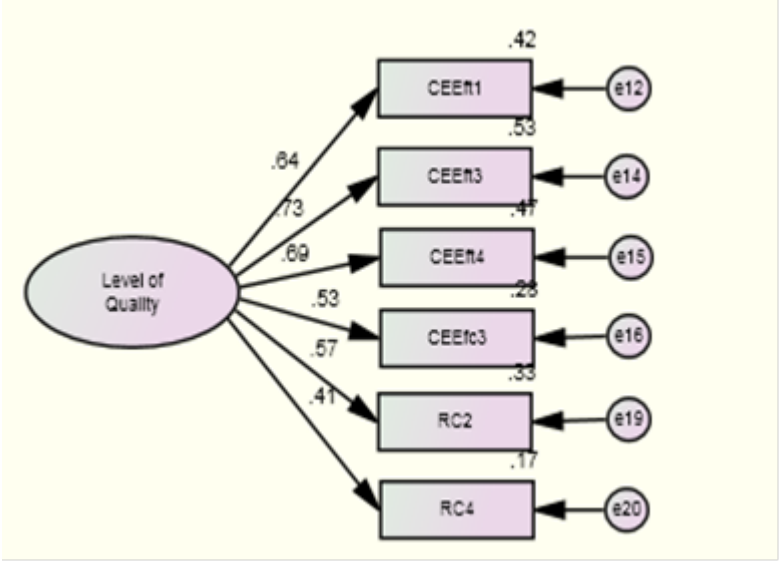


Figure 5.3 Final Revised Measurement Model of Level of Quality

A final revised measurement model of Level of Quality (Figure 5.3) shows a significant difference from zero, at <.001 level (2-tailed), between all categories. Finally, the revised covariance in the overall model greatly improved the goodness of fit statistics detailed below.

Table 5.10 Final Revised Measurement Model of Level of Quality

Indicators of Level of Quality	URW Estimate	SRW Revised	SRW Generic	Standard Error	Critical Ratio	P value
Acquisition Integration	1.000	.644	0.627			
Department Contribution to Organization Objectives	.840	.729	0.696	.087	9.598	***
Job Reporting Satisfaction	.906	.686	0.621	.098	9.280	***
Implemented Cost Assessment	.731	.530	0.584	.095	7.652	***
Regulatory Application	.506	.572	0.681	.062	8.137	***
Regulatory Reporting	.547	.414	0.411	.088	6.196	***

***<.001 (2-tailed) significance
Abbreviation Notes: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

Unstandardized regression weights from the revised final model were analyzed for statistical significance for $p < .05$. Statistical significance was verified at $p < .001$ (Table 5.10). A comparison of the standardized regression weights from the generic model and those from the final revised model of Process Adequacy reveals similarities. However, the largest difference in standardized regression weights is in RC2 (Regulatory Application), with a difference of 0.109 (.681 - .572). All variance errors for Process Adequacy (e_{12} , e_{14}- e_{16}, e_{19}-e_{20}) reached statistical significance at p=.001 (2-tailed). No major additional MIs were recommended by AMOS.

The largest variance in Level of Quality can be attributed to CEEft3 (Department Contribution to Organization Objectives), at .531 or approximately 53%. The least contribution to variance in this construct is from RC4 (Regulatory Reporting), at .172 or approximately 17%, as anticipated from the Generic model.

Table 5.11 Goodness of Fit Statistics: Level of Quality Measurement Model

Index	Criterion	Initial	Final
Chi-square ($\chi 2$)	Low	310.153	23.851
Degrees Of Freedom (df)	≥.0	27	9
Likelihood Ratio ($\chi 2$/df)	<4	11.49	2.650
Probability	>0.05	0.000	0.005
Goodness of Fit Index (GFI)	>.90 x <1.0	0.814	0.975
Adjusted GFI (AGFI)	>.90 x <1.0	0.690	0.941
Normative Fit Index (NFI)	>.90	0.684	0.944
Tucker Lewis Index (TLI)	>.90	0.601	0.940
Comparative Fit Index (CFI)	>.90	0.701	0.964
Root Mean Square Error of Approximation (RMSEA)	≤.05 optimum or .05< value <.08 acceptable	0.182	0.072
Hoelter's Critical N (CN) (.05)	> 200	41	225

The final revised Structural Complexity model's Chi-square Likelihood Ratio, ($\chi 2$/df) of 2.65, meets the recommended condition for results <4. The RMSEA .072 is within the acceptable range; good precision indicated by a lower/upper boundary of .038/.108 of a two-sided 90% confidence interval for the population with a pClose=.130. GFI=.900 < .975 < 1, and AGFI=.9 < .941<1, as recommended (Table 5.11).

5.3.4 Structural Equation Model and Findings of the BEI Survey

An initial Structural Equation Model (or covariance structure model) with three latent variables was formulated under Donabedian's Triadic theoretical premise (Appendix Figure E 4). The measurement models of the latent constructs were analyzed for statistical significance using Confirmatory Factor Analysis (CFA) and were presented in the previous section. Each variable in the SEM model reached 2-tailed statistical significance at .001, with the exception of Level of Quality in relation to Process

Adequacy (.003) and Level of Quality in relation to Structural Complexity (.003) (Table 5.18). The generic model's Chi-square Likelihood Ratio ($\chi 2/df$) of 2.119 meets the conditions for results <4. The RMSEA is .060, which is slightly above the recommended value of <.05, with good precision indicated by a lower/upper boundary of .050/.069 of a two-sided 90% confidence interval for the population, with pClose=.044. GFI=.900 < .904< 1 is within the recommended range, with AGFI=.9 < .875 <1 slightly lower than recommended.

Unstandardized regression weights on the generic model were analyzed for statistical significance for p<.05 (Appendix Table E 4). All inputs exceeded recommended criteria at .001 (2-tailed), indicating a statistically significant difference from zero, except as noted, Level of Quality in relation to both Process Adequacy and Structural Complexity reached significance at .003 <.05. The probability of getting a critical ratio as large as |12.463| in the survey question OC2 regarding Appropriate Professional Job Training is .001 in relation to Structural Complexity. An example of the interpretation of the estimate of .974 is that when recorded rating of the overall Appropriate Professional Job Training (OC2) increases by 1.000 in Structural Complexity, Level of Quality will increase by .974.

AMOS yielded Modification Indices (MI) on the covariance between the epsilon error measurements in e_{16} (CEEfc3 Implemented Cost Assessment) and e_{19} (RC2 Regulatory Application), indicating a marginal drop in Chi-Square statistic by 14.657 if allowed to assume an independent value. Two factors were also removed for low variance contribution in the SEM model. They were 1) ITM2 (Between-Patients Sanitation Training) at .132 or 13.2% and 2) IMDM1 (Device Consistency) at .165 or 16.5%.

Control variables were then added to the final model as explanatory variables for Level of Quality (Appendix Figure E 5), with SEM analysis (Appendix Table E 5). However, none of the control variables achieved a statistically significant relationship to Level of Quality. Though the final SEM model does not contain control variables, the information was retained to report frequency distribution because it adds descriptive value to the study population for future research.

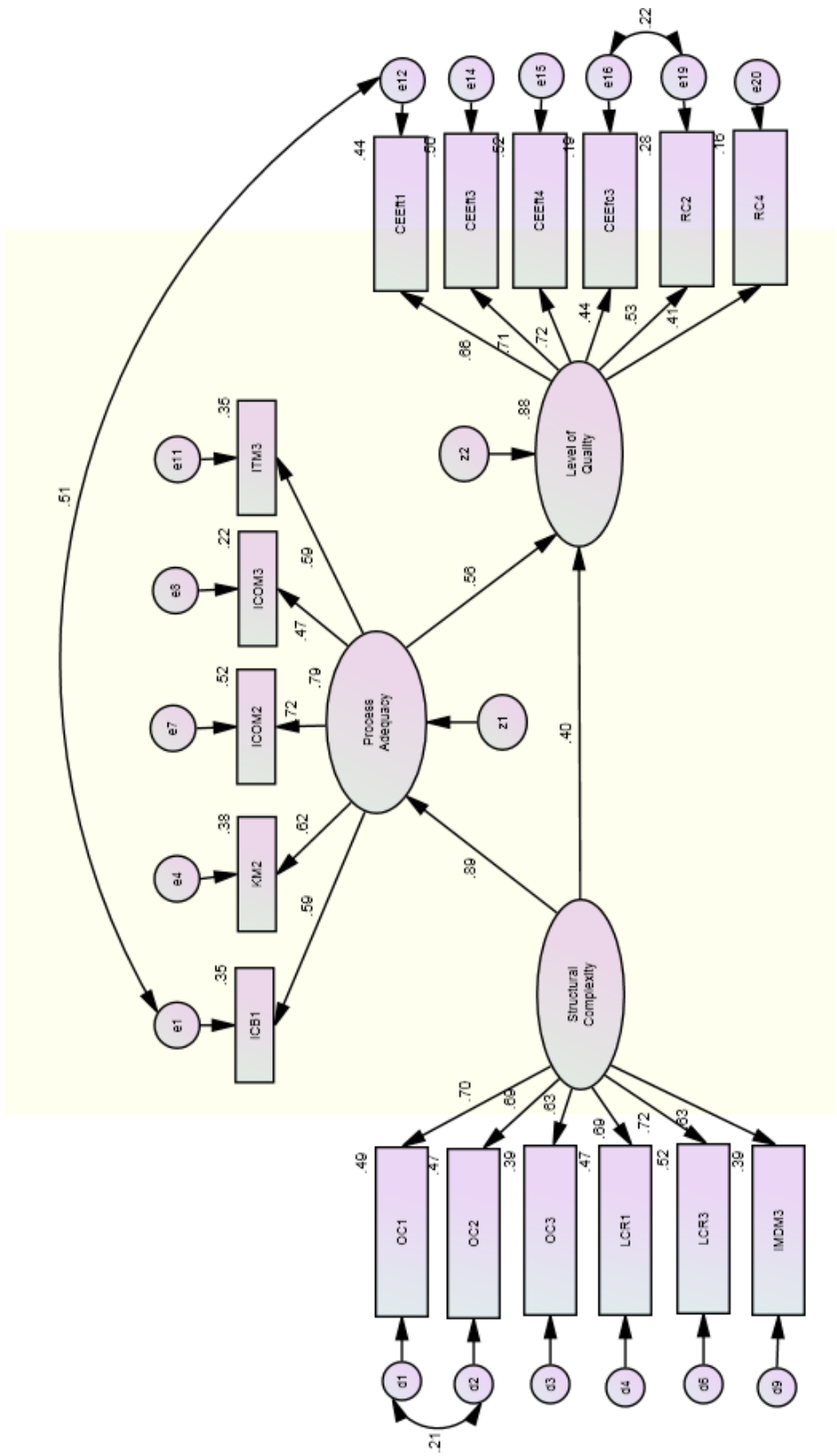


Figure 5.4 Intermittent Revised Congeneric Structural Equation Model of Structural Complexity and Process Adequacy as Organizational Determinants of Level of Quality in the Hospital Environment of Care

Table 5.12 Structural Equation Model for BEI Survey, Without Controls: Latent Variable Comparisons, Lambda Factor Loading Applied to First Factor of Each Latent Construct

Predictors	URW Estimate	SRW Revised	SRW Generic	Standard Error	t	P
Process Adequacy ← Structural Complexity[1]	.923	.889	.892	.103	8.929	***
Level of Quality ← Process Adequacy[2]	.654	.563	.493	.191	3.426	***
Level of Quality←Structural[2] Complexity	.485	.402	.473	.192	2.523	.012

***<0.001 (2-tailed) significance level
Abbreviation Notes: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.
Note[1]: Equation 1 Process Adequacy = f (Structural Complexity) where R^2=79%.
Note[2]: Equation 2 Level of Quality = f (Structural Complexity + Process Adequacy) where R^2 = 88.1%.

An intermittent revised SEM of Structural Complexity and Process Adequacy as Organizational Determinants of Level of Quality in the Hospital Environment of Care derived from the BEI Survey (Figure 5.4) shows a significant difference from zero at p<0.001 (2-tailed), between all categories with the exception of the dependent variable of Level of Quality at p=0.012 (Table 5.12). Finally, the inclusion of covariance of error terms in the overall model greatly improved the goodness of fit statistics (Table 5.13) detailed below.

Table 5.13 Revised Goodness of Fit Statistics: BEI Survey without Control Variables, Lambda Factor Loading Applied to First Factor of Each Latent Construct

Index	Criterion	Initial	Final
Chi-square ($\chi 2$)	Low	429.427	234.683
Degrees Of Freedom (df)	$\geq .0$	166	113
Likelihood Ratio ($\chi 2$ /df)	<4	2.586	2.076
Probability	>0.05	0.000	0.000
Goodness of Fit Index (GFI)	>.90 x <1.0	.878	.918
Adjusted GFI (AGFI)	>.90 x <1.0	.846	.888
Normative Fit Index (NFI)	>.90	.818	.891
Tucker Lewis Index (TLI)	>.90	.861	.928
Comparative Fit Index (CFI)	>.90	.879	.940
Root Mean Square Error of Approximation (RMSEA)	$\leq .05$ optimum or .05< value <.08 acceptable	.071	.058
Hoelter's Critical N (CN) (.05)	> 200	146	187

Unstandardized regression weights from the final SEM model were analyzed for statistical significance for $p < .05$. Statistical significance was verified at $p < .001$. A comparison with the standardized regression weights from the revised SEM model reveals similarities. However, the largest difference in standardized regression weights is in the relationship between Level of Quality and Process Adequacy, with a difference of 0.07 (.563 - .493). Finally, all variance for the revised SEM of the BEI Survey without control variables reached statistical significance at $p<.001$. No major additional MI corrections were recommended by AMOS.

Statistical analysis findings show that the latent constructs derived from Donabedian's Triad are significant at $t>1.96$, indicating an approximate standard distribution. The positive, unstandardized regression weight of .923 for Structural Complexity in the prediction of Process Adequacy is statistically significant at $p<.001$ (2-

tailed). In this instance, for every increase in one standard deviation in Structural Complexity, there is a .923 increase in Process Adequacy.

Process Adequacy = f(Structural Complexity) (5.1)

Equation 5.1 demonstrates the latent variable relationship between the predictor variable Structural Complexity and the endogenous variable of Process Adequacy. Structural Complexity accounts for 79% of the variance in the endogenous variable (R^2=79%).

Level of Quality = f(Structural Complexity + Process Adequacy) (5.2)

The relationship between Process Adequacy and Level of Quality and Structural Complexity with Level of Quality is demonstrated in Equation 5.2. The combined exogenous factors on the level of quality have a variance contribution of R^2=88.1%. Process Adequacy and Level of Quality report a significant positive association at .654, p<0.001 (2-tailed); the Structural Complexity and Level of Quality findings are .485, p=0.012 (2-tailed).

The Goodness of Fit statistics for the revised BEI Survey without Control Variables model (Table 5.13) show an improved final model, with Chi-square Likelihood Ratio (χ2/df) of 2.08 meeting recommended condition for results <4. The RMSEA .058 is within the acceptable range; good precision is indicated by a lower/upper boundary of .048/.069 of a two-sided 90% confidence interval for the population, with pClose=.094. GFI=.900 < .918 < 1, and AGFI=.9 < .888<1, slightly less than recommended.

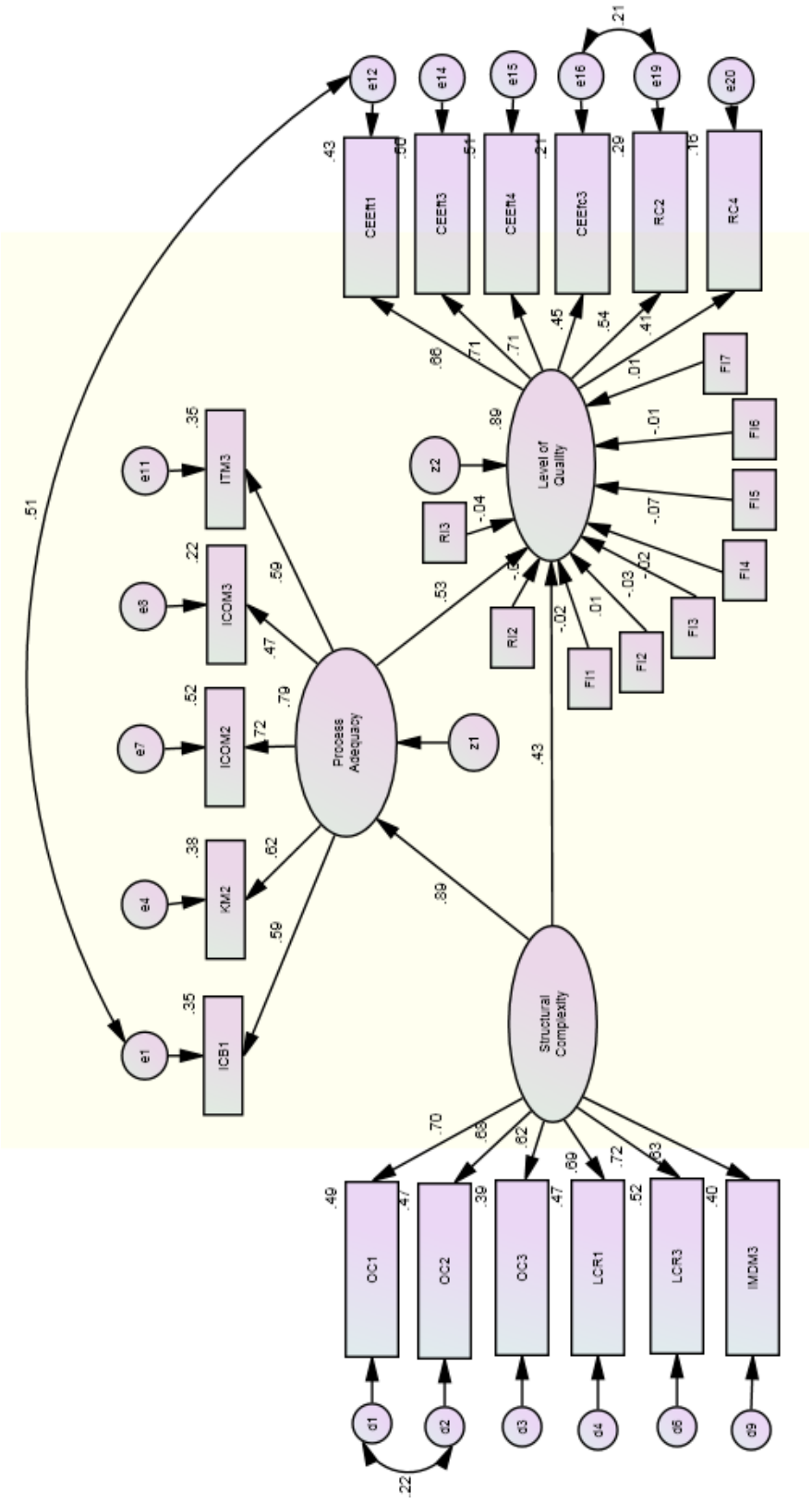


Figure 5.5 Structural Equation Model for the BEI Survey with Control Variables

Table 5.14 Structural Equation Model for BEI Survey, with Control Variables: Lambda Factor Loading Applied to First Factor of Each Latent Construct

Predictors	URW Estimate	SRW Revised	Standard Error	t	P
Process Adequacy ← Structural Complexity	.918	.889	.104	8.865	***
Level of Quality ← Process Adequacy	.620	.534	.188	3.303	***
Level of Quality ← Structural Complexity	.516	.430	.189	2.722	.006
Respondent Control Variables					
Level of Quality←Profession[1]	-	-	-	-	-
Level of Quality ←Highest Level of Education[2]	-.035	-.036	.037	-.936	.349
Level of Quality← Years of Experience[3]	-.175	-.048	.139	-1.261	.207
Facility Control Variables					
Level of Quality←State[4]	-.001	-.023	.002	-.598	.550
Level of Quality ←Joint Commission Accreditation[5]	.009	.006	.050	.170	.865
Level of Quality ←Facility Type[6]	-.014	-.015	.036	-.397	.692
Level of Quality ←Facility Location[7]	-.121	-.074	.063	-1.921	.055
Level of Quality ←Size[8]	-.026	-.015	.069	-.379	.705
Level of Quality ←Region[9]	.006	.010	.022	.262	.793
Level of Quality ←Operational Beds[10]	.000	-.031	.000	-.818	.413

***<0.001 (2-tailed) significance level

Abbreviation Note: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

Notes on scale [1-10]: 1) Biomedical Engineering Technician, no variance in this sample so item not calculated; 2) High School/General Equivalence Diploma; Associate of Arts/Associate of Science; Bachelor of Arts/Bachelor of Science; Graduate Masters or Doctorate; 3) 0-2 years, 3-4 years, and 5+ years; 4) 50 United States and the District of Columbia; 5)Yes or No; 6) Public, Private, Non-Profit, University Affiliated; 7) Rural or Urban; 8)Small 0-25, Medium 26-150, or Large >150); 9) Northeast, Midwest, Southern, Southeast, Western and 10) Continuous number of operational beds.

Statistical analysis revealed that the latent constructs derived from Donabedian's Triad are significant at t>1.96, indicating an approximate standard distribution when control variables are added to the final SEM model (Table 5.14). The positive, unstandardized regression weight of .918 for Structural Complexity in the prediction of Process Adequacy is statistically significant at p<.001 (2-tailed). In this instance, for every increase in one standard deviation in Structural Complexity, there is a .918 increase in Process Adequacy. Structural Complexity accounts for 79% of the variance in the endogenous variable (R^2=79%).

The addition of the control variables has slightly increased combined contribution

to variance in Level of Quality of Structural Complexity and Process Adequacy, at R^2=89%. Process Adequacy and Level of Quality have a significant positive association at .620, p<0.001 (2-tailed); the Structural Complexity and Level of Quality findings are .516, p=0.006 (2-tailed). However, none of the control variables achieved a significant factor loading or probability (Figure 5.5). Only one control variable is of interest: Facility Location, (whether the organizational facility where the BMET was employed was in an urban or rural location). Statistical significance for this variable is at t=-1.921 which indicates non-normal distribution and probability is p=0.055 (2-tailed), slightly higher than acceptable parameters. The final revised model *without* control variables is illustrated in Section 5.4, since the researcher wished to determine the contribution of factors that should be analyzed because of their recognized contribution to clinical engineering quality but that were held constant due to the placement of the lambda regression weight.

Earlier SEM models provided results that held regression weights (lambda) constant on the first factor in each construct, which prohibited the calculation of their specific contribution to the model. However, historically these factors have contributed to better clinical engineering quality. Hence, the same model was allowed to regress on each of the factors within each construct that established the least contribution: Regulatory Application (Level of Quality); Available Operational Equipment (Process Adequacy); and Interdepartmental Work (Structural Complexity), so that results of the potentially leading predictors could be analyzed: Acquisition Integration (Level of Quality), Equipment Purchasing Involvement (Process Adequacy), and Inter-Professional Training (Structural Complexity).

Table 5.15 Final Structural Equation Model for BEI Survey Without Controls

Predictors	URW Estimate	SRW Revised	Standard Error	t	P
Process Adequacy ← Structural Complexity	.647	.889	.089	7.248	***
Level of Quality ← Process Adequacy	.504	.563	.161	3.136	.002
Level of Quality ← Structural Complexity	.262	.402	.106	2.469	.014
Structural Complexity X_{1-6}					
Interdepartmental Work← Structural Complexity[1]	1.000	.687			
Uniform Standards ← Structural Complexity[2]	1.414	.627	.141	10.062	***
Inter-Professional Training ← Structural Complexity[3]	1.171	.701	.106	11.091	***
Coordination Evidence ← Structural Complexity[4]	1.161	.723	.101	11.445	***
Appropriate Professional Job Training ← Structural Complexity[5]	1.134	.685	.105	10.850	***
Device Failure Recognition ← Structural Complexity[6]	.992	.627	.099	10.065	***
Process Adequacy Y_{1-5}					
Available Operational Equipment ← Process Adequacy[7]	1.000	.469			
Regular Meetings ← Process Adequacy[8]	1.850	.590	.264	7.009	***
Equipment Purchasing Involvement ← Process Adequacy[9]	1.670	.593	.237	7.036	***
Formal Equipment Training ← Process Adequacy[10]	1.576	.719	.205	7.678	***
Formal Department Information ← Process Adequacy[11]	1.225	.618	.171	7.172	***
Level of Quality Y_{6-11}					
Regulatory Application ← Level of Quality[12]	1.000	.531			
Acquisition Integration ←Level of Quality[13]	2.166	.660	.259	8.371	***
Job Reporting Satisfaction ← Level of Quality[14]	2.026	.722	.231	8.785	***
Department Contribution to Organizational Objectives ← Level of Quality[15]	1.737	.709	.200	8.702	***
Implemented Cost Assessment ← Level of Quality[16]	1.294	.441	.179	7.226	***
Regulatory Reporting ← Level of Quality[17]	1.139	.406	.191	5.976	***

***<0.001 (2-tailed) significance level

Note: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

Notes on Scale[1-17]: 1) I receive and/or provide interdepartmental input in order to successfully complete work, 2) Standards are applied equally across all departments, 3) The organization values contributions to other staff members' professional development, 4) Interdepartmental coordination has resulted in

Predictors	URW Estimate	SRW Revised	Standard Error	t	P
visible positive benefits, 5) I have been provided clear training to perform my job function, 6) I receive and/or provide advice on new equipment purchases, 7) I receive and/or provide clean, operational equipment in a timely fashion, 8) Nursing and biomedical engineering conduct regularly scheduled meetings on equipment issues, 9) I receive and/or provide advice on new equipment purchases, 10) I receive and/or provide training on the proper way to operate equipment,11) I have access to formal knowledge within the department, 12) Biomedical engineering is able to apply medical equipment regulatory policy, 13) Biomedical engineers are integrated in the medical equipment purchasing process, 14) Biomedical engineers are satisfied with reporting authorities, 15) Biomedical engineers set and achieve department goals based on organizational objectives, 16) Biomedical engineering measures cost using generally accepted metrics, and17) All departments have access to hospital acquired infection data.					

AMOS statistical analysis software shows that the latent constructs are significant at t>1.96, indicating an approximate standard distribution (Table 5.15). The positive, unstandardized regression weight of .647 for Structural Complexity in the prediction of Process Adequacy is statistically significant at p<0.001 (2-tailed). The relationship between Process Adequacy and Structural Complexity has a combined explanatory contribution to variance for the Level of Quality at R^2=0.881 or 88.1%. PA and LOQ report a significant positive association at .504, p=0.002 (2-tailed); SC and LOQ findings are .262, p=.012 (2-tailed).

A detailed review of the unstandardized estimates reveals that each exogenous factor X_{1-6} of Structural Complexity in the prediction of Process Adequacy is statistically significant at t>1.96, p<0.001 (2-tailed). All endogenous variables Y_{1-11} comprising Eta_1 (Y_{1-5}) and Eta_2 (Y_{6-11}) exhibit statistical significance at t>1.96, p<0.001. Therefore, Process Adequacy and Structural Complexity in the prediction of LOQ are statistically significant.

The individual factor with the greatest relationship between the SC predictor variable and the LOQ endogenous study variable is Uniform Standards, where one standard deviation will increase the Level of Quality by 1.414. The individual factor with

the greatest relationship between PA and LOQ is Regular Meetings, at 1.850. These findings suggest that improvement in this area have the potential to nearly double expectations for the quality of care.

The most dynamic impact from the relocation of the lambda regression weight can be seen in the endogenous variable LOQ at Acquisition Integration. Previously held constant, Acquisition Integration reports the highest value, 2.166, followed closely by Job Reporting Satisfaction at 2.026. Acquisition Integration, affirming that "Biomedical engineers are integrated in the medical equipment purchasing process" and Job Reporting Satisfaction, "Biomedical engineers are satisfied with reporting authorities," can have more than double the impact on the Level of Quality.

Table 5.16 provides a summary of the squared multiple correlations of the observed variables in the SEM for the BEI survey. The "Estimate" refers to the percentage of contribution of variance in the model.

Table 5.16 Squared Multiple Correlations of the Lambda Revised Structural Equation Model of the Biomedical Engineering Interdepartmental Survey

Predictors	Estimate
Process Adequacy	.790
Level of Quality	.881
Process Adequacy	
Formal Equipment Training[1]	.516
Formal Department Information[2]	.381
Equipment Purchasing Involvement[3]	.352
Regular Meetings[4]	.348
Available Operational Equipment[5]	.220
Structural Compliance	
Coordination Evidence[6]	.522
Inter-Professional Training[7]	.492
Interdepartmental Work[8]	.472
Appropriate Professional Job Training[9]	.469
Device Failure Recognition[10]	.393
Uniform Standards[11]	.393
Level of Quality	
Job Reporting Satisfaction[12]	.521
Department Contribution to Organization Objectives[13]	.502
Acquisition Integration[14]	.435
Regulatory Application[15]	.282
Implemented Cost Assessment[16]	.195
Regulatory Reporting[17]	.165

Notes [1-17]: [1]I receive and/or provide training on the proper way to operate equipment. [2]I have access to formal knowledge within the department. [3]I receive and/or provide advice on new equipment purchases. [4]Nursing and biomedical engineering conduct regularly scheduled meetings on equipment issues. [5]I receive and/or provide clean, operational equipment in a timely fashion. [6]Interdepartment coordination has resulted in visible positive benefits. [7]The organization values contributions to other staff members' professional development. [8]I receive and/or provide interdepartmental input in order to successfully complete work. [9]I have been provided clear training to perform my job function. [10]I receive and/or provide training to recognize medical device failure. [11]Standards are applied equally across all departments. [12]Biomedical engineers are satisfied with reporting authorities. [13]Biomedical engineers set and achieve department goals based on organizational objectives. [14]Biomedical engineers are integrated in the medical equipment purchasing process. [15]Biomedical engineering is able to apply medical equipment regulatory policy. [16]Biomedical engineering measures cost using generally accepted metrics. [17]All departments have access to hospital acquired infection data.

5.4 Hypothesis Test Results

The primary objectives of this study were the assessment of the researcher-developed questionnaire as a viable research instrument and specific analysis of the latent constructs through statistical analysis. The instrument proved reliable in two separate Cronbach Alpha analysis procedures (Sections 4.3, 5.6). Hypothesis testing showed the modified Structural-Process-Outcome model to be measureable, identified hospital structural characteristics and process factors that affect the quality of care in US hospitals, and validated the relationships between the LOQ and three healthcare outcomes (e.g., clinical effectiveness, clinical efficiency, and regulatory compliance).

Table 5.17 Summary of the Statistical Evidence in Support of Study Hypotheses

Hypotheses Statements	Summary of Statistical Evidence	Results
$Hypothesis_1$: Structural complexity positively affects process adequacy in the hospital environment of care.	PA←SC: $p<0.001$ level (2-tailed); $\beta=.889$, $t=7.248$, $t>1.96$ on all factors; $R^2 = 79\%$.	Supported
$Hypothesis_2$: Structural complexity positively affects the level of quality in the hospital environment of care.	LOQ←SC; $p=0.014$ level (2-tailed); $\beta=.402$, $t=2.469$, $t>1.96$ on all factors; $R^2 = 16.2\%$.	Supported
$Hypothesis_3$: Process adequacy positively affects the level of quality in the hospital environment of care.	LOQ←PA: $p=.002$ level (2-tailed); $\beta=.563$, $t=3.136$; $t>1.96$ on all factors; $R^2 = 31.2\%$.	Supported

Abbreviation Notes: SC=Structural Complexity, PA=Process Adequacy, LOQ=Level of Quality, ← = direction of the relationship between constructs.

Table 5.17 is a summary of the statistical support detailed in Section 5.3.4 for findings on the hypotheses.

5.5 Final Reliability Analysis SEM Model

The final SEM model of the Biomedical Engineering Interdepartmental Survey submitted to the biomedical engineering technician sample population has undergone reliability analysis to determine the internal consistencies of the scales derived through the calculation of the Cronbach Alpha (α) coefficient on the overall measurement. PASW (version 18.0.0) statistical software showed a final range of Cronbach α=0.718 to 0.831 for the respondent ratings for each latent construct of Structural Complexity, Process Adequacy, and Level of Quality indicating good internal consistency >0.7 (DeVellis, 2003) (Table 5.18). These data show that all make some contribution, since no values were reported at zero, N=317 valid cases. Overall BEI Survey reliability Cronbach α = 0.905.

Table 5.18 Final SEM Cronbach Alpha Reliability Coefficient for Latent Constructs from Biomedical Engineering Interdepartmental Survey Results

Latent Constructs and Factors	Initial Cronbach's Alpha N=395; 39 Items	Final Cronbach's Alpha N=317; 17 Items
Structural Complexity Construct All	**0.774**	**0.831**
Organizational Culture	0.771	
Level of Coordination	0.833	
Medical Equipment Complexity	*-0.177*	
Interdepartmental Medical Device Management	0.469	
Process Adequacy Constructs All	**0.833**	**0.718**
Interdepartmental Collaboration	0.644	
Knowledge Management	0.748	
Complexity of Sanitation Methods	0.639	
Interdepartmental Communication	0.688	
Interdepartmental Teamwork	0.568	
Level of Quality Constructs All	**0.791**	**0.758**
Clinical Engineering Effectiveness	0.782	
Clinical Engineering Efficiency	0.695	
Regulatory Compliance	0.444	
Overall	**0.918**	**0.905**

The complete BEI survey questionnaire contained questions for three major latent constructs derived from Donabedian's Triad: Structural Complexity, Process Adequacy and Level of Quality. Structural Complexity, originally comprising four factors (Organizational Culture, Level of Coordination, Medical Equipment Complexity, and Interdepartmental Medical Device Management) for a total of 12 variables, was reduced to three factors and 6 variables. The final 6 factors of Structural complexity were Organizational Culture (three), Level of Coordination (two), and Interdepartmental Medical Device Management (one).

Process Adequacy, originally comprising five factors (Interdepartmental Collaboration, Knowledge Management, Complexity of Sanitation Methods, Interdepartmental Communication, and Interdepartmental Teamwork) for a total of 15 variables, was reduced to four factors and five variables. The final variables of Process Adequacy comprised Interdepartmental Collaboration (one), Knowledge Management (one), Interdepartmental Communication (two), and Interdepartmental Teamwork (one).

Level of Quality, originally comprising three factors (Clinical Engineering Effectiveness, Clinical Engineering Efficiency, and Regulatory Compliance) for a total of 12 variables, was reduced to six variables. The final variables of Level of Quality are comprised Clinical Engineering Effectiveness (three), Clinical Engineering Efficiency (1), and Regulatory Compliance (2).

5.6 Additional Findings: Intervening Status of Process Adequacy

At this juncture, manipulation of the final revised SEM model can reveal the actual role of the latent construct Process Adequacy, previously identified in this model as an intervening variable. Determination of the status of Process Adequacy as a mediating or moderating variable utilizes Baron & Kenny's (1980) causal step approach methodology.

A preliminary condition of the causal steps to determine mediation requires the removal of the variable under consideration from the SEM model. The model adjustment allows only the independent and dependent variables to regress (Figure 5.6).

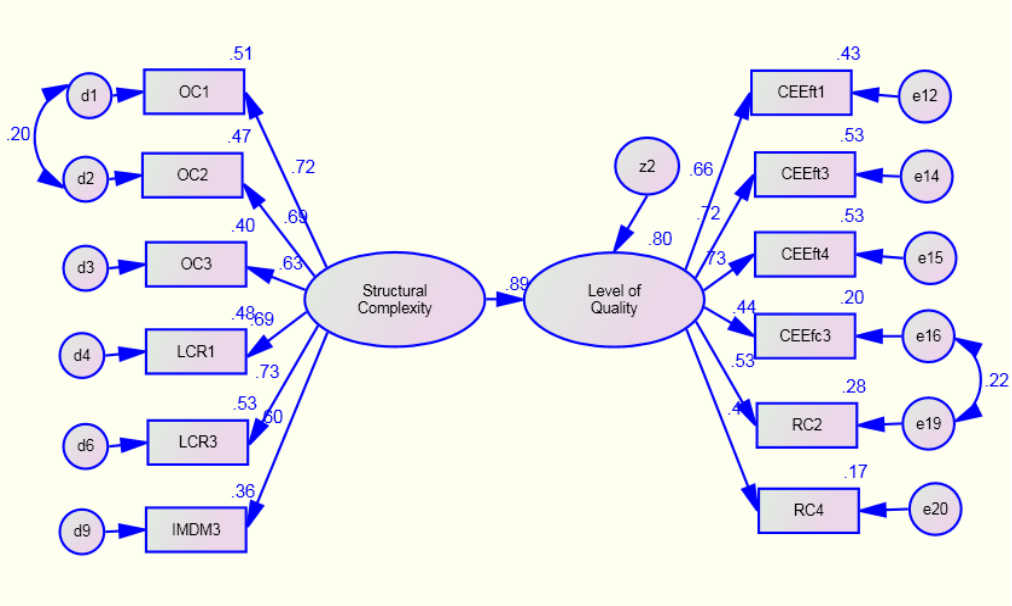


Figure 5.6. Results of the Final Structural Equation Model with Proposed Mediating Construct Process Adequacy, Removed for Illustrative Purposes

A second preliminary condition for mediation is determining if there is no longer statistical significance between the predictor and the outcome variables (Table 5.19). Elimination of the Process Adequacy term indicates a strong relationship of .89 between Structural Complexity and Level of Quality at $t>1.96$, $p<0.001$ (2-tailed). Since the relationship is significant without the Process Adequacy construct, the preliminary conditions of mediation did not occur. Consequently, it was unnecessary to perform the causal steps interpretation of the Beta coefficient in the structural equation model for the stimulus-response effect on the linear regression equations under the historically accepted maximum likelihood-based method (Hayes, 2009; Baron & Kenny, 1986).

Table 5.19 Structural Equation Model with Proposed Mediating Variable Removed

Predictors	URW Estimate	SRW	Standard Error	t	P
Level of Quality ← Structural Complexity	1.061	.894	.108	9.841	***

***<0.001 (2-tailed) significance level

Abbreviation Notes: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

A preliminary consideration to determine moderation under desirable conditions indicates that the "moderator variable be uncorrelated with both the predictor and the criterion (the dependent variable)" and "moderators and predictors are at the same level in regard to their role as causal variables antecedent or exogenous to certain criterion effects" (Baron & Kenny, 1986, p. 1174). This study does not consider the intervening variable of Process Adequacy on the same level as Structural Complexity since Process Adequacy has been established as both an exogenous and endogenous variable (e.g., Process Adequacy is endogenous to Structural Complexity; Process Adequacy is exogenous to Level of Quality). Further, correlation has been previously demonstrated between Structural Complexity and Process Adequacy (Table 5.3) and between Process Adequacy and Level of Quality (Table 5.5). Hence, the preliminary conditions of moderation were not met.

In summary, the preliminary conditions of mediation and moderation have not been met utilizing Baron & Kenny's (1986) methodology. Consequently, Process Adequacy is an intervening variable. However, other researchers have recently provided other methodologies that were not performed in this analysis which may be used to provide alternative methods for testing. In fact, several researchers suggest that these new analysis methods may improve on the causal steps approach which may have reduced power (Hayes, 2009; MacKinnon, Fairchild, & Fritz, 2007; Bauer, Preacher, & Gil,

2006). They suggest an alternative testing sequence such as the Sobel test (Sobel, 1982, 1986 as cited in Hayes, 2009), which analyzes the standard error in the direct relationship between the predictor and the outcome that may in part account for the intervening effect. But Hayes (2009) and MacKinnon et al. (2007) indicate that each potential replacement struggles with weaknesses that require further examination before a new method can gain mainstream acceptance in the statistical community.

5.7 Control Variable Frequency Distribution

The BEI Survey study directly required three respondent and five facility demographics. In addition, respondents who identified their facility as located in an urban area were asked to provide their zip codes. The researcher derived two additional facility demographics from the data for Number of Operational Beds and State, to form hospital Size and Region, respectively. Frequency distributions were calculated on all categorical variables (Tables 5.20 and 5.21). The continuous variable of Operational Beds was calculated separately because of the multiple responses. Operational Beds descriptive statistics are valid at N=308, range of 0 to 5,000 beds, mean score =447.20 with a Standard Deviation of 505.418. The State Frequency Distribution is led by California having the most responses at 25, 7.9% of the total. Florida, Ohio, and Texas are tied for the second highest contribution at 21, at 6.6%. Tennessee (16, 5%) and Indiana (15, 4.7%) rounded out the top tier. The balance of states had 2 or more responses except for Alaska, Delaware, Montana, North Dakota, and Oklahoma, each had only one representative completing the survey. (Control variable frequency distribution for the number of respondents by state is available upon request.)

Table 5.20 Biomedical Engineering Interdepartmental Survey: Frequency Distribution of the Categorical Respondent Control Variables

Control		Frequency	Percent	Valid Percent	Cumulative Percent
Profession	Biomedical Engineering Technician	313	98.7	99.1	99.1
	Nurse	2	.6	.6	99.7
	Quality	1	.3	.3	100.0
	Total	316	99.7	100.0	
	Missing	1	.3		
Total N		317	100.0		
Years of Experience	0-2 years	2	.6	.6	.6
	2-4 years	6	1.9	1.9	2.5
	5+ years	308	97.2	97.5	100.0
	Total	316	99.7	100.0	
	Missing	1	.3		
Total N		317	100.0		
Education	High School	12	3.8	3.8	3.8
	Associate of Arts/Associate of Science	183	57.7	57.9	61.7
	Bachelor of Arts/Bachelor of Science	78	24.6	24.7	86.4
	Graduate (Masters or Doctorate)	43	13.6	13.6	100.0
	Total	316	99.7	100.0	
	Missing	1	.3		
Total N		317	100.0		

A majority of respondents reported 5+ years of experience (97.2%), at least a 2 year education (57.7%), working at large (80.8%), non-profit (68.8%), Joint Commission accredited (85.5%), urban facilities (67.8%) across 5 regions.

Regional representation was fairly consistent, with the Midwest achieving the largest representation, 85, for 26.8% of the population sample. Other regions contributing in roughly the same proportion were Southern (62, 19.6%), Northeast (58, 18.3%), and

the Southeast (56, 17.7%).The Western region had the least representation, 49, for 15.5% of the sample.

Table 5.21 Biomedical Engineering Technician Interdepartmental Survey: Frequency Distribution of the Categorical Organizational Control Variables

Control		Frequency	Percent	Valid Percent	Cumulative Percent
Joint Commission Accredited	Yes	271	85.5	86.9	86.9
	No	15	4.7	4.8	91.7
	Other Accredited	26	8.2	8.3	100.0
	Total	312	98.4	100.0	
	Missing	5	1.6		
Total N		317	100.0		
Facility Type	Public	43	13.6	13.8	13.8
	Private	24	7.6	7.7	21.5
	Non-Profit	218	68.8	69.9	91.3
	University Affiliated	27	8.5	8.7	100.0
	Total	312	98.4	100.0	
	Missing	5	1.6		
Total N		317	100.0		
Location Type	Rural	97	30.6	31.1	31.1
	Urban	215	67.8	68.9	100.0
	Total	312	98.4	100.0	
	Missing	5	1.6		
Total N		317	100.0		
Size	Small (0-25)	6	1.9	2.0	2.0
	Medium (26-150)	40	12.6	13.2	15.2
	Large (>150)	256	80.8	84.8	100.0
	Total	302	95.3	100.0	
	Missing	15	4.7		
Total		317	100.0		
Region[1]	Northeast	58	18.3	18.7	18.7
	Midwest	85	26.8	27.4	46.1
	Southern	62	19.6	20.0	66.1
	Southeast	56	17.7	18.1	84.2
	Western	49	15.5	15.8	100.0
	Total	310	97.8	100.0	
Missing	System	7	2.2		
Total N		317	100.0		

Note [1]: Northeast (Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and Washington, DC.); Midwest (Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin), Southern (Alabama, Arkansas, Kentucky, Louisiana, Mississippi, Oklahoma, Tennessee, and Texas), Southeast (Florida, Georgia, North Carolina, South Carolina, Virginia, and West Virginia), and Western (Alaska, Idaho, Montana, Oregon, Washington, Wyoming, Arizona, California, Colorado, Hawaii, Nevada, New Mexico, and Utah).

5.8 Response Distribution for the Observed Variables

A complete codebook of respondent answers listing the frequency distributions and cumulative percentages for the observed variables is available for review upon request. The data includes the variables that were eliminated due to non-normal distribution.

5.8.1.1 Summary

The relationships among the three latent constructs, based on Donabedian's Triad, were analyzed. The results indicate strong support for the three major hypotheses. The final Structural Equation Model (Figure 5.4) indicates strong, positive relationships between constructs as statistically significant 2-tailed relationships (Table 5.15): 1) between Structural Complexity and Process Adequacy at $\beta=.889$, $t=7.248$, $p<0.001$; 2) between Process Adequacy and Level of Quality at $\beta=.563$, $t=3.136$, $p=0.002$; and 3) between Structural Complexity and Level of Quality at $\beta=.402$, $t=2.469$, and $p=0.014$. Translation of these regression findings into equation form follows.

$$\text{Level of Quality} = .889\ \text{Structural Complexity} + .563\ \text{Process Adequacy} \quad (5.1)$$

Process Adequacy did positively and significantly statistically influence the variability in level of quality at $t>1.96$, $p<0.001$ (2-tailed). Finally, Structural Complexity did positively and significantly statistically influence Process Adequacy at $t>1.96$ on all factors, $p<0.001$ (2-tailed), and Level of Quality at $t>1.96$, $p<0.012$ (2-tailed).

CHAPTER 6: DISCUSSION AND RECOMMENDATIONS

6.1 Discussion

Donabedian's Triad was successfully developed and applied to the biomedical engineering technician community (BMET) in the hospital environment of care (EC), with strong support revealed by hypothesis testing. Effects of Structural Complexity and Process Adequacy on the prevalence of systemic adverse events and compliance problems were demonstrated through proxy measurements of Level of Quality that incorporated measures of Clinical Engineering Effectiveness, Clinical Engineering Efficiency, and Regulatory Compliance. Structural Complexity has a direct and indirect, positive relationship with the endogenous study variable Level of Quality.

Analysis revealed three statistically supported relationships with important and unique findings. First, the relationship between Structural Complexity and Level of Quality indicate that simple organizational changes such as applying Uniform Standards equally across departments have the greatest potential to influence the Level of Quality in the environment of care (EC). Structure's effect on the Level of Quality is supported in a range of literature in health, computer science, and manufacturing. Second, the relationship between Process Adequacy and Level of Quality has significant findings: interdepartmental activities that integrate skillsets can increase the Level of Quality. These findings strongly suggest that Regular Meetings between Nursing and the BMET to discuss equipment issues can also positively impact Level of Quality in the EC. Third, emphasizing organizational changes that promote Interdepartmental Work and Training can elicit positive processes associated with increased quality such as Equipment Purchasing Involvement and the Availability of Operation Equipment.

The application of these findings should not be dependent on the employment status of the BMET in Clinical Engineering. Specifically, whether the BMET is a direct hire of the healthcare facility and/or a third party contractor should not impact the application of these results since all BMETs must work in the environment of care.

This section discusses the research questions and hypothesis testing results in relation to each construct. Implications of the results for the theoretical, methodological, external policy, and hospital administrative management changes are discussed. Limitations of the study are presented. Finally, recommendations for future research are provided.

6.1.1 Level of Quality

Overall, the constructs presented in this study are measureable, addressing research question one: **"**Are the constructs Structural Complexity, Process Adequacy, and Level of Quality, measurable?" **S**tatistical significance and an approximate standard distribution ($t>1.96$) was found between latent constructs. The relationships between Structural Complexity and Process Adequacy, $p<0.001$ (2-tailed); Process Adequacy and Level of Quality, $p=0.002$ (2-tailed); and predictors of Structural Complexity and the study variable of Level of Quality, $p=0.014$ (2-tailed) confirm statistical significance.

Specific factors of Level of Quality in the SEM with adjusted lambda placement were analyzed for statistical significance, at $p<0.05$. All inputs exceed recommended criteria, at $p<0.001$ (2-tailed) indicating that measurements adequately represent the endogenous study variable Level of Quality. In particular, two factors of the sub-group Clinical Engineering Effectiveness have recorded estimates greater than two. Acquisition integration, which measured to what degree "Biomedical engineers are integrated in the medical equipment purchasing process") has an estimate value of 2.166. Job reporting satisfaction, which

measured to what extent “Biomedical engineers are satisfied with reporting authorities) has a value of 2.026. These values indicate that as each rating of overall acquisition integration or job reporting satisfaction increases by 1.000, the Level of Quality will more than double.

A review of the survey response rate and information in a preliminary pilot study may help place two seemingly divergent solutions with high impact in proper perspective. Approximately two-thirds of those polled either agree or strongly agree that biomedical engineering technicians are involved in the purchasing process. However, BMET inclusion does not span clinical departments. Though this study did not assess biomedical engineering at the department level, a preliminary finding in a pilot study conducted by the author (Fiedler & Agarwal, 2009) is that although integration has occurred in administrative functions such as purchasing or Management Information Systems (MIS), BMETs are not integrated into areas of high patient contact such as infection control or central sterile. In fact, only 4 of N=182 stated that they worked regularly in another department (reported as MIS) and 9 had administrative duties (Fiedler & Agarwal, 2009).

It should be noted that an ordinal question on Management Integration to determine the extent to which “Biomedical engineers are integrated into facility management (e.g., Central Sterile, Infection Control, Management Information Systems) was eliminated in the measurement model of Level of Quality because of similarities in measurements of acquisition integration. Using that measure instead of acquisition integration results in a non-parametric indication, since $t<1.96$ does not indicate an approximate standard distribution, and $p=0.052$ is slightly higher than the $p<0.05$

criterion. Future studies may consider a Poisson distribution analysis method with this indicator.

A review of the response rate for job reporting satisfaction, which measured to what extent "Biomedical engineers are satisfied with reporting authorities," shows that 42.9 per cent of the respondents agreed with this statement. But nearly as many indicated that they 'Neither Agreed or Disagreed' (27.8%), 'Disagreed' (9.1%), or 'Strongly Disagreed' (4.1%) with the statement. Therefore, for nearly half of the BMETs their role in relation to other departments appears clearly defined, while others clearly express dissatisfaction with this facet of their duties. The disparity may be attributed to the present nature of the biomedical engineering technician community, in that the BMET has not achieved professional status but is making strides to do so in order to solidify a presence in the clinical environment. Also, the possibility exists that even as BMETs report involvement, there may be organizational cultural boundaries that put boundaries on their contributions and hence limit reporting satisfaction in their particular facility.

Conclusions from these findings on the Level of Quality indicate that inter-professional interaction, but not necessarily biomedical engineering integration into other departments (which may further complicate the disparate reporting structure), will increase the level of quality. The premise of Integrated Empirical Ethics supports the maintenance of professional autonomy in this scenario while allowing for more collaborative contributions by biomedical engineering technicians in clinical service operations.

6.1.2 Structural Complexity

Research question two asked, "What is the relationship between structural complexity and process adequacy?" Findings support the conclusion that structural complexity, representative of components from organizational culture, level of coordination, and interdepartmental device management, has a positive relationship that is statistically significant with the intervening variable of process adequacy (Section 5.6).

Statistical findings in response to research question three, which asked, "What is the relationship between structural complexity and the level of quality in the hospital environment of care?" lead to the conclusion that structural complexity has a statistically significant positive relationship, both directly and indirectly, with the endogenous study variable. The relationship between Structural Complexity and Level of Quality implies that several simple, cost effective changes in the hospital structure can improve hospital level of quality in terms of clinical effectiveness, efficiency and regulatory control.

The two leading factors of Structural Complexity that contribute to Level of Quality are subscales of organizational culture: 1) uniform standards which measures the extent that "Standards are applied equally across all departments" and 2) inter-professional training, which measures the extent that "The organization values contributions to other staff members' professional development". Organizational culture has played a distinct role in assessing performance in hospital units such as the ICU (Minvielle et al., 2008) and clinical engineering (Cao & Frize, 2003; Frize, 1989). A third leading Structural Complexity factor in the prediction of Level of Quality is from the subscale of level of coordination—coordination evidence. Coordination evidence measures the extent that "Interdepartmental coordination has resulted in visible positive benefits". The combination of those two terms

echoes forth the notions of “I’ll believe it when I see it” or “Put your money where your mouth is.” Intuitively, respondents expect to see visible evidence of teamwork and collaboration efforts that not only promotes professional development when a didactic occurs, but results in visible changes. A promise of positive change is inherently different from visible evidence, especially when standards are applied differently in departments or only to specific personnel. Hence, structural changes that strive for common goals leading to uniform standards should consider the benefits of inter-professional training and convergence of ethical motivation.

6.1.3 Process Adequacy

Research question four asked, “What is the relationship between process adequacy and the level of quality in the hospital environment of care?” Findings point to the conclusion that the intervening variable of process adequacy has a positive relationship that is statistically significant with the endogenous study variable.

The intervening effect of Process Adequacy (composed of interdepartmental collaboration, knowledge management, interdepartmental communication and interdepartmental teamwork constructs) has significant findings which reveal that interdepartmental activities can be used to increase the Level of Quality in the EC. Not surprisingly, the three leading factors between Process Adequacy and the Level of Quality are a combination of subscales including interdepartmental teamwork, collaboration and communication, suggesting regular meetings (“Nursing and biomedical engineering conduct regularly scheduled meetings on equipment issues”), equipment purchasing involvement (“I receive and/or provide advice on new equipment purchases”), and formal equipment training (“I receive and/or provide training on the proper way to operate equipment”).

One factor of knowledge management—formal department training ("I have access to formal knowledge with the department") is of further note. Training for a biomedical engineering technician consists of two-years of civilian education and an internship leading to an Associate of Science or military training. From the author's personal experience, a great deal of BMET education is informal through exchanges that closely resemble apprenticeships. Given that situation, the statistical significance of access to formal knowledge is surprising, yet understandable due to the personal responsibility of being the first line of defense ensuring that practitioners have operational equipment to perform their tasks. The responsibility requires the accumulation of diverse knowledge about a vast array of equipment types, which the informal means of apprenticeship may not achieve.

6.1.4 Clinical Effectiveness, Clinical Efficiency, and Regulatory Compliance

This study's results are important in that they are measured against critical evaluation performance indicators and derived from credible healthcare theorists and experts in this field. The findings also are consistent with evaluations in the literature and in some cases provide supplemental findings as noted previously. For example, the finding that organizational culture influences clinical engineering effectiveness is supported by the Frize (1989) clinical engineering model. Chuang and Inder (2009) concur with the finding that regulatory compliance may exert less influence than supposed, but is a necessary component for some uniformity in the delivery of health care. The opportunity to increase efficiency through optimizing knowledge of personnel and equipment management (Podgorelec et al., 2009) is consistent with the statistical relevance of implemented cost assessment and biomedical engineering technician interdependencies in this study. The incorporation of a multidisciplinary meeting to

increase communication and therefore patient outcomes (Ruhstaller, Roe, Thurlimann, & Nicoli, 2006) has been validated in this study population.

The results of this study show opportunities to promote positive organizational change through internal transparencies that improve patient outcomes (Perez & DiDona, 2009; Donabedian, 1989). Predictors identified from inter-departmental partnerships and associated processes suggest that integration of the biomedical engineering technician into the hospital delivery system can improve the quality of care. Administrators can manage and improve quality through employing simple, effective and efficient solutions such as 1) updating internal hospital policy to require regularly scheduled meetings between nursing and biomedical staff regarding equipment issues, 2) linking the BMET department goals to organization objectives, 3) interdepartmental reporting of hospital acquired infections, and 4) standardizing clinical engineering practices to facilitate increased internal and external hospital quality.

6.2 Implications

The study has implications for theory, external policy, and internal hospital management policy. Details follow in the next sections.

6.2.1 Theoretical Implications

The theoretical contributions of the study include the instrument development and measurement models for hospital level of quality. Donabedian's Triad is statistically analyzed, indicating that structural complexity and process adequacy are explanatory of the outcome variable, level of quality. Further, the outcome measures of Quality—Effectiveness, Efficiency, and Regulatory Compliance were defined in the context of Clinical Engineering.

Several statistically significant predictors of quality support an interdepartmental approach to systemic problems; they are Uniform Standards, Inter-Professional Training, and Coordination Evidence. The application of Integrated Empirical Ethics provides a foundation for management resolution of divergence in internal and external controls, which can improve hospital level of quality through consolidation.

The Assessment Measurement Classes of Organization Performance, better known as Donabedian's Structure-Process-Outcome Theory, have been applied to many studies. However, the biomedical engineering technician profession's interaction with the nursing professional has not been explored under Donabedian's Triad. Further, the results of this study concerning BMET perceptions of how structural complexity and process adequacy in the hospital EC affect the prevalence of systemic adverse events and compliance problems will fill a gap in scientific literature on symbiotic professional relationships in healthcare (D'Amour et al., 2005). Healthcare–long identified as different from other organizations in their adherence to hierarchy-driven professional interactions, has a significant symbiotic character that though heretofore recognized, has not been quantified in literature.

6.2.2 External Policy

The implications of these results suggest several recommendations for external policy, foremost of which is the perception about Uniform Standards ("Standards are applied equally across all departments.") The survey of BMETs revealed that only about 20 per cent strongly agree with this statement and approximately 33 per cent agree. Because of the divergent ethical and regulatory policies applied to professional affiliations rather than the medical community at large, adapting regulatory initiatives with the same focus on patient

outcomes (e.g., CMS Conditions of Payment; National Patient Safety Goals; Joint Commission Infection Control 8.10) can elicit the best initiatives to reduce systemic adverse events and conflicting policies.

In this assessment of level of quality based on external regulatory compliance, two of four factors remained in the final model. Regulatory reporting ("All departments have access to hospital acquired infection data") and regulatory application ("Biomedical engineering is able to apply medical equipment regulatory policy") were retained in the model. Despite the significance of these items, the survey data shows that about one-third of the study respondents do not have access to data on hospital-acquired infection (HAI). Although a marked improvement from the pilot study (Fiedler & Agarwal, 2009) where 86.08% of respondents (more diversified in reported years of experience), had no access to HAI tracking data, results from this study suggest that internal HAI reporting should be targeted for required data sharing. Although hospitals will argue that all equipment is treated with care, knowledge of the actual infection rates in a facility may give it the necessary motivation to facilitate interdepartmental interaction that promotes reduction of HAI and other adverse events.

6.2.3 Internal Hospital Administrative Management Policy

Hospital regulatory bodies like The Joint Commission, mandated by the federal government to monitor medical facilities, have not consistently managed to mobilize enforcement measures and adherence to their policy directives that continue to carry the weight of mere suggestions. Healthcare policy makers must consider local, internal mechanisms that optimize resources with more immediate impact. Hospital administrators

can find simple, cost-effective solutions to increase the hospital level of quality through a cursory review of the structural complexity predictors of the level of quality, observed through the factors of clinical effectiveness, efficiency and regulatory compliance. Such solutions include promoting communication and collaboration through inter-professional skills training that may help to resolve the inconsistency of standards across departments. Additional options might include BMET inter-professional training of nurses in order to recognize medical device failure, implementing an interim cleansing and sanitation procedures for medical equipment, and scheduling a BMET for a certain number of hours each week in other departments (e.g., Central Sterile, Infection Control, Facility Maintenance) to determine regulatory conflicts that could be resolved in weekly interdisciplinary meetings.

Items for action can also be identified by reviewing the factors of process adequacy, for example, linking the BMET department goals to Organization Objectives, or budgeting for equipment manuals so that BMETs can have access to critical maintenance and/or repair information conveniently available in a department repository. When BMETs see tangible results from interaction with management, the preceding action can become an example of Coordination Evidence that promotes increased quality. Clinical Engineering managers may also request that BMETs cross-reference their work order repair database with specific manuals that match existing inventoried equipment. An absence of documentation for medical equipment can become a task to determine if a manual exists in proximity to the medical equipment. If so, BMETs can document the location of the manual and/or refer to any master list that may already exist in hospital policy. Alternatively, if a manual cannot be located, this represents an opportunity for BMETs to engage original equipment manufacturers for needed material, information on the availability of alternative 'green'

cleaning products, and perhaps a 'refresher' demonstration on medical equipment operation, repair, or sanitation. These activities generate knowledge, establish communication, and promote interdisciplinary action that leads to increased quality. Local applications of the tools demonstrated here can help to improve long-term patient outcomes by addressing known problems in the environment of care.

6.3 Limitations

Some potential weaknesses of the research design are in the use of cross sectional data collected for one time period which may bring into question cause→effect relationships. However, this limitation may be overcome in future studies enabling longitudinal analysis. In addition, future multi-group analysis that adds nursing and quality personnel to gauge their perceptions of interdependence could also remedy this deficiency. The inherent limitations of perspective studies are applicable.

Other limitations are that the selected study variables may not account for an unknown, perhaps larger causal relationship or an unknown effect on quality from uncontrolled respondent or facility factors. Fennigkoh's (2005) environmental facility design is partially taken into consideration under the structural complexity construct, but does not include a detailed incorporation of the physical environment to the extent of his human factors perspective. The physical environment as a primary factor (air quality, temperature, distance between co-dependent functional units, noise, lighting, patient transport problems due to different floor styles, and varying sizes of corridors and elevators) was not addressed here, though it contributed to a number of sentinel events reported to the Joint Commission.

Another aspect that may be a topical research construct in healthcare but is not explicitly addressed here is the cumulative culture of psychometric patient safety associated with an organization, which may have an unspecified contribution to the level of quality. Flin, Burns, Means, and Robertson (2006) examined the issue in an extensive quantitative literature review which places assessments of quality safety culture in context with patient outcomes. The authors conclude that consideration of this additional specific perspective has been valuable in validating certain experimental studies, but access to hospital administrative and patient records to substantiate quality is severely limited.

In addition to detailed constructs that address a wide variety of contextual features, other problems of information access prompted the use of proxy measures on the Level of Quality endogenous study variable. Specifically, access to organizational administrative data is limited because of the fear that a facility's proprietary processes or financial status may reflect negatively on it. For example, specific financial indicators are often excluded, thereby prohibiting detailed cost-efficiency analysis. Also, reporting of the prevalence of hospital-acquired infections and other sensitive organizational information often has a significant lag time for public release of the information, relegating this quality metric to proxy measures, as well.

One final limitation may not be readily apparent but is noteworthy. Since the emphasis in this study is focused on medical equipment with direct patient contact, the study does not extensively consider medical equipment used in the laboratory, which may indirectly affect HAIs (Corner & Shaw, 1989).

6.4 Recommendations for Future Study

Future study recommendations include administration of the study survey to nursing and quality professionals in order to assess their perspectives on the contribution of clinical engineering, to validate the survey instrument across other populations, and to gather evidence to perform an analysis of variance in unit perception (Appendix F).

Increased understanding of the BMET profession in the environment of care should advance information sharing that quantifies the current study variables. Further, the quantitative approach can lead to strong research designs that apply the notion of experimental BMET integration into high patient contact departments in hospital facilities across the United States. The goal of such research will be to establish empirical evidence to support integration based on the theoretical premise of Organization Performance Theory suggested by Donabedian, by existing healthcare regulations, and by the results of this study.

6.5 Summary

In summary, the environment of care still lacks in the integration of key personnel with the skills to help alleviate iatrogenic conditions. However, constructs relevant to the hospital environment of care from this study has shown how multiple independent variables that should be considered for their interactive effects in a post-hierarchical organizational environment. The examination of the perceptions of biomedical engineering technicians in clinical engineering, using a highly reliable and valid method

of structural equation modeling, has provided reasonable information from which to draw conclusions about the effects of structural complexity and process adequacy in the BMET profession or the hospital environment of care on the prevalence of systemic adverse events and compliance problems. The SEM method, through path analysis and confirmatory factor analysis, statistically defines relationships with the endogenous variable, level of quality that can quantify the interdepartmental effects of the structure, process, and outcomes defined in the original variables.

The study offers two overarching conclusions. First, the findings validate the proposition that biomedical engineering technician integration can satisfy the Joint Commission Infection Control IC.8.10 recommendation to place qualified personnel within the infection control program as well as the Environment of Care EC.4.1 to both collect information and to make an integrated response to patient safety problems as they arise. Second, increasing the role of BMETs to manage systemic problems involving medical equipment, by using statistically indicated processes of increased communication, collaboration, and teamwork among healthcare workers, can achieve effectiveness and efficiency through professional equity by addressing a missing component in previous quality efforts—the interaction among patients, healthcare personnel, and medical equipment.

APPENDIX A: STUDY AUTHORIZATION AND IMPLEMENTATION

The researcher has completed Internal Review Board University of Central Florida Collaborative Institutional Training Initiative (CITI). This study has been evaluated and approved by the University of Central Florida Institutional Review Board under number SBE-10-07285 in accordance with the ethical principles of any experimentation involving live subjects. If you have any questions regarding participant rights in research studies, you may contact the UCF IRB by telephone at (407) 823-2901.

APPENDIX B: INTERNAL REVIEW BOARD LETTER OF APPROVED RESEARCH

University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Approval of Exempt Human Research

From: **UCF Institutional Review Board #1**
FWA00000351, IRB00001138

To: **Beth A. Fiedler**

Date: **December 16, 2010**

Dear Researcher:

On 12/16/2010, the IRB approved the following activity as human participant research that is exempt from regulation:

Type of Review:	IRB Initial Application Form
Project Title:	Effects of Structural Complexity and Process Adequacy in the Hospital Environment of Care on the Prevalence of Systemic Adverse Events and Compliance Issues
Investigator:	Beth A Fiedler
IRB Number:	SBE-10-07285
Funding Agency:	None

This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these changes affect the exempt status of the human research, please contact the IRB. When you have completed your research, please submit a Study Closure request in iRIS so that IRB records will be accurate.

In the conduct of this research, you are responsible to follow the requirements of the Investigator Manual.

On behalf of Joseph Bielitzki, DVM, UCF IRB Chair, this letter is signed by:

Signature applied by Janice Turchin on 12/16/2010 03:09:35 PM EST

Janice M Turchin

IRB Coordinator

University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Approval of Exempt Human Research

From: **UCF Institutional Review Board #1**
FWA00000351, IRB00001138

To: **Beth A. Fiedler**

Date: **January 20, 2011**

Dear Researcher:

On 1/20/2011, the IRB approved the following activity as human participant research that is exempt from regulation:

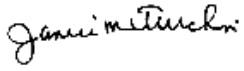
Type of Review:	Addendum/Modification Request Form
Modification Type:	Revised survey submitted
Project Title:	Effects of Structural Complexity and Process Adequacy in the Hospital Environment of Care on the Prevalence of Systemic Adverse Events and Compliance Issues
Investigator:	Beth A Fiedler
IRB Number:	SBE-10-07285
Funding Agency:	None

This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these changes affect the exempt status of the human research, please contact the IRB. When you have completed your research, please submit a Study Closure request in iRIS so that IRB records will be accurate.

In the conduct of this research, you are responsible to follow the requirements of the Investigator Manual.

On behalf of Joseph Bielitzki, DVM, UCF IRB Chair, this letter is signed by:

Signature applied by Janice Turchin on 01/20/2011 04:24:15 PM EST



IRB Coordinator

APPENDIX C: RELIABILITY ANALYSIS

Table C 1. Reliability Item Descriptive Statistics

	Mean	Std. Deviation	N
Inter-professional Training	1.98	.910	317
Appropriate Professional Job Training	2.13	.903	317
Uniform Standards	2.71	1.231	317
Inter-Departmental Work	1.89	.794	317
Coordination Efforts	2.16	.952	317
Coordination Evidence	2.01	.877	317
Device Consistency	2.81	1.196	317
Centrally Located Equipment Access	3.24	1.280	317
Device Failure Recognition	2.17	.863	317
Equipment Purchasing Involvement	2.26	1.122	317
Trust in Clinical Expertise	2.56	.961	317
Professional Equity	1.77	.731	317
Informal Exchange	1.60	.693	317
Formal Department Information	1.90	.787	317
Formal System Knowledge	1.88	.756	317
Manual Sanitation	1.90	.683	317
Internal Sanitation	3.41	1.041	317
Internal Standard	3.49	1.042	-317
Equipment Discussion Ease	1.77	.811	317
Formal Equipment Training	2.07	.871	317
Available Operational Equipment	2.12	.846	317
Equipment Reporting Standards	2.20	.924	317
Between-Patients Sanitation Training	2.92	1.030	317
Regularly Scheduled Meetings	3.14	1.245	317
Acquisition Integration	2.40	1.175	317
Management Integration	2.63	1.127	317
Department Measures Tied to Organizational Goals	2.04	.872	317
Job Reporting Satisfaction	2.42	.999	317
Device Failure Tracking System	1.37	.538	317
Medical Device Inventory	1.28	.522	317
Implement Cost Assessment	2.05	1.043	317
Implemented Productivity Assessment	2.23	1.004	317
Regulatory Comprehension	1.62	.607	317
Regulatory Application	1.74	.670	317
Regulatory Reporting	2.21	.999	317

Table C 2 Reliability Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
1 Inter-Professional Training	76.11	280.417	.573	.557	.920
2 Appropriate Professional Job Training	75.97	280.749	.566	.525	.920
3 Uniform Standards	75.38	274.357	.560	.486	.920
4 Inter-Departmental Work	76.21	281.398	.626	.582	.920
5 Coordination Efforts	75.94	277.699	.634	.623	.919
6 Coordination Evidence	76.09	278.774	.654	.628	.919
7 Device Consistency	75.28	280.038	.431	.292	.922
8 Centrally Located Equipment Access	74.85	283.700	.310	.214	.924
9 Device Failure Recognition	75.92	280.984	.587	.449	.920
10 Equipment Purchasing Involvement	75.83	275.819	.580	.609	.920
11 Trust in Clinical Expertise	75.53	281.997	.489	.441	.921
12 Professional Equity	76.33	286.227	.483	.450	.921
13 Informal Exchange	76.49	287.580	.453	.435	.922
14 Formal Department Information	76.19	282.960	.571	.555	.920
15 Formal System Knowledge	76.21	284.066	.552	.528	.921
16 Manual Sanitation	76.20	291.033	.309	.226	.923
17 Internal Sanitation	74.68	287.046	.300	.748	.924
18 Internal Standard	74.61	289.302	.235	.755	.925
19 Equipment Discussion Ease	76.32	279.637	.679	.546	.919
20 Formal Equipment Training	76.03	279.604	.630	.515	.920
21 Available Operational Equipment	75.97	284.952	.456	.356	.922
22 Equipment Reporting Standards	75.90	283.863	.449	.364	.922
23 Between-Patients Sanitation Training	75.17	285.929	.336	.269	.923

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
24 Regularly Scheduled Meetings	74.96	273.371	.578	.473	.920
25 Acquisition Integration	75.69	272.922	.629	.654	.919
26 Management Integration	75.46	277.528	.530	.454	.921
27 Department Measures Tied to Organizational Goals	76.05	279.304	.639	.565	.920
28 Job Reporting Satisfaction	75.67	275.924	.656	.517	.919
29 Device Failure Tracking System	76.73	290.382	.438	.533	.922
30 Medical Device Inventory	76.81	292.291	.344	.478	.923
31 Implement Cost Assessment	76.04	282.552	.429	.499	.922
32 Implemented Productivity Assessment	75.86	287.297	.305	.410	.924
33 Regulatory Comprehension	76.47	288.535	.476	.635	.922
34 Regulatory Application	76.36	286.282	.528	.663	.921
35 Regulatory Reporting	75.89	283.573	.420	.272	.922

APPENDIX D: ASSUMPTION TESTS

Table D 1 Descriptive Statistics N=395 Original, All Construct and Subscales, Valid N=317

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
Structural Complexity								
Organizational Culture								
1 Inter-professional Training	352	4	1	5	2.02	.049	.923	.851
2 Appropriate Professional Job Training	352	4	1	5	2.16	.048	.905	.820
3 Uniform Standards	352	4	1	5	2.71	.064	1.203	1.447
Level of Coordination								
4 Inter-Departmental Work	342	4	1	5	1.93	.044	.822	.675
5 Coordination Efforts	342	4	1	5	2.17	.051	.943	.890
6 Coordination 6 Evidence	342	4	1	5	2.02	.048	.883	.780
Medical Equipment Complexity								
7 Knowledge Limits	331	4	1	5	2.13	.052	.944	.891
8 Excessive Options	331	4	1	5	2.59	.048	.881	.776
9 Expert Knowledge Requirements	331	4	1	5	3.40	.053	.971	.943
Interdepartmental Medical Device Management								
10 Device Consistency	329	4	1	5	2.84	.066	1.201	1.442
11 Centrally Located Equipment Access	329	4	1	5	3.25	.070	1.275	1.627
12 Device Failure Recognition	329	4	1	5	2.18	.048	.864	.747
Process Adequacy								
Interdepartmental Collaboration								
13 Equipment Purchasing Involvement	327	4	1	5	2.28	.062	1.115	1.243
14 Trust in Clinical Expertise	327	4	1	5	2.57	.053	.959	.920
15 Professional Equity	327	4	1	5	1.77	.040	.730	.533
Knowledge Management								
16 Informal Exchange	325	4	1	5	1.62	.039	.705	.497
17 Formal Department Information	325	4	1	5	1.90	.043	.779	.608
18 Formal System Knowledge	325	4	1	5	1.89	.041	.747	.558

	N	Range	Minimum	Maximum	Mean	Std. Deviation	Variance	N
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
				Complexity of Sanitation Methods				
19 Manual Sanitation	321	4	1	5	1.90	.039	.694	.481
20 Internal Sanitation	321	4	1	5	3.40	.058	1.039	1.079
21 Internal Standard	321	4	1	5	3.49	.058	1.037	1.076
				Interdepartmental Communication				
22 Equipment Discussion Ease	322	4	1	5	1.79	.046	.823	.678
23 Formal Equipment Training	322	4	1	5	2.08	.049	.884	.781
24 Available Operational Equipment	322	4	1	5	2.13	.048	.852	.727
				Interdepartmental Teamwork				
25 Equipment Reporting Standards	321	4	1	5	2.21	.052	.930	.866
26 Between-Patients Sanitation Training	321	4	1	5	2.93	.058	1.033	1.067
27 Regularly Scheduled Meetings	320	4	1	5	3.14	.070	1.247	1.555
				Level of Quality				
				Clinical Engineering Effectiveness				
28 Acquisition Integration	319	4	1	5	2.41	.066	1.178	1.387
29 Management Integration	319	4	1	5	2.64	.063	1.126	1.269
30 Department Measures Tied to Organizational Goals	319	4	1	5	2.04	.049	.873	.762
31 Job Reporting Satisfaction	319	4	1	5	2.43	.056	1.000	1.000
				Clinical Engineering Efficiency				
32 Device Failure Tracking System	319	3	1	4	1.37	.030	.538	.290
33 Medical Device Inventory	319	3	1	4	1.28	.029	.522	.272
34 Implement Cost Assessment	319	4	1	5	2.06	.059	1.048	1.097
35 Implemented Productivity Assessment	319	4	1	5	2.24	.056	1.008	1.017

	N	Range	Minimum	Maximum	Mean	Std. Deviation	Variance	N
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
				Regulatory Compliance				
36 Regulatory Comprehension	317	3	1	4	1.62	.034	.607	.368
37 Regulatory Application	317	4	1	5	1.74	.038	.670	.449
38 Competing Regulatory Application	317	4	1	5	2.81	.057	1.018	1.036
39 Regulatory Reporting	317	4	1	5	2.21	.056	.999	.999
Valid N (listwise)	317							

Table D 2 Additional Initial Descriptive Statistics N=395 Original, All Construct and Subscales, Valid N=317

	N	Skewness		Kurtosis	
	Statistic	Statistic	Std. Error	Statistic	Std. Error
Structural Complexity					
Organizational Culture					
Inter-professional Training	352	1.098	.130	1.333	.259
Appropriate Professional Job Training	352	.763	.130	.249	.259
Uniform Standards	352	.212	.130	-1.068	.259
Level of Coordination					
Inter-Departmental Work	342	1.055	.132	1.402	.263
Coordination Efforts	342	.779	.132	.253	.263
Coordination Evidence	342	.752	.132	.258	.263
Medical Equipment Complexity					
Knowledge Limits	331	.862	.134	.228	.267
Excessive Options	331	.262	.134	-.222	.267
Expert Knowledge Requirements	331	-.403	.134	-.522	.267
Interdepartmental Medical Device Management					
Device Consistency	329	.068	.134	-1.266	.268
Centrally Located Equipment Access	329	-.192	.134	-1.221	.268
Device Failure Recognition	329	.978	.134	1.092	.268
Process Adequacy					
Interdepartmental Collaboration					
Equipment Purchasing Involvement	327	.883	.135	.028	.269
Trust in Clinical Expertise	327	.612	.135	-.170	.269
Professional Equity	327	.908	.135	1.329	.269
Knowledge Management					
Informal Exchange	325	1.394	.135	3.407	.270
Formal Department Information	325	1.000	.135	1.849	.270
Formal System Knowledge	325	.903	.135	1.436	.270
Complexity of Sanitation Methods					
Manual Sanitation	321	.866	.136	1.974	.271
Internal Sanitation	321	-.148	.136	-.920	.271
Internal Standard	321	-.318	.136	-.581	.271

	N	Skewness		Kurtosis	
	Statistic	Statistic	Std. Error	Statistic	Std. Error
Interdepartmental Communication					
Equipment Discussion Ease	322	1.285	.136	2.319	.271
Formal Equipment Training	322	1.061	.136	1.383	.271
Available Operational Equipment	322	.925	.136	1.061	.271
Interdepartmental Teamwork					
Equipment Reporting Standards	321	.885	.136	.663	.271
Between-Patients Sanitation Training	321	.195	.136	-.733	.271
Regularly Scheduled Meetings	320	-.067	.136	-1.204	.272
Level of Quality					
Clinical Engineering Effectiveness					
Acquisition Integration	319	.611	.137	-.529	.272
Management Integration	319	.359	.137	-.714	.272
Department Measures Tied to Organizational Goals	319	1.033	.137	1.211	.272
Job Reporting Satisfaction	319	.622	.137	.110	.272
Clinical Engineering Efficiency					
Device Failure Tracking System	319	1.339	.137	2.251	.272
Medical Device Inventory	319	1.949	.137	4.481	.272
Implement Cost Assessment	319	.828	.137	-.156	.272
Implemented Productivity Assessment	319	.570	.137	-.428	.272
Regulatory Compliance					
Regulatory Comprehension	317	.581	.137	.341	.273
Regulatory Application	317	.748	.137	1.356	.273
Competing Regulatory Application	317	.266	.137	-.546	.273
Regulatory Reporting	317	.536	.137	-.266	.273
Valid N (listwise)	317				

Table D 3 Spearman Rho Correlation Matrix Structural Complexity, N=317

	Inter-Professional Training	Appropriate Professional Job Training	Uniform Standards	Inter-Departmental Work	Coordination Evidence	Device Failure Recognition
.						
1 Appropriate Professional Job Training	.554**	1.000				
2 Uniform Standards	.522**	.496**	1.000			
3 Inter-Departmental Work	.440**	.448**	.375**	1.000		
4 Coordination Evidence	.474**	.416**	.403**	.495**	1.000	
5 Device Failure Recognition	.345**	.429**	.380**	.398**	.421**	1.000

**. Correlation is significant at the 0.01 level (2-tailed).

Abbreviation Notes: Correlation Coefficient (CC); Significant, 2-tailed, (Sig.).

Table D 4. Spearman Rho Correlation Matrix Process Adequacy, N=317

	Equipment Purchasing Involvement	Formal Department Information	Formal Equipment Training	Available Operational Equipment	Regularly Scheduled Meetings
1 Equipment Purchasing Involvement	1.000 .				
2 Formal Department Information	.364**	1.000			
3 Formal Equipment Training	.361**	.461**	1.000		
4 Available Operational Equipment	.153**	.336**	.369**	1.000	
5 Regularly Scheduled Meetings	.344**	.281**	.432**	.215**	1.000

**. Correlation is significant at the 0.01 level (2-tailed).

Abbreviation Notes: Correlation Coefficient (CC); Significant, 2-tailed, (Sig.).

Table D 5 Spearman Rho Correlation Matrix Level of Quality, N=317

	Acquisition Integration	Department Measures Tied to Organizational Goals	Job Reporting Satisfaction	Implement Cost Assessment	Regulatory Application	Regulatory Reporting
Acquisition Integration	1.000					
Department Measures Tied to Organizational Goals	.447**	1.000				
Job Reporting Satisfaction	.462**	.523**	1.000			
Implement Cost Assessment	.364**	.403**	.302**	1.000		
Regulatory Application	.304**	.447**	.357**	.458**	1.000	
Regulatory Reporting	.299**	.238**	.304**	.208**	.260**	1.000

**. Correlation is significant at the 0.01 level (2-tailed).

Abbreviation Notes: Correlation Coefficient (CC); Significant, 2-tailed, (Sig.).

Table D 6 Spearman Correlation Coefficient Table of Control Variables

		1	2	3	4	5	6	7	8	9	10
1 Profession	CC	1.000									
2 Years of Experience	CC	.016	1.000								
3 Education Level	CC	**.116**	**.003**	1.000							
4 State	CC	**.085**	.063	**.112***	1.000						
5 The Joint Commission accredited	CC	**.022**	**.118***	.015	**.135***	1.000					
6 Number of Operational Beds	CC	.023	.049	**.134***	**.078**	**.217****	1.000				
7 Facility Type	CC	.016	.034	.069	**.053**	**.049**	**.222****	1.000			
8 Location Type	CC	.038	**.022**	**.172****	**.074**	**.106**	**.344****	**.042**	1.000		
9 Size	CC	.024	.054	**.133***	**.083**	**.130***	.620**	.163**	**.292****	1.000	
10 Region	CC	.085	.022	**.090**	**.190****	**.132***	.021	**.012**	.045	.008	1.000

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

Abbreviation Notes: Correlation Coefficient (CC); Significant, 2-tailed, (Sig.); Bold facing indicates negative correlations. Notes[1-10]: [1]Biomedical Engineering Technician (future study options include Nurse and Quality personnel. [2] 0-2 Years, 3-4 years, 5+ years. [3] High School/GED; Associate of Arts, Associate of Science; Bachelor of Arts, Bachelor of Science; Graduate (Master or Doctorate). [4]United States and Washington, DC. [5]Joint Commission affiliated accreditation. [6]Actual number of beds (not part of stored equipment or pending expansion). [7]Public, Private, Non-Profit, University affiliated facility. [8]Rural or Urban general location. [9]Bed Size Small 0-25; Medium 26-150; and Large>150. [10]Northeast (Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and Washington, DC.); Midwest (Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin), Southern (Alabama, Arkansas, Kentucky, Louisiana, Mississippi, Oklahoma, Tennessee, and Texas), Southeast (Florida, Georgia, North Carolina, South Carolina, Virginia, and West Virginia), and Western (Alaska, Idaho, Montana, Oregon, Washington, Wyoming, Arizona, California, Colorado, Hawaii, Nevada, New Mexico, and Utah).

APPENDIX E: REGRESSION ANALYSIS

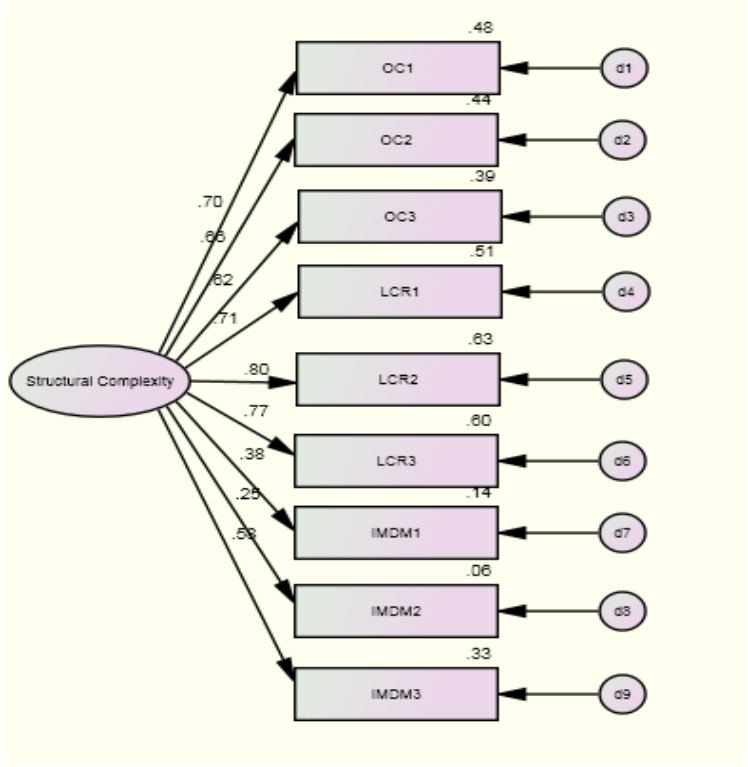


Figure E 1. Generic Initial Measurement Model of Structural Complexity

Table E 1 Generic Measurement Model of Structural Complexity

Predictors	URW Estimate	SRW Generic	Standard Error	Critical Ratio	P
Inter-Professional Training ← Structural Complexity	1.000	.695			
Appropriate Professional Job Training ← Structural Complexity	.948	.664	.088	10.717	***
Uniform Standards ← Structural Complexity	1.208	.621	.120	10.061	***
Structural Complexity					
Inter-Departmental Work ← Structural Complexity	.897	.715	.078	11.464	***
Coordination Efforts ← Structural Complexity	1.196	.795	.095	12.590	***
Coordination Evidence ← Structural Complexity	1.073	.774	.087	12.304	***
Device Consistency ← Structural Complexity	.715	.378	.115	6.244	***
Centrally Located Device Failure ← Structural Complexity	.515	.255	.122	4.228	***
Device Failure Recognition ← Structural Complexity	.787	.577	0.08	9.382	***

***.001 (2-tailed) significance level

Abbreviation Notes: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

Table E 1A Squared Multiple Correlations of the Generic Measurement Model of Structural Complexity

Predictor	R^2
Device Failure Recognition	.332
Centrally Located Equipment Access	.065
Device Consistency	.143
Coordination Evidence	.599
Coordination Efforts	.632
Inter-Departmental Work	.511
Uniform Standards	.385
Appropriate Professional Job Training	.441
Inter-Professional Training	.483

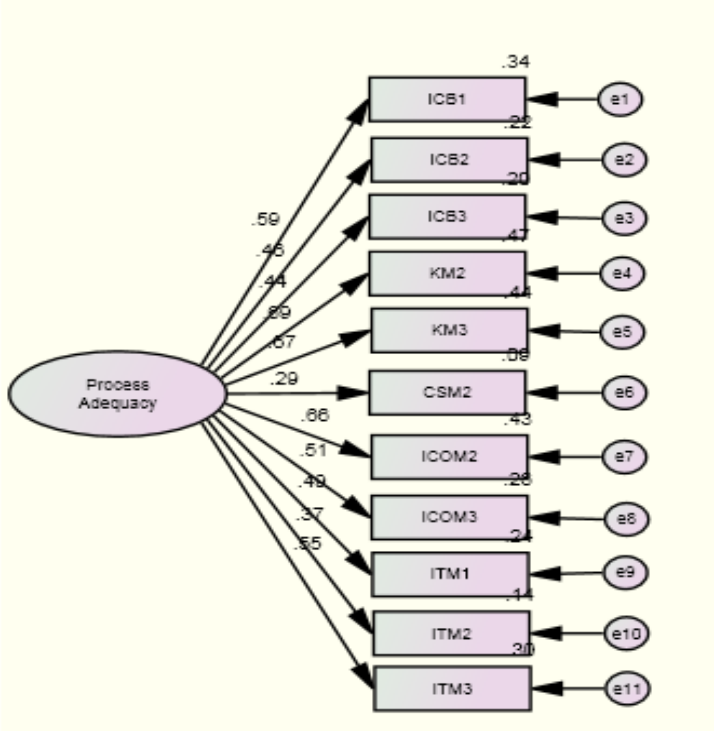


Figure E 2 Generic Measurement Model of Process Adequacy

Table E 2 Generic Measurement Model of Process Adequacy

Predictors	URW Estimate	SRW Generic	Standard Error	Critical Ratio	P value
Equipment Purchasing Involvement←Process Adequacy	1.000	.586			
Expertise Trust←Process Adequacy	.679	.465	.100	6.778	***
Professional Equity←Process Adequacy	.493	.443	.076	6.522	***
Formal Department Information←Process Adequacy	.824	.689	.091	9.027	***
Formal System Knowledge←Process Adequacy	.767	.667	.087	8.845	***
Internal Sanitation←Process Adequacy	.462	.292	.102	4.524	***
Formal Equipment Training←Process Adequacy	.872	.659	.099	8.774	***
Available Operational Equipment←Process Adequacy	.657	.511	.090	7.306	***
Equipment Reporting Standards←Process Adequacy	.687	.489	.097	7.056	***
Between-Patients Sanitation Training←Process Adequacy	.582	.372	.104	5.614	***
Regular Meetings←Process Adequacy	1.043	.551	.135	7.737	***

***.001 (2-tailed) significance level

Abbreviation Notes: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

Table E 2A Squared Multiple Correlations of the Generic Measurement Model of Process Adequacy

Predictor	R^2
Regular Meetings	.303
Between-Patients Sanitation Training	.138
Equipment Reporting Standards	.239
Available Operational Equipment	.261
Formal Equipment Training	.434
Internal Sanitation	.085
Formal System Knowledge	.445
Formal Department Information	.474
Professional Equity	.197
Expertise Trust	.216
Equipment Purchasing Involvement	.344

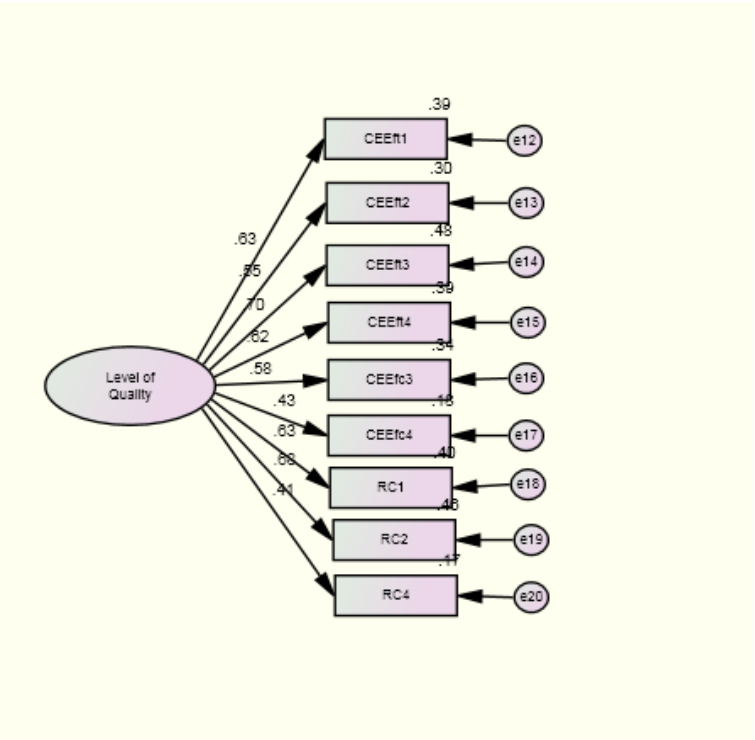


Figure E 3 Generic Measurement Model of Level of Quality

Table E 3 Generic Measurement Model of Level of Quality

Predictors	URW Estimate	SRW Generic	Standard Error	Critical Ratio	P
Acquisition Integration ← Level of Quality	1.000	.627			
Management Integration ← Level of Quality	.836	.547	.103	8.081	***
Department Contribution to Organization Objectives ← Level of Quality	.824	.696	.085	9.735	***
Job Reporting Satisfaction ← Level of Quality	.841	.621	.094	8.940	***
Implemented Cost Assessment ← Level of Quality	.827	.584	.097	8.523	***
Productivity Assessment ← Level of Quality	.581	.426	.089	6.529	***
Regulatory Comprehension ← Level of Quality	.519	.630	.057	9.043	***
Regulatory Application ← Level of Quality	.619	.681	.065	9.583	***
Regulatory Reporting ← Level of Quality	.557	.411	.088	6.319	***

***.001 (2-tailed) significance level

Abbreviation Notes: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

Table E 3A Squared Multiple Correlations of the Generic Measurement Model of Level of Quality

Predictor	R^2
Regulatory Reporting	.169
Regulatory Application	.464
Regulatory Comprehension	.397
Productivity Assessment	.182
Implemented Cost Assessment	.341
Job Reporting Satisfaction	.385
Department Contribution to Organization Objectives	.485
Management Integration	.299
Acquisition Integration	.394

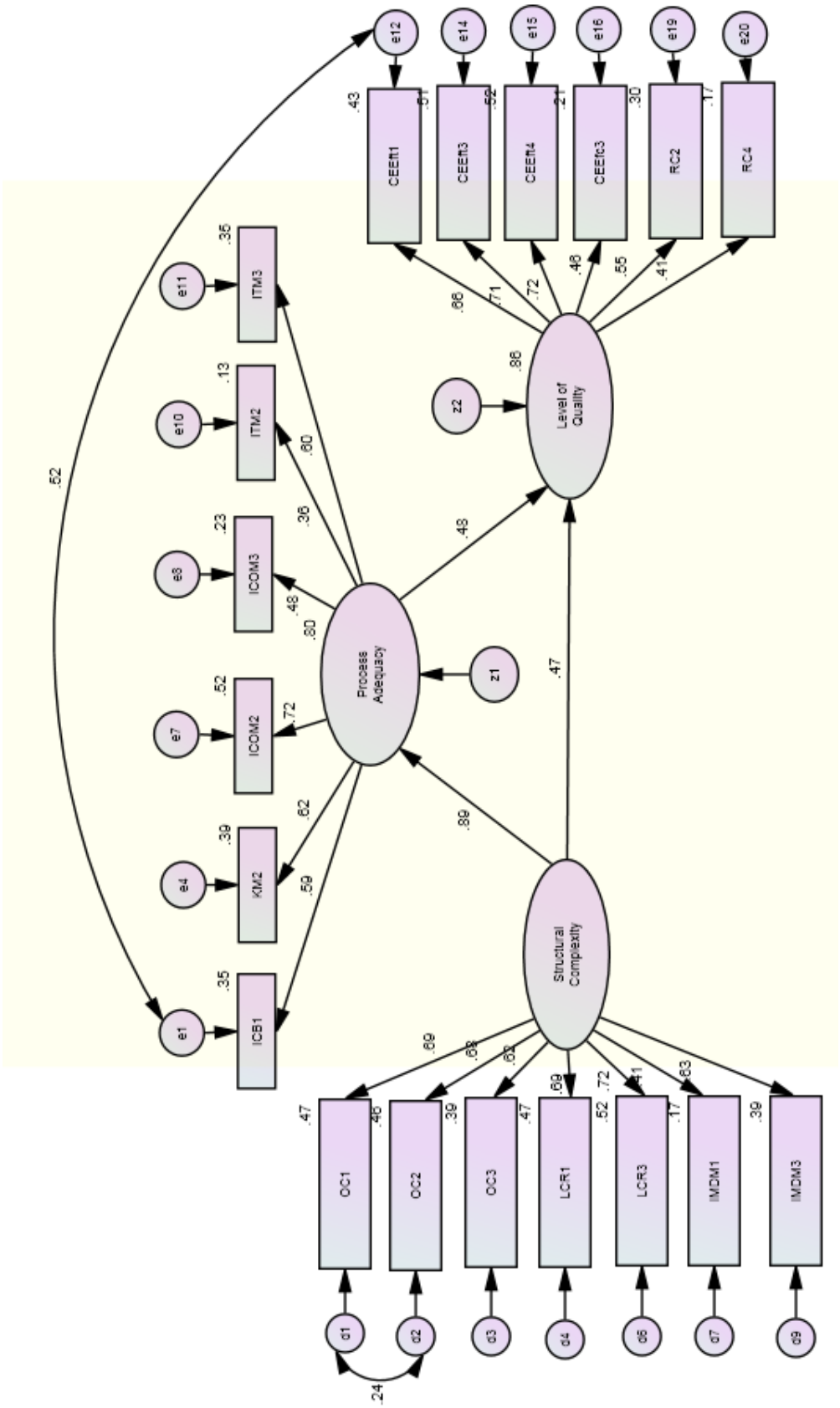


Figure E 4 Initial Congeneric Structural Equation Model for the BEI Survey

Table E 4 Initial Structural Equation Model of the BEI Survey Without Control Variables

Predictors	URW Estimate	SRW Generic	Standard Error	Critical Ratio	P
Process Adequacy ← Structural Complexity	.940	0.892	.106	8.887	***
Level of Quality ← Process Adequacy	.561	0.493	.187	2.993	.003
Level of Quality ← Structural Complexity	.579	.473	.196	2.955	.003
Level of Quality					
Acquisition Integration ← Level of Quality	1.000	.659			
Department Contribution to Organization Objectives ← Level of Quality	.808	.711	.075	10.789	***
Job Reporting Satisfaction ← Level of Quality	.937	.720	.086	10.904	***
Implemented Cost Assessment ← Level of Quality	.625	.460	.085	7.357	***
Regulatory Application ← Level of Quality	.478	.548	.055	8.626	***
Regulatory Reporting ← Level of Quality	.535	.411	.081	6.622	***
Structural Complexity					
Inter-Professional Training ← Structural Complexity	1.000	.689			
Appropriate Professional Job Training ← Structural Complexity	.974	.677	.078	12.463	***
Uniform Standards ← Structural Complexity	1.221	.622	.122	10.010	***
Interdepartmental Work ← Structural Complexity	.872	.689	.079	10.985	***
Coordination Evidence ← Structural Complexity	1.006	.720	.088	11.421	***
Device Failure Recognition ← Structural Complexity	.775	.406	.116	6.683	***
Inter-Professional Training ← Structural Complexity	.862	.626	.086	10.072	***
Process Adequacy					
Equipment Purchasing Involvement ← Process Adequacy	1.000	.592			
Formal Department Information ← Process Adequacy	.740	.622	.084	8.775	***
Formal Equipment Training ← Process Adequacy	.947	.719	.098	9.696	***
Available Operational Equipment ← Process Adequacy	.618	.483	.086	7.216	***
Regular Meetings ← Process Adequacy	.565	.363	.100	5.650	***
Equipment Purchasing Involvement ←Process Adequacy	1.121	.595	.132	8.503	***
Formal Department Information ← Process Adequacy					

***<.001 (2-tailed) significance

Abbreviation Notes: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

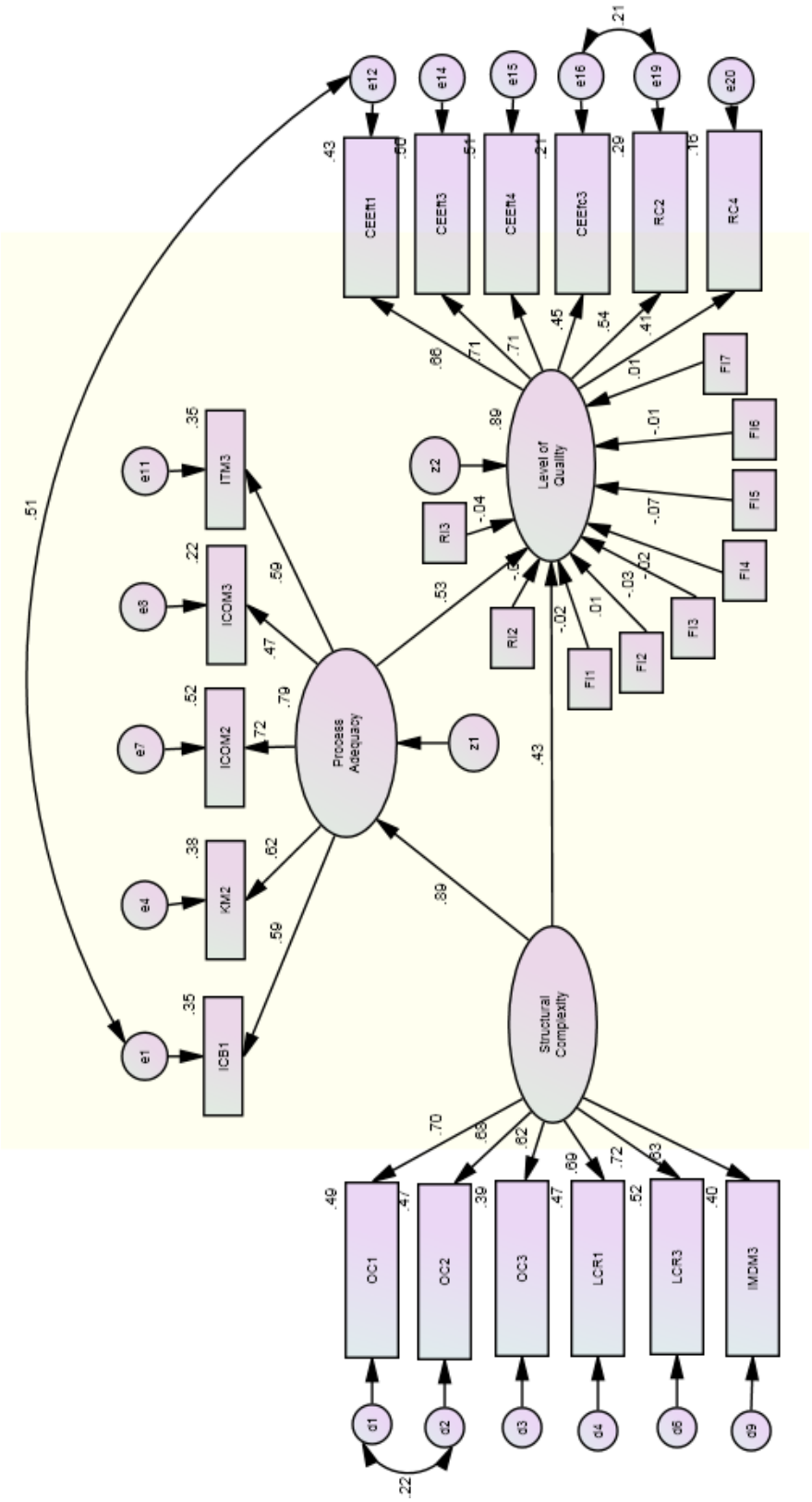


Figure E 5 Revised Structural Equation Model for the BEI Survey with Control Variables

Table E 5 Structural Equation Model for BEI Survey with Control Variables

Predictors	URW Estimate	SRW Revised With Controls	Standard Error	Critical Ratio	P
Process Adequacy ← Structural Complexity	.918	.889	.104	8.865	***
Level of Quality ← Process Adequacy	.620	.534	.188	3.303	***
Level of Quality ← Structural Complexity	.516	.430	.189	2.722	.006
Control Variables					
Level of Quality ← Highest Level of Education	-.035	-.036	.037	-.936	.349
Level of Quality ← Years of Experience	-.175	-.048	.139	-1.261	.207
Level of Quality ← State	-.001	-.023	.002	-.598	.550
Level of Quality ← Joint Commission Accreditation	.009	.006	.050	.170	.865
Level of Quality ← Facility Type	-.014	-.015	.036	-.397	.692
Level of Quality ← General Facility Location	-.121	-.074	.063	-1.921	.055
Level of Quality ← Size	-.026	-.015	.069	-.379	.705
Level of Quality ← Region	.006	.010	.022	.262	.793
Level of Quality ← Number of Operational Beds	.000	-.031	.000	-.818	.413
Level of Quality					
Acquisition Integration ← Level of Quality	1.000	.656			
Department Contribution to Organization Objectives ← Level of Quality	.808	.708	.075	10.716	***
Job Reporting Satisfaction ← Level of Quality	.932	.713	.086	10.778	***
Implemented Cost Assessment ← Level of Quality	.622	.455	.086	7.250	***
Regulatory Application ← Level of Quality	.474	.540	.056	8.487	***
Regulatory Reporting ← Level of Quality	.531	.405	.081	6.527	***
Structural Complexity					
Inter-Professional Training ← Structural Complexity	1.000	.699			
Appropriate Professional Job Training ← Structural Complexity	.970	.684	.077	12.575	***
Uniform Standards ← Structural Complexity	1.208	.624	.119	10.126	***
Interdepartmental Work ← Structural Complexity	.859	.689	.077	11.091	***
Coordination Evidence ← Structural Complexity	.997	.723	.086	11.600	***
Device Failure Recognition ← Structural Complexity	.853	.629	.084	10.188	***
Process Adequacy					
Equipment Purchasing Involvement ←Process Adequacy	1.000	.589			
Formal Department Information ← Process	.743	.620	.085	8.698	***

Predictors	URW Estimate	SRW Revised With Controls	Standard Error	Critical Ratio	P
Adequacy					
Formal Equipment Training ← Process Adequacy	.954	.721	.099	9.627	***
Available Operational Equipment ← Process Adequacy	.606	.471	.086	7.032	***
Regular Meetings ← Process Adequacy	1.113	.588	.133	8.363	***

***<.001 (2-tailed) significance

Abbreviation Notes: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

APPENDIX E 1: DETAILED REGRESSION ANALYSIS

Table E 1.1 Structural Equation Model for BEI Survey Without Controls, Structural Complexity Predictors of Process Adequacy, Lambda Factor Loading Applied to First Factor of Each Latent Construct

Predictors	URW Estimate	SRW Revised	SRW Generic	Standard Error	t	P
Process Adequacy ← Structural Complexity	.923	.889	.892	.103	8.929	***
Structural Complexity (Eta 1)						
Inter-Professional Training[1]	1.000	.701	.701	.689		
Appropriate Professional Job Training[2]	.969	.685	.685	.677	12.594	***
Uniform Standards[3]	1.208	.627	.627	.622	10.177	***
Inter-Departmental Work[4]	.854	.687	.687	.689	11.091	***
Coordination Evidence[5]	.992	.723	.723	.720	11.612	***
Device Failure Recognition[6]	.847	.627	.627	.626	10.180	***
Process Adequacy (Eta 2)						
Equipment Purchasing Involvement[7]	1.000	.593	.593	.592		
Formal Department Information[8]	.734	.618	.618	.622	8.719	***
Formal Equipment Training[9]	.944	.719	.719	.719	9.672	***
Available Operational Equipment[10]	.599	.469	.469	.483	7.036	***
Regular Meetings[11]	1.108	.590	.590	.595	8.430	***

***<0.001 (2-tailed) significance level

Abbreviation Notes: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight. Note on Scale[1-11]: 1) The organization values contributions to other staff members' professional development, 2) I have been provided clear training to perform my job function, 3) Standards are applied equally across all departments, 4) I received and/or provide inter-departmental input in order to successfully complete work, 5) Inter-departmental coordination has resulted in visible positive benefits, 6) I receive and/or provide training to recognize medical device failure, 7) I receive and/or provide advice on new equipment purchases, 8) I have access to formal knowledge within the department, 9) I receive and/or provide training on the proper way to operate equipment, 10) I received and/or provide clean, operational equipment in a timely fashion, and 11) Nursing and biomedical engineering conduct regularly scheduled meetings on equipment issues.

A detailed review of the findings of the predictor variable of Structural Complexity in relation to Process Adequacy is demonstrated in Table E 1.1. (Note, the first factors in each category were allowed to regress at lambda=1 and hence, do not report probability or estimated t values.) First, the unstandardized regression weights for

each exogenous factor X_1 to X_6 of Structural Complexity in the prediction of Process Adequacy is statistically significant at $t>1.96$, $p<0.001$. The individual factor with the greatest impact within Structural Complexity is Uniform Standards where one standard deviation increase will increase Process Adequacy by 1.208. Second, the unstandardized regression weights for each endogenous factor Y_1 to Y_5 of Eta 2 is statistically significant at $t>1.96$, $p<0.001$. Structural Complexity accounts for 79% of the variance in the endogenous variable (R^2=79%).

Table E 1.2 Structural Equation Model for BEI Survey Without Controls, Process Adequacy (Eta 2) Predictors of Level of Quality (Eta 3), Lambda Factor Loading Applied to First Factor of Each Latent Construct

Predictors	URW Estimate	SRW Revised	SRW Generic	Standard Error	t	P	R^2
Level of Quality ← Process Adequacy	.654	.563	.493	.191	3.426	***	.312
Level of Quality (Eta 3)							
Acquisition Integration[1]	1.000	.660	.659				
Department Contribution to Organization Objectives[2]	.802	.709	.711	.075	10.751	***	
Job Reporting Satisfaction[3]	.935	.722	.720	.086	10.908	***	
Implemented Cost Assessment[4]	.598	.441	.460	.085	7.052	***	
Regulatory Application[5]	.462	.531	.548	.055	8.371	***	
Regulatory Reporting[6]	.526	.406	.411	.081	6.532	***	
Process Adequacy (Eta 2)							
Equipment Purchasing Involvement[7]	1.000	.593	.592				
Formal Department Information[8]	.734	.618	.622	.084	8.719	***	
Formal Equipment Training[9]	.944	.719	.719	.098	9.672	***	
Available Operationa1 Equipment[10]	.599	.469	.483	.085	7.036	***	
Regular Meetings[11]	1.108	.590	.595	.131	8.430	***	

***<0.001 (2-tailed) significance level

Abbreviation Notes: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

Note on Scale[1-11] : 1) Biomedical engineers are integrated in the medical equipment purchasing process, 2) Biomedical engineers set and achieved department goals based on organizational objectives, 3) Biomedical engineers are satisfied with reporting authorities, 4) Biomedical engineering measures cost using generally accepted metrics, 5) Biomedical engineering is able to apply medical equipment regulatory policy, 6) All departments have access to hospital acquired infection data, 7) I receive and/or provide advice on new equipment purchases, 8) I have access to formal knowledge within the department, 9) I receive and/or provide training on the proper way to operate equipment, 10) I received and/or provide clean, operational equipment in a timely fashion, and 11) Nursing and biomedical engineering conduct regularly scheduled meetings on equipment issues.

Table E 1.2 provides the findings of the predictor variable of Process Adequacy in relation to the Level of Quality. First, the unstandardized regression weights for each exogenous factor Y_1 to Y_5 of Process Adequacy in the prediction of Level of Quality is statistically significant at $t>1.96$, $p<0.001$ (2-tailed). The individual factor with the greatest impact within the exogenous variable is Regular Meetings where one standard

deviation increase will increase Level of Quality by 1.108. Second, the unstandardized regression weights for each endogenous factors of Eta 3 (Y_6 to Y_{11}) is statistically significant at $t>1.96$, $p<0.001$ (2-tailed). Process Adequacy accounts for 31.2% of the variance in the endogenous variable (R^2=31.2%).

Table E 1.3 Structural Equation Model for BEI Survey Without Controls, Structural Complexity Predictors (Eta 1) of Level of Quality (Eta 3), Lambda Factor Loading Applied to First Factor of Each Latent Construct

Predictors	URW Estimate	SRW Revised	SRW Generic	Standard Error	t	P
Level of Quality ← Structural Complexity	.485	.402	.473	.192	2.523	.012
Level of Quality (Eta 3)						
Acquisition Integration[1]	1.000	.660	.659			
Department Contribution to Organization Objectives[2]	.802	.709	.711	.075	10.751	***
Job Reporting Satisfaction[3]	.935	.722	.720	.086	10.908	***
Implemented Cost Assessment[4]	.598	.441	.460	.085	7.052	***
Regulatory Application[5]	.462	.531	.548	.055	8.371	***
Regulatory Reporting[6]	.526	.406	.411	.081	6.532	***
Structural Complexity (Eta 1)						
Inter-Professional Training[7]	1.000	.701	.689			
Appropriate Professional Job Training[8]	.969	.685	.677	.077	12.594	***
Uniform Standards[9]	1.208	.627	.622	.119	10.177	***
Inter-Departmental Work[10]	.854	.687	.689	.077	11.091	***
Coordination Evidence[11]	.992	.723	.720	.085	11.612	***
Device Failure Recognition[12]	.847	.627	.626	.083	10.180	***

***<0.001 (2-tailed) significance level

Note: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

Note on Scale[1-13]: 1) Biomedical engineers are integrated in the medical equipment purchasing process, 2) Biomedical engineers set and achieved department goals based on organizational objectives, 3) Biomedical engineers are satisfied with reporting authorities, 4) Biomedical engineering measures cost using generally accepted metrics, 5) Biomedical engineering is able to apply medical equipment regulatory policy, 6) All departments have access to hospital acquired infection data, 7) The organization values contributions to other staff members' professional development, 8) I have been provided clear training to perform my job function, 9) Standards are applied equally across all departments, 10) I received and/or provide inter-departmental input in order to successfully complete work, 12) Inter-departmental coordination has resulted in visible positive benefits, 13) I receive and/or provide training to recognize medical device failure.

The relationship of the predictor variables of Structural Complexity in relation to the Level of Quality are found in Table E 1.3. First, the unstandardized regression weights for each exogenous factors X_1 to X_6 of Structural Complexity in the prediction of Level of Quality is statistically significant at $t>1.96$, $p<0.001$ (2-tailed). The individual factor with the greatest impact within the exogenous variable is Regular Meetings where one standard deviation increase will increase Level of Quality by 1.108. Second, the

unstandardized regression weights for each endogenous factors of Eta 3 (Y_6 to Y_{11}) is statistically significant at $t>1.96$, $p<0.001$ (2-tailed). Structural Complexity accounts for 16.2% of the variance in the endogenous variable (R^2=16.2%).

Table E 1.4 Structural Equation Model for BEI Survey Without Controls, Process Adequacy (Eta2), Lambda Factor Loading Applied to First Factor of Each Latent Construct

Predictors	URW Estimate	SRW Revised	SRW Generic	Standard Error	t	P
Equipment Purchasing Involvement[1]	1.000	.593	.592			
Formal Department Information[2]	.734	.618	.622	.084	8.719	***
Formal Equipment Training[3]	.944	.719	.719	.098	9.672	***
Available Operation Equipment[4]	.599	.469	.483	.085	7.036	***
Equipment Regular Meetings[5]	1.108	.590	.595	.131	8.430	***

***<0.001 (2-tailed) significance level

Abbreviation Notes: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

Notes on scale[1-5]: 1) I receive and/or provide advice on new equipment purchases, 2) I have access to formal knowledge within the department, 3) I receive and/or provide training on the proper way to operate equipment, 4) I received and/or provide clean, operational equipment in a timely fashion, and 5) Nursing and biomedical engineering conduct regularly scheduled meetings on equipment issues.

A detailed review of the findings of the intervening variable of Process Adequacy is demonstrated in Table E 1.4. The unstandardized regression weights for each factor Y_1 to Y_5 is statistically significant at $t>1.96$, $p<0.001$ (2-tailed). The individual factor with the greatest impact is Formal Equipment Training contributing to 51.6% of the variance (R^2=51.6%).

Table E 1.5 Structural Equation Model for BEI Survey Without Controls Structural Complexity (Eta1), Lambda Factor Loading Applied to First Factor of Each Latent Construct

Predictors	URW Estimate	SRW Revised	SRW Generic	Standard Error	t	P
Inter-Professional Training[1]	1.000	.701	.689			
Appropriate Professional Job Training[2]	.969	.685	.677	.077	12.594	***
Uniform Standards[3]	1.208	.627	.622	.119	10.177	***
Inter-Departmental Work[4]	.854	.687	.689	.077	11.091	***
Coordination Evidence[5]	.992	.723	.720	.085	11.612	***
Device Failure Recognition[6]	.847	.627	.626	.083	10.180	***

***<0.001 (2-tailed) significance level

Abbreviation Notes: URW=Unstandardized Regression Weight; SRW=Standardized Regression Weight.

Note on Scale[1-6]: 1) The organization values contributions to other staff members' professional development, 2) I have been provided clear training to perform my job function, 3) Standards are applied equally across all departments, 4) I received and/or provide inter-departmental input in order to successfully complete work, 5) Inter-departmental coordination has resulted in visible positive benefits, and 6) I receive and/or provide training to recognize medical device failure.

A detailed review of the findings of the intervening variable of Structural Complexity is demonstrated in Table F 1.5. The unstandardized regression weights for each factor X_1 to X_6 is statistically significant at $t>1.96$, $p<0.001$ (2-tailed). The individual factor with the greatest impact is Coordination Evidence contributing to 52.2% of the variance (R^2=52.2%).

APPENDIX F: BIOMEDICAL ENGINEERING INTERDEPARTMENTAL SURVEY INSTRUMENT

Biomedical Engineering Interdepartmental Survey

1. Biomedical Engineering Interdepartmental Survey

Principal Investigator(s): Beth Ann Fiedler, ABD
Faculty Supervisor: Thomas T. H. Wan, PhD
IRB Number: SBE-10-07285

WORKING TITLE: Effects of Structural Complexity and Process Adequacy in the Hospital Environment of Care on the Prevalence of Systemic Adverse Events and Compliance Issues

Participants:

Thank you for taking the time to complete the Biomedical Engineering Interdepartmental Survey. This project was approved by the University of Central Florida Internal Review Board for Human Research under IRB Number SBE-10-07285. Your voluntary participation indicates that you have read the informed consent and that you meet the criteria for inclusion. That is, you are over 18 years of age, are (were) a biomedical engineering technician and/or performed or supervised the tasks of the position.

Please refer to the Informed Consent and UCF IRB approval letter already provided for details regarding research purpose and confidentiality. The survey will only be available from January 15th through January 31, 2011. Since I will not have any method to identify who has already completed the survey, you will receive one final reminder email on or about January 28th.

If you have questions, concerns, or complaints, or think the research has hurt you, talk to Beth Ann Fiedler, Doctoral Candidate, Health Informatics Management, College of Health and Public Affairs, (321) 277-7393 or Dr. Thomas Wan, Faculty Supervisor, Associate Dean of Research at (407) 823-3678 or preferably by email at twan@mail.ucf.edu. If we have not adequately responded to your questions, you may also contact Institutional Review Board, University of Central Florida, Office of Research & Commercialization, 12201 Research Parkway, Suite 501, Orlando, FL 32826-3246 or by telephone at (407) 823-2901.

Thank you for your time and consideration!

Beth Ann Fiedler, ABD
7529 Park Promenade Drive, #1622
Winter Park, FL 32792
321-277-7393

University of Central Florida
College of Health and Public Affairs
Orlando, FL

PS: Please do not forward the URL link to anyone else. You have been selected specifically for participation. Your participation is voluntary and will be kept confidential.

* **1. I meet the inclusion criteria for this survey as noted above.**

- ○ Yes
- ○ No

Biomedical Engineering Interdepartmental Survey

2. ORGANIZATION CULTURE

Please respond to each question by mouse clicking on your selection.

* 2. The organization values contributions to other staff members' professional development.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 3. I have been provided with clear training to perform my job function.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 4. Standards are applied equally across departments.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

Biomedical Engineering Interdepartmental Survey

3. LEVEL OF COORDINATION

Please respond to each question by mouse clicking on your selection.

* 5. I receive and/or provide interdepartmental input in order to successfully complete work.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 6. Efforts have been made to value interdepartmental solutions to systemic issues.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 7. Interdepartmental coordination has resulted in visible positive benefits.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

Biomedical Engineering Interdepartmental Survey

4. MEDICAL EQUIPMENT COMPLEXITY

Please respond to each question by mouse clicking on your selection.

* 8. I have adequate knowledge of all of the equipment functions available to me.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 9. There are excessive operations on equipment that increase the difficulty of use.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 10. I require assistance to understand operation and/or maintenance.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

Biomedical Engineering Interdepartmental Survey

5. INTERDEPARTMENTAL MEDICAL DEVICE MANAGEMENT

Please respond to each question by mouse clicking on your selection.

* 11. Medical devices (models and types) are consistent across departments.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 12. The biomed department is centrally located for easy access.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 13. I receive and/or provide training to recognize medical device failure.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

Biomedical Engineering Interdepartmental Survey

6. INTERDEPARTMENTAL COLLABORATION

Please respond to each question by mouse clicking on your selection.

* 14. I receive and/or provide advice on new equipment purchases.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 15. I trust the equipment/clinical knowledge of other departments.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 16. I recognize other departments as professional equals.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

Biomedical Engineering Interdepartmental Survey

7. KNOWLEDGE MANAGEMENT

Please respond to each question by mouse clicking on your selection.

* 17. I share informal knowledge to benefit patient care.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 18. I have access to formal knowledge within the department.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 19. I have access to cross-functional knowledge through electronic or other methods.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

Page 7

Biomedical Engineering Interdepartmental Survey

8. COMPLEXITY OF SANITATION METHODS

Please respond to each question by mouse clicking on your selection.

* 20. We utilize manual sanitation methods on the surface of medical equipment.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 21. New high technology methods that cleanse and sanitize internal parts of medical equipment have been introduced to the facility.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 22. High technology internal sanitation methods have been adopted as a standard.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

Biomedical Engineering Interdepartmental Survey

9. INTERDEPARTMENTAL COMMUNICATION

Please respond to each question by mouse clicking on your selection.

* 23. I can easily discuss equipment issues.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 24. I receive and/or provide training on the proper way to operate equipment.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 25. I receive and/or provide clean, operational equipment in a timely fashion.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

Biomedical Engineering Interdepartmental Survey

10. INTERDEPARTMENTAL TEAMWORK

Please respond to each question by mouse clicking on your selection.

* 26. I receive and/or provide detailed information regarding out of service equipment.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 27. I receive and/or provide training to properly clean and sanitize equipment between patient use.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 28. Nursing and biomedical engineering conduct regularly scheduled meetings on equipment issues.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

Biomedical Engineering Interdepartmental Survey

10. INTERDEPARTMENTAL TEAMWORK

Please respond to each question by mouse clicking on your selection.

* 26. I receive and/or provide detailed information regarding out of service equipment.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 27. I receive and/or provide training to properly clean and sanitize equipment between patient use.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 28. Nursing and biomedical engineering conduct regularly scheduled meetings on equipment issues.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

Biomedical Engineering Interdepartmental Survey

11. CLINICAL ENGINEERING EFFECTIVENESS

Please respond to each question by mouse clicking on your selection.

* 29. Biomedical engineers are integrated in the medical equipment purchasing process.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 30. Biomedical engineers are integrated into facility management (e.g., Central Sterile, Infection Control, Management Information Systems).

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 31. Biomedical engineers set and achieve department goals based on organizational objectives.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 32. Biomedical engineers are satisfied with reporting authorities.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

Biomedical Engineering Interdepartmental Survey

12. CLINICAL ENGINEERING EFFICIENCY

Please respond to each question by mouse clicking on your selection.

* 33. Biomedical engineering tracks device failure through a repair work order system.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 34. Biomedical engineering maintains an inventory of medical devices.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 35. Biomedical engineering measures cost using generally accepted metrics (e.g., labor cost/hour; labor cost/repair; total cost/repair; cost/bed supported; number of medical devices/bed supported; or cost of support as a percentage of the Acquisition Value of Capital Inventory).

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

Biomedical Engineering Interdepartmental Survey

* 36. Biomedical engineering measures labor costs as a function of productivity (number of hours worked on completed or uncompleted jobs/total available hours).

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

Biomedical Engineering Interdepartmental Survey

13. REGULATORY COMPLIANCE

Please respond to each question by mouse clicking on your selection.

* 37. Biomedical engineering understands medical equipment regulatory policy.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 38. Biomedical engineering is able to apply medical equipment regulatory policy.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 39. Biomedical engineers must sometimes choose between medical equipment regulation compliance and patient-centered outcomes.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

* 40. All departments have access to hospital acquired infection data.

- 1. Strongly Agree
- 2. Agree
- 3. Neither Agree or Disagree
- 4. Disagree
- 5. Strongly Disagree

Biomedical Engineering Interdepartmental Survey

14. RESPONDENT INFORMATION

Please respond to each question by mouse clicking on your selection.

*** 41. My profession is**

- Biomedical Engineering Technician
- Nurse
- Quality

*** 42. The years of experience I have in my profession**

- 0-2 years
- 2-4 years
- 5+ years

*** 43. My highest level of education is**

- High School or General Education Diploma Equivalent
- Associate of Arts/Associate of Science
- Bachelor of Arts/Bachelor of Science
- Graduate Degree (Masters or Doctorate)

Biomedical Engineering Interdepartmental Survey

15. FACILITY INFORMATION

Please respond to each question by either mouse clicking on the radial button, selecting from the drop down menu, or filling in the blanks where appropriate.

44. Please provide the state where you facility is located.

State:

* **45. The facility where I am employed is accredited by the Joint Commission.**

- Yes
- No
- Other

* **46. The number of operational beds in the facility where I am employed is**

* **47. The facility where I am employed is**

- Public
- Private
- Non-Profit
- University Affiliated

* **48. The facility where I am employed is considered**

- Rural
- Urban

Biomedical Engineering Interdepartmental Survey

16. FACILITY INFORMATION

You have designated URBAN location. If your facility is not located in an URBAN region, please review your answer to the prior question by selecting PREV BEFORE you enter the five digit zip code.

* 49. If your facility is urban, please provide your five digit zip code.

ZIP:

Biomedical Engineering Interdepartmental Survey

17. REMARKS

Please share any additional comments you may have in the box provided below.

50. Please share any additional comments you may have in the box provided below.

Biomedical Engineering Interdepartmental Survey

18. UNABLE TO MEET INCLUSION CRITERIA

This page is included as an automated message link if you answered NO to the first question of this survey. HOWEVER, if you answered YES to question 1 and were able to complete the questions, please ignore this comment and simply select DONE. THANK YOU.

Thank you for attempting to complete the survey. But, it does not appear that you meet the inclusion criteria at this time.

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