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Another Step in Diagnostics Consultation Model© Actualization: Examining the Impact of Consultation Workflow Processes on Providers' Clinical Decision Making

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Another Step in Diagnostics Consultation Model© Actualization: Examining the Impact of Consultation Workflow Processes on Providers' Clinical Decision Making

A dissertation submitted in partial fulfillment of the requirements
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Dedication

This work is dedicated to the One who inspired it, the one true God:

Lord Almighty (Psalm 24:12), Lord of Heaven's Armies (Psalm 46:7), Lord of Heaven and Earth (Matthew 11:25), King of Kings and Lord of Lords (Revelation 19:16);

Creator (Genesis 1:1) and Redeeming Word (John 1:1);

the One in whom "we live, move and have our being" (Acts 17:28).

God's Word will not return empty or void but will accomplish what He desires and achieve the purpose for which He sent it (Isaiah 55:11).

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LIST OF ABBREVIATIONS

AI	Artificial Intelligence
CDS	Clinical Decision Support
CDM	Clinical Decision Making
CI	Community Intervention setting of the Diagnostics Consultation Model©
CL	Clinical Laboratory
CLS	Clinical Laboratory Science/Scientists
CPOE	Computerized Physician Order Entry
CPT	Current Procedural Terminology®
CT	Critical Thinking
DC	Diagnostics Consultant/Consultation
DCLS	Doctorate in Clinical Laboratory Sciences
DCM©	Diagnostics Consultation Model©
DRG	Diagnosis Related Group
DV	Dependent Variable
EBP	Evidence Based Practice
HP	Healthcare Provider
IPT	Interprofessional Team
IV	Independent Variable
LDS	Limited Data Set

LIS/LIMS	Laboratory Information System/Laboratory Information Management System
ML	Machine Learning
MLP	Medical Laboratory Professional
MLT/MLS	Medical Laboratory Technician/Medical Laboratory Scientist (Types of MLP)
NAM	National Academy of Medicine (formally Institute of Medicine, IOM)
PCI	Patient Care Intervention setting of the Diagnostics Consultation Model©
PHI	Protected Health Information
SEIPS	Systems Engineering Initiative for Patient Safety
STEEEP	**S**afe, **T**imely, **E**ffective, **E**fficient, **E**quitable, and **P**atient-centered Care
TJC	The Joint Commission

ABSTRACT

ANOTHER STEP IN DIAGNOSTICS CONSULTATION MODEL© ACTUALIZATION: EXAMINING THE IMPACT OF CONSULTATION WORKFLOW PROCESSES ON PROVIDERS' CLINICAL DECISION MAKING
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The medical literature is replete with reports of the impact on quality of communication errors in health services delivery and the disproportionate contribution of incomplete, inadequate, and conflicting communications to errors in medical decision making. Diagnostic information generated by clinical laboratories is foundational to any consideration of efficiency and effectiveness of health service delivery given that as much as 93% of the objective data in the clinical record is contributed by the laboratory, much of which impacts clinical decision making. The purpose of this study was to describe the Diagnostics Consultation Model© (DCM©), a clinical laboratory (CL) communications portal, designed and proposed to support clinical decision making (CDM) within interprofessional teams, providers, and institutions. Specific aims supporting the purpose were to design, develop and validate a workflow prediction index (the complexity index, CI) that could assign consultation requests for resolution based on an algorithm comprised of consultation characteristics available at the point of consultation initiation. The CI is intended to function as the entry point into a workflow process directing diagnostics consultation requests, first, to the appropriately qualified medical laboratory

professional (MLP) for investigation and then branching into processes for tracking medical history and clinical information accumulation, documenting resolution logic and detail, verifying conclusions, and communicating recommendations to all health professionals involved in consultation CDM and to the health record.

Data to develop and validate the CI were collected during clinical laboratory (CL) daily activities and describe types of consultation requests brought to the CL, types of health professionals requesting consultation, steps and health professionals involved in the request resolution process, and processes involved in results and recommendations reporting. From analysis of data collected at the point of consultation initiation, diagnostics test cycle phase (pre-analytic, analytic, post-analytic) related to the consultation question and medical service of origin emerged as statistically significant pre-consultation predictors of the MLP practice level best prepared to resolve particular consultations. A second workflow predictive model was constructed from data collected after consultation completion. Number of handoffs/logic steps among health professionals in consultation resolution and medical subject emerged as statistically significant post-consultation predictors of the MLP practice level best prepared to resolve particular consultations. Findings from the post-consultation model were then employed to assess and validate the predictive performance of the CI.

The work has produced methodology for establishing processes to generate data for streamlining workflow and improving clinical decision support for MLP and other health professionals throughout the health system. Methodology developed to direct workflow and document and communicate consultation findings in the CL, including the design of data collection processes and collection tools, can be adapted to the operations of other clinical

services. Implementation of these DCM© methods in health professions' daily practice has the potential to change health services delivery by the redistribution of care through interprofessional teams (IPT) coordinated by standardized workflow and communication processes. IPT membership would be determined by documented clinical developments necessitating changes in individuals' care paths and would follow patient/consumers through all care environments and levels of care. In addition, this care delivery structure provides the capability to follow individuals' medical histories longitudinally and, through regular consultations, to address issues of access, equity, and compliance for the purpose of development of an evidence based, individualized care plan for every patient/consumer.

INDEX WORDS: A6 Method for Healthcare Clinical and Quality Research, Artificial Intelligence, Care Path, Care Pathway, Clinical Decision Making, Clinical Decision Support, Clinical Research, Critical Thinking, Diagnostics Algorithms, Diagnostics Consultant, Doctor of Clinical Laboratory Science (DCLS), Evidence Based Medicine, Evidence Based Practice, Health Services Research, Health Services Science, Human Factors, Human Factors Science, Interprofessional Teams, Machine Learning, Organizational Theory, Patient Centered Care, Quality Improvement, Quality Theory, Shared Decision Making, System Factors

CHAPTER 1

Introduction

Context of the Problem

Increasingly, the attention of clinical laboratory scientists (CLS) is being directed toward assessment of quality of clinical laboratory information as correlated with patient outcomes, clinical decision making, and cost. Gaining increased attention is the concept of "value-based healthcare" in which information regarding quality and cost of services is made accessible to consumers, who generate demand for these products and services. Producers compete to increase the value of services which is defined as quality of patient outcomes relative to the cost (Castañeda-Méndez, 1996; Cattell et al, 2020; Porter, 2009; Porter, 2010; Porter et al., 2020). For CLS, the distillate of these developments is that the quality of diagnostics services will be evaluated, not only on analytic validity, but on value of services, that is, by how well they support positive health outcomes, the extent to which they favorably influence clinical decisions, and the benefit/cost ratio of services delivered.

Options for ordering and utilizing diagnostic laboratory testing are burgeoning. In a 2017 *World Health Organization Bulletin*, it was estimated that more than 40,000 diagnostic, monitoring, and prognostic laboratory tests, performed in the clinical lab and via point of care testing, are available to providers to aid in disease diagnosis and treatment (Kasack et al., 2017) The bulk of the *in vitro* diagnostics (IVD) market is concentrated in developed countries; the U.S. market is estimated at $19 billion (Morel et al., 2016). With an increase in genomic testing

capability, the changing regulatory environment encouraged by the rapid SARS-CoV-2 response, incorporation of AI-assisted *in vitro* diagnostics (IVD) evaluation, and the proliferation of direct-to-consumer diagnostics, numbers of tests and their costs are increasing daily (Bandeiras, 2020; Fitzgerald et al., 2021; Iacobucci, 2021; Isbell, 2020). Unfortunately, the services delivery gap between analytic accuracy (laboratorians' providing valid, actionable test results) and medical meaningfulness (providers' understanding of what to do with them) is growing larger, as well (Carayon et al., 2006; Carayon et al., 2018). Issues related to re-interpretation of diagnostic laboratory information produced by older generations of technology considering information from new, more sensitive and specific generations are increasing, also, because of the rapid advancement of technology and computerization (Graziadio et al., 2020; Zuckerman, 2021). Rapid advancements in diagnostics technologies coupled with similar growth in testing options and choices mandate the development of evidence based testing algorithms linked to the care paths of the major chronic diseases and health challenges encountered most frequently (Church & Naugler, 2020; Kratz & Laposata, 2002). There is an equally compelling mandate to provide these evidence based algorithms to providers and patients for their use in shared clinical decision making (Carayon et al., 2018; Baker & Waller, 2008; Leibach, 2008b; Leibach, 2011).

In 2015, the National Academy of Medicine (formerly the Institute of Medicine, IOM) published a landmark report, "Improving Diagnosis in Health Care," identifying diagnostic error as a major contributor to the general category of medical error (NAM, 2015). Based on the seminal work in healthcare quality of Donabedian (1988), the diagnostic process is described as a series of activities engaging patient/consumers with healthcare throughout their lifetimes

embedded in a work system comprised of structures, processes, and outcomes. The report continues with evidence that most patient/consumers will experience at least one diagnostic error with possible negative outcomes in their lifetimes.

Diagnostic information generated by clinical laboratories is foundational to any consideration of efficiency and effectiveness of health service delivery given that as much as 93% of the objective data in the clinical record is contributed by the laboratory, much of which impacts the clinical decision making process (Armstrong & Metlay, 2020; Forsman, 2002; Hallman, 2011; Zhi et al., 2013). Inefficiencies involving the generation of orders (pre-analytical processing) and utilization of laboratory data (post-analytical processing) increase the possibility of inappropriate resource utilization. An estimated 50-60% of all laboratory orders may be inappropriate (Bissell, 2000); and most laboratory errors (68-87%), including inappropriate orders, have been shown to be non-analytic (Bonini et al., 2002). In fact, the ordering of diagnostic tests is rarely based on evidence of comparative effectiveness over the entire cycle of care (Christenson et al, 2011; Glaser, 2020; NAM, 2015; Porter, 2009).

The medical literature is replete with reports of the impact on quality of communication errors in health services delivery (Desmedt et al., 2020; NAM, 2001; NAM 2015). Also widely reported is the disproportionate contribution of incomplete, inadequate, and conflicting communications to errors in medical decision making (Bate et al., 2012; Blazin, 2020; Cheloff & Huang, 2021); medical errors are not just the result of miscommunications by individual practitioners but are also precipitated by systems, processes, and conditions that have failed

(Abraham et al., 2021a; Applebaum et al., 2021; Blazin et al., 2020; Classes et al., 2020; Krasowski et al., 2015; NAM, 2001).

To address the outcomes of these communication failures, standardized communication tools to be used in the handoff/handover of patient/consumer information among healthcare providers during transitions of care have been designed, implemented, and evaluated (Desmedt et al, 2020). Most of these tools are structured to be used during care transitions involving unit to unit transfers, e.g., surgery to ICU, anesthesia to surgery; within unit transfers, e.g., nursing shift report, within radiology communications; or during inpatient rounding (Blazin et al, 2020; Brown et al., 2020; Burns et al., 2021; Cao et al., 2018). Reports of the use of standardized tools for care transitions between different institutions are less common even though the probability of breakdowns in patient care communications is acknowledged to increase without in person exchanges (Helmig et al., 2020).

Universal implementation of the electronic health record (EHR) has also been implicated in healthcare communications failures (Palojoki et al., 2020). Lapses in clinical reasoning leading to inadequate clinical decision making (CDM) have been attributed to EHR structure as primarily transactional data repositories, i.e., EHRs, simultaneously provide a glut and dearth of information (Glaser, 2020). EHRs lack meaningful organization schemes, e.g., a library of care plans, and synthetic and cumulative sections for interprofessional team synopses to guide CDM throughout the care continuum (Arsoniadis, 2020). Difficulties involved in following complex treatment plans and formulating evidence based priorities and next steps have led to patient-related safety incidents and practitioner burnout (Adler-Milstein et al., 2020; Classes et al., 2020;

Palojoki et al., 2020; Williams, 2021). As a result of these system design flaws, application program interfaces (APIs) connecting EHR frameworks to middleware providing expanded CDS capability are being envisioned and developed (Casey et al., 2020; Caudell-Feagen & Thompson, 2021; Krasowski et al., 2015; Shanbhag & Bender, 2020; Stendhl et al., 2021).

Though the need for more closely controlled communications among healthcare providers is being addressed in these various ways, a brief review of the designs of the communication tools in use reveals gaps related to electronic health record (EHR) integration of summaries of care activities from handoff communications, which can be considered significant steps in patient/consumers' care paths (Casey et al., 2020; Glaser, 2020; Palojoki et al., 2020). A contributor to the integration gap in continuity of care is the lack of an evidence based method for determining interprofessional team (IPT) member roles and functions. A recent international review of the utility and quality of IPT rounding practices in intensive care units summarizes the wide variation in IPT composition and lack of evidence related to impact of IPT practices on consumer/patient clinical outcomes (Amaral et al., 2020). In North America, according to Amaral et al. (2020), both handoff (sending) and receiving physicians and nurses are consistently included as IPT, clinical pharmacists are common IPT members, and other health professions (HP) are included *ad hoc* according to the identified clinical problem. However, medical laboratory professions (MLP) were not reported as either designated or *ad hoc* IPT members.

Statement of the Problem

Diagnostics information should be delivered by specialized laboratory professionals in the context of best evidence and risk assessment tailored to patient/consumers' medical

circumstances. Communication of diagnostics information by a specialized team would expand the MLP consultative role and significantly facilitate, substantiate, and improve the shared decision making process among healthcare professionals and patient/consumers participating in IPT health services (Bate et al., 2012; Booth et al, 2019; Church & Naugler, 2020; Laposata & Cohen, 2016; Theparee et al., 2018; Stendhl et al., 2021). Therefore, the emerging role for MLP, specifically doctoral clinical laboratory scientists, is to design and conduct clinical research to generate evidence for development of testing algorithms positively impacting patient safety and health outcomes as part of laboratory and institutional quality improvement programs (Burns et al, 2019; Cheloff & Huang, 2021; Christenson et al, 2011; Church & Naugler, 2019; Crews et al., 2020; Laposata & Cohen, 2016; Leibach, 2008a; Leibach, 2008b; Porter, 2010; Theparee et al., 2018; Stendhl et al., 2021). The information thus generated would be tailored specifically to the needs of providers and patient/consumers and provided as best evidence for evaluation of treatment and other care options (Bate et al., 2012; Rashidi et al., 2019).

Study Purpose

The overarching goal of this work was to describe the Diagnostics Consultation Model© (DCM©), a clinical laboratory (CL) communications portal, designed and proposed to support clinical decision making (CDM) within interprofessional teams, providers, and institutions. The study was founded on a retrospective review of records of medical laboratory professionals' (MLP) consultations with other healthcare providers and will address characterization of these consultation elements occurring in various clinical settings. This information was used to design methods describing workflow processes through each consultation scenario based on evidence

extracted from consultation characterization. Also, a typology of practice characteristics attributable to each MLP practice level involved in consultation resolution was developed from the analyses of consultation characteristics. These findings and projections based on consultation analyses and associated MLP practice characteristics suggested an approach to direction of consultation requests to appropriately educated and experienced MLP practice levels and to communication of diagnostic findings to appropriate IPT members in appropriate documentation formats (Carayon et al., 2018). This approach to healthcare communications, in turn, informs evidence based decisions regarding clinical laboratory staffing, clinical quality improvement studies, and MLP curriculum development.

Consultation characterization occurred in the following two steps that summarize the specific study aims, research questions, and hypotheses: development of the complexity index (CI) and subsequent evaluation of its predictive performance. First a prediction model will be developed from consultation case data that was used to predict consultation workflow to appropriately educated and experienced MLP to resolve consultation questions the most safely, thoroughly, and expeditiously (Shipe et al., 2019). The prediction model, the complexity index, CI, was developed from consultation characteristics available at the time of consultation initiation. Then MLP practice levels were associated with these consultation characteristics to define requisite education, CT skills, and experience required for consultation resolution among the practice levels. These MLP practice level descriptions, defining a typology of increasing scope of knowledge and professional responsibility, served to validate the predictive performance of the complexity index. The evidence based methods thus developed were applied

to describe a communications portal for clinical laboratory workflow direction and staffing assignments with parallel development of position responsibilities and training curriculum, as well.

Study Research Questions

Using data from consultation events occurring in the clinical laboratory, consultations were characterized by MLP practice level resolving the consultation. Three MLP practice levels have been associated with handoffs/logic steps and consultation final disposition: (a) MLP Level 1, MLT/MLS; (b) MLP Level 2, MLS Specialist/Manager; and (c) MLP Level 3, DCLS/Ph.D/MD. A prediction model, the complexity index (CI), was developed, using characteristics (variables) available at the point of consultation initiation, to be utilized prospectively to direct workflow to appropriately educated and experienced MLP at the point of consultation initiation. Consultation characteristics (variables) available after consultation completion were used to evaluate the predictive performance of the CI.

Research question 1. The first research question for the study was: Can the MLP practice level resolving consultations be predicted by an index derived from the variables test cycle phase and medical service/hospital location? Data from the pilot study indicated complexity varies with four descriptors. The first descriptor is test cycle phase: pre-analytic (test selection, order placement, specimen collection), analytic (obtain results), and post-analytic (results interpretation, analytic test sequencing). The second descriptor is medical service/hospital location. Both test cycle phase and medical service/hospital location are variables available at the point of consultation initiation and were tested for their contributions to

the predictive performance of the complexity index, CI. The third descriptor is handoffs/logic steps; the fourth descriptor is medical subject. These latter two variables are available only after consultation completion and were used to evaluate the predictive performance of the CI.

Research question 2. The second research question for the study was: Can MLP practice levels resolving consultations be predicted by number of handoffs/logic steps and medical subject associated with consultation cases? Preliminary findings suggested that an increasing number of handoffs/logic steps involved in consultation resolution and the medical subject involved related to increases in position responsibilities, i.e., education and scope of practice, from MLP level 1 through MLP Level 3. Analyses of associations among MLP practice levels and these variables available only after consultation completion predicted similar MLP practice levels resolving consultation as the CI. Thus, these retrospective associations were used to evaluate the prospective predictive performance of the CI.

LIST OF DEFINITIONS

Artificial Intelligence

The capacity of machines to imitate intelligent human behavior (Rashidi et al., 2019).

Care Path/Care Pathway

A care pathway is a complex intervention for the mutual decision making and organization of care processes for a well-defined group of patients during a well-defined period. (Schrijvers, van Hoorn, & Huiskes, 2012)

Clinical Decision Making

Clinical decision making (including prescribing decisions) involves the judicious use of evidence, considering both clinical expertise and the needs and wishes of individual patients. (Sackett et al., 1996)

Clinical Decision Support

Clinical decision support (CDS) provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. CDS encompasses a variety of tools to enhance decision-making in the clinical workflow. These tools include computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information, among other tools. (HealthIT.gov)

Complexity Index

The complexity index (CI) is a prediction model developed to direct diagnostics consultation workflow to MLP practitioner levels with requisite competencies, i.e., education, CT skills, and experience, to resolve consultation questions the most safely, thoroughly, and expeditiously. “The goal of prediction models is to provide patient risk stratification to support tailored clinical decision making with the hope of improving patient outcomes and quality of care” (Shipe et al., 2018). The complexity index (CI) is developed from consultation characteristics available at the time of consultation initiation.

Consultation Complexity

Consultation Complexity is defined as and measured by MLP practitioner CT competencies and position responsibilities as well as number of health professions, number of medical services, and number of data systems involved in consultation resolution.

Critical Thinking (CT) Operationalized Definition

“Critical thinking is a *metaprocess* that facilitates learning by interlinking the more basic processes associated with the different learning orientations: behaviorist, cognitivist, humanist, and situated/contextual learning.” (Kenimer, 1999; Kenimer 2002)

Critical Thinking (CT) Theoretical Definition

“Critical thinking is the intellectually disciplined process of actively and skillfully conceptualizing, applying, analyzing, synthesizing, or evaluating information gathered from, or generated by, observation, experience, reflection, reasoning, or communication, as a guide to belief and action.” (Paul, 1991, p. 4).

Critical Thinking (CT)-Associated Factors

Critical thinking (CT)-Associated Factors are CT skills, behaviors, competencies, and environmental (contextual, situated) elements associated with the CT metaprocess.

Critical Thinking (CT) Behaviors

Critical thinking behaviors are observable events following from the critical thinking metaprocess (operationalized, applied, competency-related CT definition). (Kenimer, 1999; Kenimer, 2002)

Critical Thinking (CT) Practice Competencies

Critical Thinking (CT) Practice Competencies are observable healthcare discipline-related practices associated with the CT metaprocess (operationalized, applied CT definition). (Kenimer, 1999; Kenimer, 2002)

Critical Thinking (CT) Practice Domain

Critical Thinking (CT) Practice Domain describes the learning domain associated with observable healthcare discipline-related competencies as defined in the CT metaprocess (operationalized, applied CT definition). (Kenimer, 1999; Kenimer, 2002)

Critical Thinking (CT) Skills

CT Skills are closely linked to Critical Thinking (CT) Behaviors as observable events following from the CT metaprocess; the terms may be used interchangeably in this study.

Diagnostics Care Pathway

A standardized, consensus algorithm of the best way to manage diagnostics related to an individual patient's condition over time. The phases of the pathway are screening, diagnosis, monitoring, and prognosis (Kosack et al., 2017).

Diagnostics Consultation Model© (DCM©)

The Diagnostics Consultation Model© (DCM©), derived from Donabedian's quality framework, is structured to document the correlation of clinical laboratory information to health outcomes for the purpose of evaluating quality of services and increasing the value (defined as quality divided by cost) of diagnostics information for all consumers, i.e., providers and the public (patient/consumers) at large.

Diagnostics Consultation Model© Settings

The four clinical settings of consultation, i.e., Community Intervention (CI), Diagnostics Management Intervention (DMI), Patient Care Intervention (PCI), and Utilization Review Intervention (URI), within the DCM©.

Diagnostics Algorithms

Diagnostics algorithms are included in a broader field under medical informatics and medical decision making. Diagnostics algorithms guide diagnostics test selection within the care path, i.e., screening, diagnosis, monitoring, prognosis, and automated/digital control of diagnostics instrumentation and other medical equipment. (Adapted from en.wikipedia.org/)

Diagnostics Consultants

Credentialed health professionals specializing in diagnostics clinical decision support guided by the validated evidence base in diagnostics literature and algorithms.

Doctor of Clinical Laboratory Science (DCLS)

The DCLS is the clinical laboratory science practice doctorate, based in healthcare quality theory and clinical research, developed to implement principles and competencies of CLS EBP to evaluate and optimize diagnostics services delivery.

Evidence/Best Evidence

Evidence/best evidence includes findings and recommendations synthesized from randomized controlled trials and other scientific methods such as descriptive and qualitative research as well as use of validated information from case reports, scientific principles, and expert opinion. (adapted from NCBI)

Evidence Based Medicine

"The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." (Sackett et al., 1996)

Evidence Based Practice (EBP) in Clinical Laboratory Science

"The conscientious, explicit, and judicious use of the best evidence from CLS in making decisions about the care of individual patients." (Leibach & Russell, 2010)

Handoffs/Logic Steps

The total number of information handovers (handoffs) among health professions and clinical question-guided information searches (logic steps) required to investigate a consultation and produce an evidence based consultation summary resolution.

Health Services Science

The foundational theories and practices describing value-based healthcare comprised of evidence based practice, quality improvement, and individualized patient/consumer care. DCM© methodology, employed as a systems approach to evidence based practice, quality improvement, and individualized patient/consumer care (i.e., health services science), provides the foundation for continuous optimization of health services delivery to address the needs of individuals, populations, and health systems throughout the continuum of care.

Human Factors/Human Factors Science

The interrelationship between humans, the tools and equipment they use in the workplace, and the environment in which they work. (WHO)

Machine Learning

An application of artificial intelligence that allows computer systems to learn iteratively from experience without explicit programming (Rashid et al., 2019).

Safety I

The traditional healthcare problem solving approach that addresses process failures leading to errors or unsafe care (Smith & Valenta, 2018).

Safety II

Systems thinking applied to healthcare problem solving in which errors and adverse events are investigated as aberrations in systems rather than consequences of personal and/or team fallibility (Mannion & Braithwaite, 2017).

System Factors

Environmental, contextual elements embedded within healthcare systems, i.e., interprofessional team communications protocols, database structures, and number of medical services, impacting the complexity of consultation services within the care continuum.

Validity, External

The extent to which results from a study can be applied (generalized) to other situations, groups or events. External validity, i.e., reliability or generalizability, can be one of two types: (1) generalizability to different populations from a study sample (population validity) or (2) generalizability to different, natural (real world) settings from a population sample (ecological validity). (Scribbr)

Validity, Internal

The degree of confidence that the causal relationship being tested is trustworthy and not influenced by other factors or variables. Internal validity is defined as the extent to which the observed results represent truth in the population being studied and, thus, are not due to methodological errors. (adapted from NCBI)

CHAPTER 2

Literature Review

To address gaps in services delivery for the clinical laboratory, healthcare diagnostics services can be evaluated through a quality framework that correlates CL structures (inputs), operations (activities), and information (diagnostic and health outcomes) (Crews et al., 2020; Donabedian, 1988; Carayon et al., 2018). First, significant health services delivery issues can be identified and characterized through continuous quality improvement systems (Crews et al., 2020). Next, evidence based protocols and processes are implemented to address these quality gaps (Delahanty et al., 2019). Finally, outcomes, both clinical and operational, are evaluated for their value as assessed by measures of clinical effectiveness and cost-efficiency (Crews et al., 2020; Leibach, 2008a; Leibach, 2008b; Porter, 2010).

Justification for expansion of quality theory in this study was advanced from current thinking in quality in the industry. Literature was accessed through key word searches in PubMed, Biomed Central, and Google Scholar along with review of publications of professional organizations related to quality measurement (e.g., AcademyHealth, ASQ, Clinical Laboratory Standards Institute) and quality assessment (e.g., AABB, American Association for Clinical Chemistry, American Society for Clinical Laboratory Science, American Society for Microbiology).

Elements of CLS evidence based consultation practice were defined through review of literature in quality, critical thinking, knowledge transfer, decision science, healthcare communications, and health services research domains. The theoretical basis of the structure and implementation methods of workflow processes and communications within the DCM© integrates critical thinking; knowledge translation; decision, implementation, and safety science; and health services research theory with evidence based practice implementation methods all under the Donabedian quality frame.

Critical Thinking

Critical thinking theory is employed in the more qualitative aspects of characterizing consultations, e.g., identifying actionable questions brought to the diagnostics consultant, evaluating diagnostics information through the lens of patient/consumers' medical and testing history, and identifying recommendations based on analysis of medical information and evidence based guidelines from the literature (Aiken et al., 2003; Benner, 1984; Carayon et al., 2006; Carayon et al., 2014; Dighe et al., 2001; Kratz & Laposata, 2002; Leibach, 2007; Leibach, 2008a, Leibach, 2008b).

Knowledge creation/knowledge transfer theory, then, frames the interface between individual cognitive knowledge and shared community knowledge through delivery methods like evidence based practice (EBP). In knowledge translation, existing validated knowledge, e.g., randomized clinical trials, evidence based clinical (observational, qualitative) studies, is synthesized to produce action targeted toward improvement in quality measures (Khoddam et al., 2014).

Critical thinking and knowledge translation provide sequential theoretical frames for EBP methods as described for laboratory medicine by Christenson, et al. (2011). This seminal work, the Laboratory Medicine Best Practices (LMBP) A6 Method, defined methods for discovery of best practices in laboratory medicine, measuring test performance indicators as well as health outcomes, from the systematic review and meta-analysis of data collected from studies of clinically relevant questions. Data for systematic reviews come from primary publications and unpublished quality improvement studies addressing the same question. After synthesis of practices and identification of best practices, the method yields recommendations (strategies) for implementation of quality improvement studies to resolve the clinical question under study. Thus, the method is used to guide standardized quality improvement efforts in laboratory medicine. The method has been employed widely and recently in the systematic review published by the U.S. Centers for Disease Control and Prevention LMBP Initiative, "Effectiveness of Practices to Support Appropriate Laboratory Test Utilization: A Laboratory Medicine Best Practices Systematic Review and Meta-Analysis" (Rubinstein et al., 2018).

Over the past decade, healthcare quality endeavors have involved the input of patient/consumers themselves. Patient/consumer involvement in the healthcare delivery system can occur at any point in delivery, from access to community services to construction of patient and family-centered environments (Bombard, et al., 2018). Most frequently, patient involvement has focused on direct discourse between patients and providers for the purpose of engaging patients in the decision making process and/or patient education to improve self-care (Coulter, 2005; Légaré & Witteman, 2013). Efforts to include patient/consumer voices in all aspects of

health services delivery, e.g., from health facility construction to sharing decisions about treatments, have been generally accepted and promoted (Bate et al., 2006; Boivin et al., 2014; Crawford et al., 2002; Johnson et al., 2008). And the focus of all these efforts is to improve the quality of healthcare delivery throughout patient/consumers' lifetimes in the healthcare continuum by involving consumer/patient input, i.e., young to old, in the healthcare cycle (non-patient to out-patient to in-patient to specialty care to return to out-patient consumer, etc.) (Carman et al., 2003; Parand et al., 2014).

Much of the methodology for identification of evidence based best practices shown to increase the value (quality to patient/consumers divided by cost) of diagnostics information, led to the 2015 National Academy of Medicine (NAM) report, *Improving Diagnosis in Health Care*, defined diagnostic error as critical in the assessment of healthcare quality. Identifying, quantifying, and reducing diagnostic error is the first of three themes of the report. Reducing diagnostic error is well within the quality goals of diagnostics services because of the pivotal role of diagnostics information in clinical decision making of all healthcare providers (NAM, 2015).

Patient/consumer involvement in healthcare diagnostics services delivery, targeting their involvement in improving diagnosis, is the second major theme of the 2015 report. Diagnostic error is defined from the patient/consumer perspective as: "the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient" (IOM/NAM, 2015, p. 85). This emphasis on patient/consumer involvement as central to a solution for diagnostic errors serves as the mandate for those providing diagnostics

services and/or interpreting and recommending applications of diagnostics information (IOM/NAM, 2015).

The 2015 NAM report emphasized the patient-centric role of diagnostics laboratories as the third major theme. The development of methodology for derivation of best practices in laboratory medicine defined the framework for evidence based investigations into the relationships of diagnostics information and individual patient/consumers' health outcomes (Carayon et al, 2014). This evidence based practice methodological framework has focused clinical research and quality initiatives on optimization of population-based treatment and diagnostics guidelines for all individuals who access the healthcare system (Carayon et al., 2018). Because diagnostics consultants provide information that informs the clinical decision making (CDM) of all healthcare providers, "consultation" for diagnostics consultants is defined as the synthesis, analysis, production, evaluation, optimization, and dissemination of diagnostics information to maximize value for patient/consumers (Leibach, 2012). The activities embodied in "diagnostics consultation" subsume any encounters among healthcare provider, patient/consumer, and diagnostics consultant. Thus, the diagnostics consultant is the point of initiation of patient/consumers' and IPT involvement in the diagnostics consultation process.

Literature domain review choices for this study facilitated development of a research agenda to evaluate the value of diagnostics information for consultation. For diagnostics consultants, this agenda addresses the strategic challenges raised in the NAM report, *Health professions education: A bridge to quality* (Greiner & Knebel, 2003) as well as the NAM report, *Improving Diagnosis in Health Care*: (1) addressing the multiple aspects of quality in the

education of healthcare practitioners and (2) understanding the drivers of diagnostic error to target interventions to reduce the impact of medical error in the total healthcare process.

Quality

Two major areas of literature relevant to the goals of the NAM reports and the consultation communication portal model description are presented: quality and evidence based practice. Quality theory provides the framework for the identification and evaluation of quality measures in healthcare and subsumes the growing body of literature in health services research (Carayon et al., 2006; Carayon et al., 2014; Carayon et al., 2018; Deming, 1986; Donabedian, 1988; Porter, 2010; Westgard, 2006; Westgard, 2013; Wilson, 2015). Within the quality framework, critical thinking literature frames studies related to acquiring and processing information for the purpose of creating new knowledge. Observable indicators of critical thinking (CT) quality in the cognitive, behavioral, affective, and situational/contextual learning domains can be identified and measured (Grosser et al., 2020; Kenimer, 2002). These observable CT behaviors can be markers for achievement of quality discourse among diagnostics consultants, healthcare providers, and patient/consumers.

Within the last decade, the Donabedian healthcare quality framework, i.e., structures, processes, outcomes, has been expanded further with constructs developing in non-healthcare safety management environments. An emerging field of human factors and ergonomics examines the interaction of humans with machines and technology, deepening our understanding of human characteristics contributing to communication errors occurring at the EHR interface or as the result of environmental distractions and interruptions (Mannion & Braithwaite, 2017). This area

of research produced the SEIPS (Systems Engineering Initiative for Patient Safety) model of work systems and patient safety which expands the Donabedian structures, processes, and outcomes framework to include measures of interactions among healthcare providers and their environments that affect clinical performance, provider and patient physical safety, and moral injury (Carayon et al., 2006; Carayon et al., 2014; Carayon et al., 2018). More recently, areas of safety research have bifurcated into traditional interpretations of error measurement and assessment, e.g., root cause analysis, plan-do-check-act, DMAIC (define, measure, analyze, improve, and control), and real-time assessment of variances for purposes of refining systems and processes (Blokland & Reniers, 2020). The more traditional view is designated "Safety I" and includes the designs of most quality studies performed in healthcare. "Safety II" studies are those emphasizing the more iterative, learning concepts of quality analyses involving the impact of structures and processes on clinical outcomes (Hollnagel, 2012; Smith & Valenta, 2018; Swuste et al., 2020). Safety II studies, therefore, include quality designs involving measures of effectiveness of standardized handoff communication tools, artificial intelligence/machine learning methods for guideline development from EHR data extraction and analysis, and development of public health diagnostics recommendations (Caudell-Feagen & Thompson, 2021; Isbell, 2020; Shah et al., 2021; Zuckerman, 2021).

Knowledge creation/translation theory, also within the quality framework of this study, provides context for investigation of effective knowledge transfer from creation to application (De Simone, 2014; Khoddam et al., 2014; Salehi et al., 2015). Guidance of this body of work informs development of measures evaluating the medical effectiveness of diagnostics

information and communications in improvement of health outcomes of individual patient/consumers (Bate et al., 2012). The total care process, from access of health services to inpatient discharge planning can be investigated under the constructs of knowledge creation/translation theory (Del Mas et al., 2020).

Evidence Based Practice

The second major area of literature providing a frame to operationalize the aims of the NAM reports and the consultation research agenda presented in this study is evidence based practice (EBP) methodology (Christenson et al., 2011; Leibach & Russell, 2010; Sacket et al., 1996). The general approach to systematic synthesis of evidence of effectiveness in medical practice, attributed first to Sacket (1996) and later customized for laboratory medicine through identification of laboratory medicine best practices (Christenson et al., 2011; Procop et al., 2019), has revolutionized the measure and evaluation of quality in health services delivery. EBP methods have guided the translation of knowledge into practice applications in numerous healthcare venues at the organizational level as well as in healthcare job development, continuing healthcare education, and healthcare consultation initiatives (Bombard et al., 2018; Heyer et al., 2012; Liebow et al., 2012; Snyder et al., 2012a; Snyder et al., 2012b; Yang, 2015; Yang, 2016).

The A6 cycle method for Laboratory Medicine Best Practices. The LMBP A6 Method is a validation outline for the LMBP systematic review process and describes a stepwise approach for synthesizing and evaluating the strength of literature in the investigation of diagnostics-related clinical questions (A1: ASK); data collection (A2: ACQUIRE); synthesis (A3: APPRAISE), analysis (A4: ANALYZE), implementation (A5: APPLY), and process

improvement and evaluation (A6: ASSESS) required for recommendation of best practices in diagnostics quality investigations. The LMBP A6 Method has been described in detail elsewhere (Christenson et al., 2011) as have many applications in clinical investigations (Rubinstein et al., 2018).

A6 method for Healthcare Clinical and Quality Research (A6 HCQR). This current work describes an integration, augmentation, and expansion in scope of the CDC LMBP A6 Method, reported in 2011, which was developed to guide best practices systematic literature review processes. The method expansion, the A6 Method for Healthcare Clinical and Quality Research (A6 HCQR), described and reported here for the first time, integrates the rigor of this literature synthesis process into the classic Quality Theoretical Framework developed and first reported in 1988 by Donabedian, "the father of quality measurement," and detailed more thoroughly in the SEIPS Model, a work system design for patient safety (Carayon et al., 2006; Carayon et al., 2014; Carayon et al., 2018; Donabedian, 1988; Reinke, 2017). The integration of the systematic literature review process with Donabedian's operational quality model describes a systematic, evidence based approach to the development, implementation, and evaluation of primary clinical research and quality improvement (QI) studies. The A6 HCQR method guides the critical thinking and analysis required to formulate, implement, and evaluate not only processes but health outcomes of clinical research and quality improvement initiatives, i.e., safety, timeliness, efficiency, effectiveness, equity, and patient-centeredness (i.e., the STEEEP variables) (IOM/NAM, 2001). The six steps of the method reported here begin with the identification of a specific clinical question (step A1, topic nomination), and then move through

steps A2-A6 to topic development, literature review/study design, protocol/materials development, protocol training/deployment, and evaluation of the evidence based intervention (EBI) to address the clinical quality question. Templates have been designed to help develop processes, track progress, and analyze barriers in the accomplishment of project milestones related to each A6 step. (Templates not shown.) Completion of the templates will necessitate accumulation of pertinent information and synthesis of critical processes and analyses required for development, implementation, and evaluation of an evidence based clinical research and quality improvement initiative, i.e., EBI.

The A6 HCQR Method life cycle is comprised of two phases. Phase 1, Topic Nomination and Development, includes steps A1-A3: ask, acquire, and appraise, respectively. The second phase includes the remaining three steps: Phase 2, Topic Implementation and Evaluation, A4-A6: analyze, apply, and assess, respectively. Each of the method steps is further defined by substeps related to activities described in Donabedian's classic quality model and expanded by Canayon and Colleagues in the SEIPS Model (Canayon et al., 2006; Canayon et al., 204; Canayon et al, 2018; Donabedian, 1988; Reinke, 2017).

Step A1: ASK. In step A1, a topic area is identified that is considered to contribute significantly in performance related to failure, achievement, and/or maintenance of a quality goal. The topic area could be derived from population level data sources, e.g., national, regional, and local public health databases, from public-reportable quality indicators, e.g., Centers for Medicare and Medicaid Services/Agency for Healthcare Research and Quality (CMS/AHRQ) Hospital Compare and Hospital Consumer Assessment of Healthcare Providers and Systems

(HCAHPS) Survey, and/or from internal system data sources, e.g., enterprise quality plans, incident reporting, and/or clinical laboratory error detection processes. There should be stakeholder consensus that the topic area is of significant quality importance and/or concern based on evidence from baseline process, clinical, and provider wellness outcomes (Proctor, 2011).

In Step A1, stakeholders involved in the clinical research and quality improvement study, the evidence-based initiative (EBI), are guided through the processes of forming a stakeholders' quality research group, identifying possible topic areas, choosing and setting priority among topic suggestions, and becoming familiar with the A6 HCQR structure, functions, and requirements. The topic nomination template will guide the critical thinking (CT) required to complete Step A1 ASK.

STEP A2: AQUIRE. In step A2, the EBI topic nominated in Step 1 is further distilled into a specific and measurable clinical question. A preliminary review of the literature related to the EBI question is conducted to determine the strength of the body of evidence supporting the clinical impact of the question and to discover seminal reports that could inform further, more extensive literature search strategies.

In Step A2, stakeholders refine a specific and measurable EBI clinical question from the broader topic area discussed in Step A1. Beginning with key words compiled from reports of practices addressing similar clinical questions, a search strategy is designed to identify many if not most reports of best practices relevant to the clinical question. The search strategy is designed to filter reports based on inclusion and exclusion criteria. A topic development template

guides the collection of information and criteria necessary to formulate a search strategy that will yield a sufficient number of rigorously designed and executed practices, with relevance to the clinical question, for the purpose of synthesizing an EBI practice suitable not only for the clinical question but also for the clinical environment described by the inclusion/exclusion criteria. In development of this A2 template, guidelines developed by the Prevention Recovery Information System for Monitoring and Analysis (PRISMA) Group for reporting systematic reviews were adopted to assure that criteria for conduct and reporting of the results of literature searches are followed and documented (Liberati et al., 2009; Moher, Liberati, Tetzlaf, Altman, & The PRISMA Group, 2009).

STEP 3: APPRAISE. In Step A3, a pool of candidate practices is generated from the extensive, if not exhaustive, review of literature evaluated on strength of reported evidence as well as relevancy to the clinical situation for which the EBI is being designed. Also, a pool of variables, i.e., measures reported to vary with changes in an EBI-related practice, is accumulated. Literature identified previously will be analyzed in two processes, article abstraction and variable extraction. The article abstraction procedure, using both an evidence abstraction and evidence abstraction summary template, provides guidance through an abstraction of pertinent elements of the practice reported in the reference article under review. The variable extraction procedure, using a variables assignment template, provides guidance through identification and characterization of variables measured in those same studies in practices in clinical settings similar to the EBI under development. The templates for this step will guide the CT required to analyze and judge the strength of the evidence supporting the effectiveness of candidate best

practices. In addition, the templates will facilitate the characterization of variables according to type, i.e., clinical (STEEEP), process, or client (wellness) variables, and subtypes within each of those category types (Bodenheimer & Sinsky, 2014; Harvey, 2020; Liddy & Keely, 2018; Otto, 2011; Proctor, 2011; Rathert, Williams, & Linhart, 2018; Zhao & Granger, 2018;).

STEP 4: ANALYZE. The purpose of Step A4, the final step in the EBI life cycle phase 1, "the build," is to bring together all the products of the previous planning steps into an implementation model represented by the analytic frame. The analytic frame diagrammatically summarizes the EBI path for ready assimilation by stakeholders and aids in the understanding of requisite steps and their prioritization in a timeline sequence. The EBI analytic framework template provides a generic model that can be adapted for specific EBIs. The EBI logic model template provides a format to document the evolving detail of milestone activities required throughout the EBI life cycle. During Step A4, an EBI protocol is synthesized from candidate practices from the literature, the path of the baseline comparator practice is carefully documented, and variables identified and characterized that are to be measured and statistically compared in both the comparator (pre-intervention) and intervention (post-EBI) processes.

Protocol refinement and variable identification can occur simultaneously. Candidate best practices from the literature are further analyzed for homology with the clinical situation under investigation, i.e., considering inclusion/exclusion criteria and existing structures and processes. During those analyses, structures and processes that are the data sources of the variables measured in candidate practices are identified. These structures and processes are compared to those available for the EBI under development and the feasibility of data collection is

considered. The ultimate choice of variables depends on the balance between impact in the EBI path and feasibility of measurement.

Also, in Step A4, details regarding implementation are considered. For instance, plans must include a projection of participant roles and responsibilities and a map of the informatics infrastructure needed to collect variable data. Production of training materials for and credentialing of all participants in EBI implementation are anticipated and data access and storage considered. During Step A4 after roles and responsibilities and data handling processes are defined, individuals are identified for each role and an Institutional Review Board (IRB) application submitted.

STEP 5: APPLY. Step A5 begins EBI life cycle phase 2, "the execution." These two steps incorporate the remaining processes required for implementation and evaluation of the EBI. In Step A5, the customization of the EBI is completed and any consents needed for participation are garnered from individuals named in the IRB application. Data collection mechanisms (tools), intervention training materials, and training schedules are developed. In addition, a plan for variable analyses is devised that describes assessment of hypotheses related to STEEEP (clinical), process, and wellness indicators; the assessment plan should include overall effect measures that pool the impact assessments of all the different types of variables (Proctor, 2011; Zhao & Granger, 2018.) During Step A5, baseline, comparator practice data collection can begin.

STEP 6: ASSESS. In Step A6, EBI evaluation strategies are conducted. Analysts prepare data for assessment to include pooling of indicators from different collection sources and by

different variable types, missing data analyses, sensitivity analyses, and power determinations. Data are then analyzed descriptively by individual variables (subtypes) as well as variable types, i.e., STEEEP (clinical), process, and client (wellness). These analyses are then used to assess significant differences between baseline and EBI performance on specific indicators and to perform inferential analyses to determine the contribution of variable combinations to overall EBI path effectiveness (Horwitz, Kunetsova, & Jones, 2019; Proctor, 2011). Analyses are also undertaken to develop an overall effect measure, e.g., meta-analysis for types and subtypes with enough power, describing the efficiency and effectiveness of the EBI path. Lastly, analyses of barriers and implementation protocol breaches, identified as anticipated possible harms in the analytic frame and/or from preliminary implementation results, are assessed for contributions to bias in implementation and evaluation of conclusions and recommendations (Viswanathan et al., 2012). The EBI evaluation template provides CT guidance through design of these hypotheses-driven descriptive and inferential analyses for EBI evaluation.

POST-A6 HCQR COMMUNICATION. Substantive attention is focused on communication of EBI development, implementation, evaluation, and post-EBI conclusions and recommendations. Throughout all A6 HCQR Steps, education is paramount to timely and organized planning and implementation. Most healthcare providers involved in clinical and quality research have not been exposed, through formal or continuing education, to quality theory and associated research structures and processes. In addition, clinical and quality research is not usually included in practitioner position responsibilities. However, with the advent of value-based reimbursement, acknowledgement of the clinical value of personalized team-

based services delivery, and the accelerated shift to telehealth, research to develop best practices for delivery of these high value services is increasing (D'Avena et al., 2020). Therefore, adequate time should be added for communication of EBP literature related to quality gap/clinical question development, study design, methods, findings, bias analysis, suggestions for EBP processes improvements, and recommendations for future EB clinical and quality research initiatives. Communication should be both written (in manuscript form for publication and internal distribution) and oral (platform and poster presentations) and should be developed for both internal and external audiences.

For evaluation and communication of the results of continuous quality improvement EBIs, e.g., daily updates of patient-centered care path diagnostics plans, communication formats include IPT clinical notes, internal secure messages, email, and formal consultation reports entered into the medical record. The current study, developing communication workflow processes for diagnostics consultants, is an example of a continuous quality improvement EBI. The A6 HCQR frame of this study will be described in detail later.

EBIs represent a timely, logical, and meaningful approach to developing an evidence base of best practices describing high value services that can be customized uniquely for individual health systems and their constituent populations. And perhaps just as important, the mechanisms developed in the A6 HCQR Method are applicable throughout the total health system ecosystem and amenable to and congruent with burgeoning artificial intelligence and telehealth capabilities. That is, the A6 HCQR Method prescribes the nexus of human factors, clinical and quality research strategies, and automation and digital platforms for services delivery

as described in the DCM© Research Program as displayed in Figure 1. Further, the Method outlines the integration of these components of health services delivery into high impact, measurable interventions that improve quality in healthcare as assessed by clinical, process, and provider wellness outcomes.

Healthcare knowledge creation/translation and A6 HCQR Method applications will develop further the quality framework of this study and inform possible study designs to define diagnostics consultation more fully. Literature from domains representing the major theoretical underpinnings and applications of quality in practice was reviewed to fairly and adequately describe inconsistencies between existing practices and evidence based approaches to CL services delivery. Collectively, this body of work supports the formulation of strategies for design of communications workflow processes to address diagnostics quality gaps/clinical questions within the framework of the Diagnostics Consultation Model©. See Figure 1.

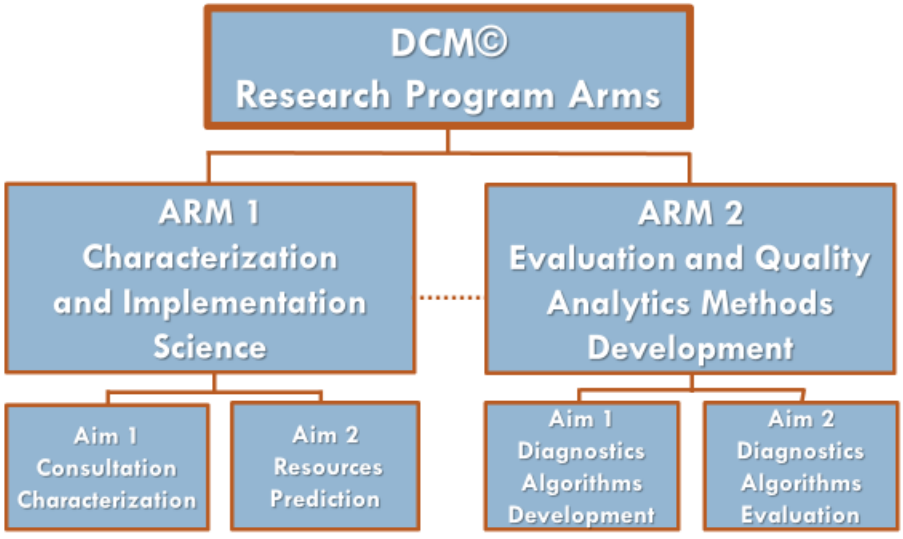


Figure 1. Structure of the Diagnostics Consultation Model© Research Program Establishing a Continuous Quality Improvement System to Improve Health Outcomes

Diagnostics Consultation Model© (DCM©) Research Program

In Arm 1 of the Consultation Model Research Program (Figures 1 and 2), Consultation Characterization and Decision Science, qualitative studies informed by CT and knowledge translation theory define the characteristics of consultations that indicate where in the care process diagnostics consultation is needed to decrease the risk of poor health outcomes (Blokland & Reniers, 2020; Swuste et al., 2020). Likewise, these theories provide guidance for development of indicators of effectiveness in the evaluation studies of Arm 2, IT Systems, Evaluation, and Quality Analytics. Studies in both Arms would employ EBP methods and speak to quality improvement in both patient/consumer clinical, process, and human factors (client) outcomes (Smith & Valenta, 2018).

Theory Base: Quality theory, operationalizing the Donabedian quality framework, and Critical Thinking (CT), Knowledge Transfer, Shared Decision Making, Problem Based Learning theories, Institutional Organizational theories

Design: (Program)
ARM 1: Consultation Characterization and Implementation Science
(1) Descriptive, cross sectional case study for
Aim 1: Consultation Characterization
Research Question: **What are the characteristics of healthcare professionals' consultations?**
(2) Inferential, cross sectional case study subgroup comparisons by independent variables (inputs, e.g., consultation characteristics) and by complexity levels, variance predicted by dependent variables (outputs, e.g., critical thinking, handoffs, prediction index) for
Aim 2: Consultation Resources Priority Prediction
Research Question: **What factors influence the priority of healthcare professionals' consultations?**
ARM 2: IT Systems, Evaluation, and Quality Analytics
(3) Predictive, cross sectional case study subgroup utilization correlated to mean sub group utilization for determination of
Aim 3: Consultation Quality Improvement Assessment
Research Question: **Does consultation improve the quality and value of clinical diagnostics?**

Methods: (Examples)
A6 HCQR Method (for consultation characterization)
Participant Observation and Narrative Analysis (for priority prediction)
A6 HCQR Method (for quality improvement and value assessment)

Results Implementation of a Consultation Model for Healthcare Clinical and Quality Improvement

Figure 2. DCM© Research Program Description. A6 HCQR Method = The A6 Method for Healthcare Clinical and Quality Research (Leibach, Personal Communication, 2020)

In summary, Figure 3 graphically represents the relationships of the relevant literature areas leading to the theoretical constructs foundational to development of the concept and practice of diagnostics consultation. Development of the Diagnostics Consultation Model©, as a structure for consultation implementation, will be discussed in detail in the pages following.

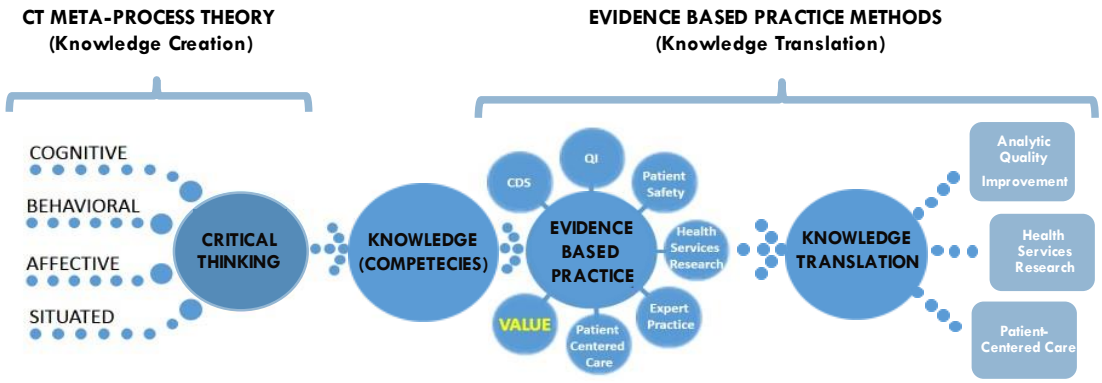


Figure 3. Theory Translation to Evidence Based Practice Methods. Cognitive and knowledge translation theories are translated through evidence-based practice methods for the improvement of value of diagnostics services for patient/consumers.

The Diagnostics Consultation Model© (DCM©) Operational Theory

Shared decision making theory. Supporting the indication for and design of the DCM© are several evolutions in health services delivery following from the quest for services delivery improvement through value based care (Cattell et al, 2020; Dubois et al., 2020; Porter, 2009; Porter, 2010; Porter et al., 2020). For over a decade now, healthcare providers have understood that to provide adequate healthcare access, patients/consumers must be involved in healthcare decisions related to diagnosis, monitoring, and treatment options to feel ownership, along with providers and payers, in the healthcare services delivery process (Bate & Robert, 2006; Bliss et al., 2020). This patient/consumer-involved approach includes a commitment to meeting patient/consumers in their own environments and in their own primary language (Applebaum et al., 2016). In this model of healthcare services delivery, patient/consumers are the

focus of the healthcare delivery system and should assume pivotal roles in decision making and quality improvement (Boivin et al., 2014; Cao et al., 2018). As care paths are discussed, patient/consumers become partners in healthcare delivery. They need to be thoroughly, honestly, and accurately informed of risks and benefits of alternatives for care (Braschi et al., 2020). Then the information compiled for and generated from care should be kept private yet readily available to and analyzed for their healthcare providers. The competing goals of assuring timely access to best evidence for all providers while maintaining the confidentiality of protected health information (PHI) also link the realms of research and clinical care as interpretations regarding the definitions of research and human protections are weighed (Damman et al., 2020; Dogba et al., 2020).

Figure 4 is a schematic of an MLP consultation services logic model for intervention in the shared decision making and informed consent process. In informatics terms, MLPs providing this patient-centered information would supply clinical decision support (CDS) to providers and patient/consumers. From an ethical perspective, provision of best available evidence addressing the unique needs of patient/consumers as the basis of shared treatment and planning decisions includes not only a thorough review and synthesis of current guidelines but consideration of the patient/consumer's environmental and social (ES) context, as well. Complete presentation of current treatment evidence with impact to the ES context not only reduces potential bias related to power inequality in the provider-patient relationship, but also addresses directly the six IOM (STEEEP) aims characteristic of improved healthcare delivery: safe, timely, effective, efficient, equitable, and patient-centered (Ballard et al., 2014; Craig et al, 2020). The three elements

considered essential in shared decision making are recognizing and acknowledging that a decision is required, knowing and understanding the best available evidence, and incorporating patients' values and preferences into the decision (Légaré et al., 2008; Légaré et al., 2011; Légaré & Witteman, 2013). The role described for MLP would address the second element, i.e., compiling and formatting the best available evidence for the individual patient's circumstances; these steps can also be considered MLP knowledge creation (Graham et al., 2006). The patient-centered information provided should include an informed consent questionnaire that would facilitate the discussion of treatment options and serve to document the patient/consumer's values and preferences. Consultation with providers and patient/consumers would be considered MLP knowledge translation through the work processes related to structures (inputs), activities, and measurement of clinical outcomes (Carayon et al., 2006; Carayon et al., 2014; Carayon et al., 2018; Graham et al., 2006).

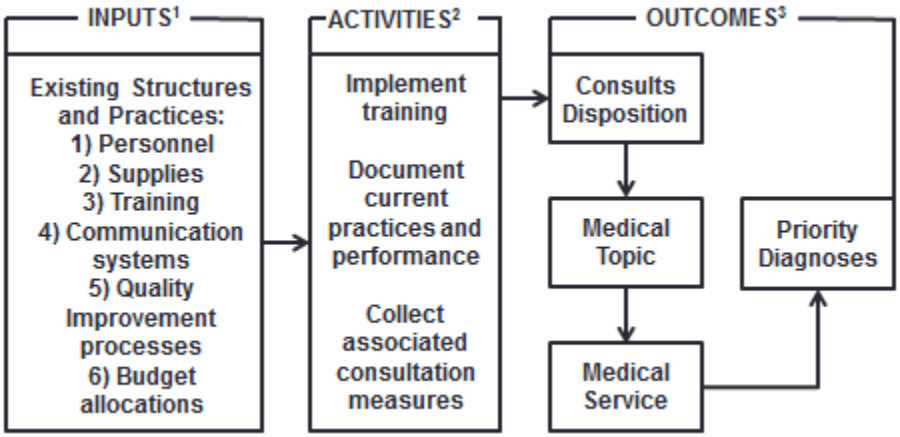


Figure 4. MLP Consultation Logic Model MLP consultation involves directing existing resources (INPUTS[1]) for the design of CDS materials (ACTIVITIES[2]) tailored for use in shared decision making during the informed consent process. Medical subjects and services involved in MLP consultation can be analyzed to discover and evaluate resource-intensive care paths and establish priority diagnoses (OUTCOMES[3]) within the healthcare delivery system, e.g., medical home, accountable care organization.

MLP evidence based practice theory. This MLP consultative role as described represents an approach to increasing the value of CL information through MLP evidence based practice, that is, the quest for increased value in health services delivery through patient-centered clinical decision support (CDS) and quality improvement practices (Christenson et al., 2011; Eichberger et al., 2020; Epner, 2017; Porter, 2009; Porter, 2010; Procop et al., 2019).

MLP role in healthcare services delivery has traditionally surrounded the production of accurate and precise diagnostics test results. Consequently, quality measurements have been focused on the analytic phase of the testing cycle to include instruments, assay methods, and statistical control, i.e., analytic QC/QA or Safety I constructs (Hollnagel, 2012; Westgard, 2004; Westgard, 2006). With the emergence of value-based concepts in healthcare services delivery, non-analytic events impacting analyses, e.g., inappropriate orders, failures in results

communications, substandard specimen collection, inadequate results interpretation, are being included in quality investigations, i.e., Safety II constructs (Christenson, 2011; Hill et al., 2020; Smith & Valenta, 2018). These evidence based quality improvement (QI) methodologies, provide the clinical research strategies and structure to evaluate efficacy vis-à-vis effectiveness of clinical laboratory services and provide evidence based benefit/cost analyses for provider and consumer decision support (Procop et al., 2019). Also inherent in this methodology is the capability to determine the medical effectiveness of emerging technologies like pharmacogenomics and other molecular testing options (Armstrong & Metlay, 2020; Leibach, 2011; Westkopf & Weng, 2013).

Figure 5 summarizes the relationship of evidence based practice (EBP) to the total quality management (TQM) process. Outside market pressures, e.g., competition, regulation, and benchmarking best practices, suggest process standardization within healthcare delivery systems. Implementing EBP, MLP practitioners then apply and evaluate those standards through quality improvement (QI) processes like the Plan-Do-Act-Check (PDAC) cycle for assessing laboratory analytics and the A6 method for measurement of non-analytic factor impact (Christenson, 2011; Carayon et al., 2018; Deming, 1986). The summation of findings from these laboratory QI processes is evaluated for quality impact at the systems level as part of the institution-wide TQM program. Improvements to laboratory processes are made based on the evidence garnered from these QI assessments. Findings from well-designed, well-executed QI studies can be generalized to other (external) systems and thus modify the initiating outside market pressures in a quality feedback loop (Blokland & Reniers, 2020). In MLP practice, the quality improvement cycle

generated by EBP combines clinical care (clinical decision support, CDS, through shared decision making) and research for improvement in patient safety and health outcomes (Carayon et al., 2018; Leibach, 2010; Leibach, 2011).

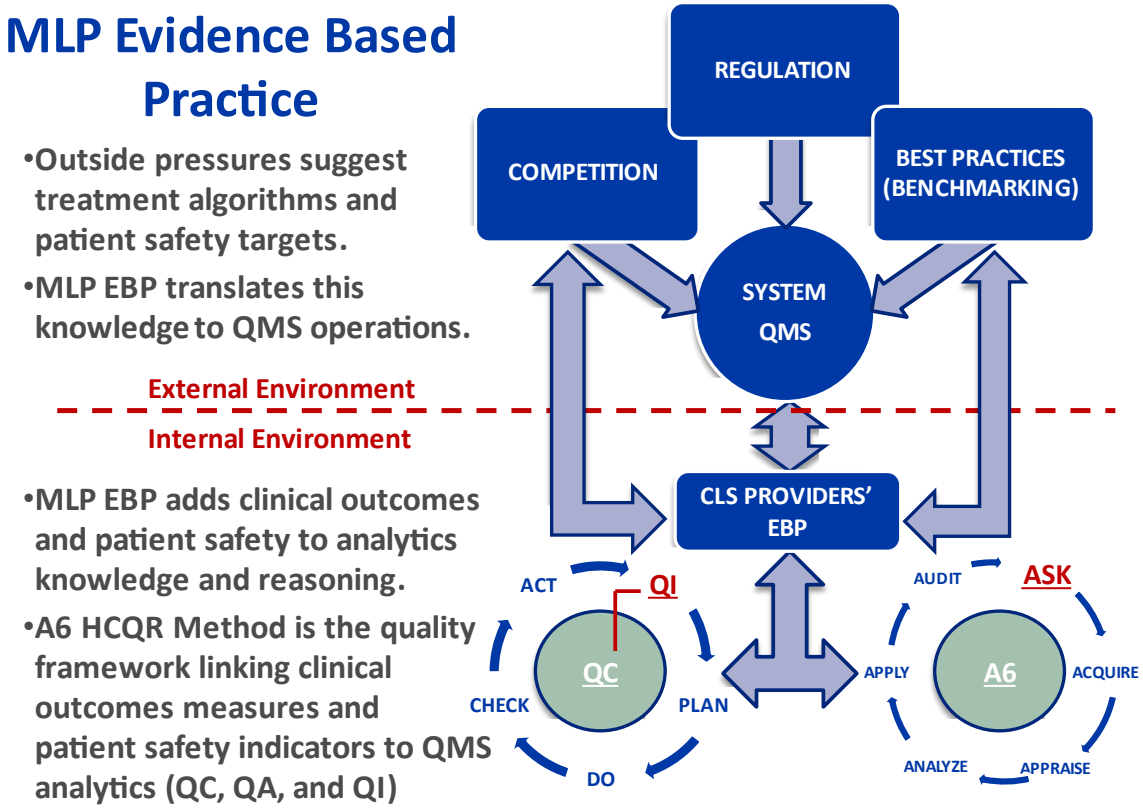


Figure 5. Medical Laboratory Professionals' (MLP) Evidence Based Practice. MLP evidence based practice (EBP) is defined as, "the conscientious, explicit, and judicious use of the best evidence from clinical laboratory information in making decisions about the care of individual patients" (Leibach & Russell, 2010; Sackett et al., 1996). EBP involves the systematic evaluation of existing evidence and incorporation of relevant conclusions from those evaluations into clinical practice using quality methods, e.g., Plan-Do-Check-Act and the A6 Method for Healthcare Clinical and Quality Research (A6 HCQR).

In MLP EBP, the impact of laboratory information on patient outcomes is assessed and compared to existing clinical care guidelines. Variances from expected outcomes are investigated and processes involved targeted for QI study if observed outcomes are judged to fall short of targeted quality thresholds. The iterative EBP process involves the analysis of individually identifiable health information ("protected health information," PHI) and, in some instances related to evaluation of alternative treatment interventions, patient participation in human subjects research. Figure 6 represents the interconnectivity (i.e., "interoperability," in informatics terms) among clinical and research databases (Arsoniadis, 2020; Weiskopf & Weng, 2013).

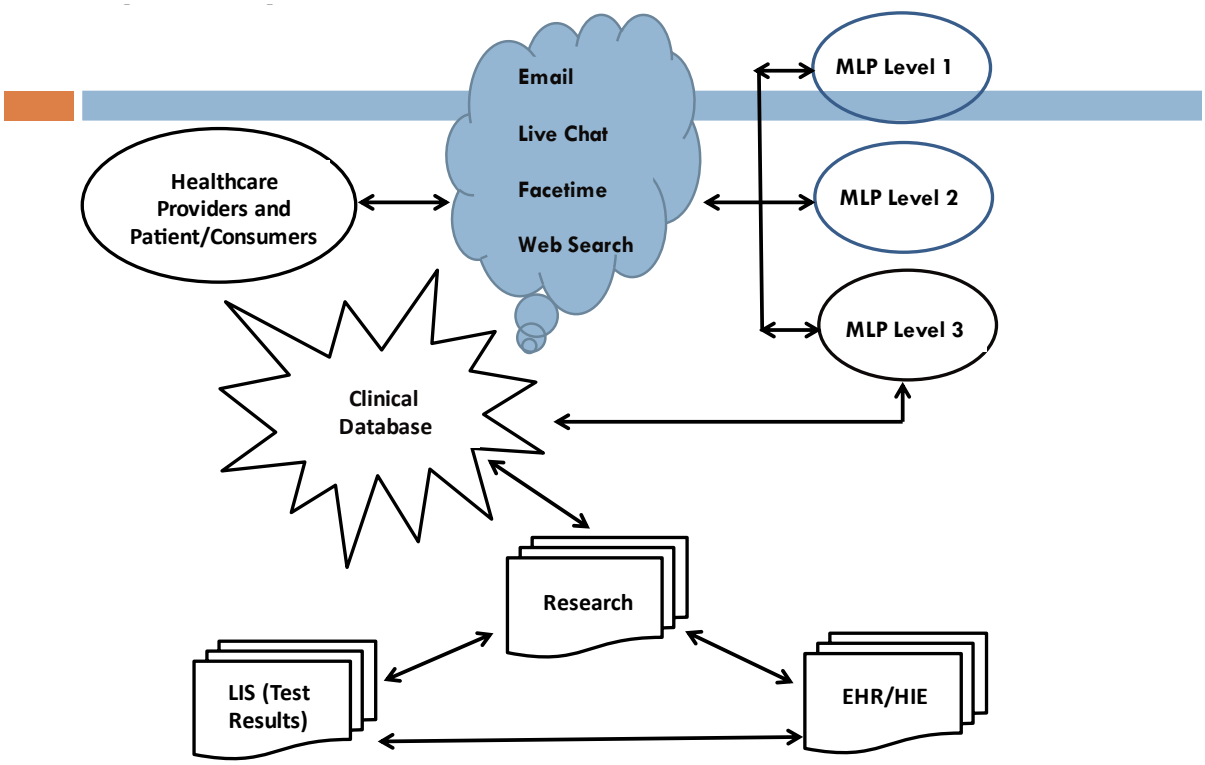


Figure 6. Interoperability of Databases Used in MLP Evidence Based Practice (EBP). MLP EBP promotes the assessment of evidence, related to outcomes of laboratory information, garnered from web searches, laboratory information systems (LIS), electronic health records (EHR) and health information exchanges (HIE), and research databases. LIS, EHR, and HIE clinical care databases are regulated, at a minimum, by HIPPA privacy and patient confidentiality requirements; research databases are regulated by Common Rule standards for human subjects research. If data are exchanged electronically, research databases must also meet HIPPA requirements for privacy and patient confidentiality.

In the consultative role described, MLP practitioners' interface with other healthcare providers, patient/consumers, and information databases to provide the scientifically best, most relevant laboratory evidence, tailored for the particular patient/consumer and care giver dyad, for meaningful informed consent and shared decision making. Information would be drawn from web sources (e.g., medical libraries and health information exchanges) as well as sources within

the medical home (e.g., laboratory information systems and electronic health records). If patient/consumers participate in clinical research studies, documentation of status and any findings will become a part of consultation materials. In addition, patient/consumers would review materials with the option to add their preferences in and document their understanding of the issues surrounding the informed consent and shared decision making process (Arsoniadis, 2020; Légaré & Witteman, 2013; Leibach, 2014; Carayon et al., 2018).

With increasing emphasis on value-based healthcare services delivery, attention has been focused on the substantial percentage of U.S. healthcare dollars wasted on overutilization of laboratory resources, that is, dollars that include those spent on unnecessary testing or testing that is too expensive to be feasible. Evidence based practice in MLP has (1) provided the methodology for evaluating the impact of laboratory information on patient safety and other health outcomes (Huang et al., 2020; Procop et al., 2019) and (2) supplied the measures for calculating medical effectiveness and cost efficiency of laboratory information in clinical decision support (Kavsak, 2019; Ko et al., 2019). Algorithms, i.e., order sets guiding diagnostics test selection within the care path, i.e., screening, diagnosis, monitoring, prognosis, and automated/digital control of diagnostics, instrumentation and other medical equipment, to guide the behavior of practitioners ordering diagnostics tests, can be developed from the evaluation of evidence based quality improvement studies (Kudler & Pantanowitz, 2010; Lippi et al., 2020; Luo et al., 2016; Procop et al., 2019).

Providing a team of MLP practitioners to select diagnostics tests with evidence based ordering algorithms adapted for unique patient/consumers' circumstances, i.e., an individualized

diagnostics care plan, would help to remove many forms of cognitive bias from this portion of the care path (Armstrong & Metlay, 2020; Bate et al., 2012; Cheloff & Huang, 2021; Maillet et al., 2018). Provider and patient/consumer dyads could then use these evidence based materials in the shared decision making process to arrive at a thoroughly informed consent for next steps in patient/consumer care (Leibach, 2014).

For MLP, this consultative process dictates that the highest clinical research standards be incorporated into each individual patient/consumer diagnostic care plan generated (Cheloff & Huang, 2021). The knowledge created from evaluation of each care path implementation can be generalized to refine diagnostics algorithms in an iterative quality improvement cycle that will foster better value (quality outcomes per dollar spent) in healthcare services delivery (Del Mas et al., 2020; Glaser, 2020). Because new information, potentially unique to individual patients/consumers, would be discovered through this QI/CDS process, MLP should understand and integrate the highest ethical standards in the generation and interpretation of clinical research findings; the DCM© implementation requires unimpugnable provider integrity, knowledge, objectivity, and ethics (Del Mas et al., 2020; Cheloff & Huang, 2021).

Patient-centered clinical decision support in MLP EBP. The recommendation to incorporate Academy of Medicine (NAM) aims into practice, and the subsequent requirement to develop measures in each of the national quality strategy domains and document their uptake, obviates the debate regarding MLP responsibility for patient safety and health outcomes assessment (Craig et al., 2020). Table 1 summarizes the relationship among the NAM aims and

the quality measurement domains of the HHS. Also included in Table 1 are MLP examples of measures in each quality domain.

Table 1

Examples of Quality Domain Measures Providing Evidence of IOM/NAM Aims Operationalized in MLP Practice

NAM/IOM Aims[1] for Healthcare Delivery	**U.S. HHS Quality Measurement Domains[2]**	**Example Measures[3]**
Safe	Safety	Specimen collection; Patient Identification
Effective	Clinical Care	Diagnostic (test ordering) algorithm development
Patient-centered	Population and Community	Informed consent; Shared decision making
Timely	Care Coordination	Critical values reporting; Appropriate Ordering; Information interpretation
Efficient	Cost and Efficiency	Best practices reporting; Benchmarking value-based processes
Equitable	Patient Experience and Engagement	Consultations

[1] Institute of Medicine (IOM)/National Academy of Medicine (NAM), 2001
[2] U.S. Department of Health and Human Services, 2012
[3] Measures developed for the informed consent and shared decision making processes would evaluate patient-centeredness of MLP services delivery. Also measured in the informed consent and shared decision making process would be effectiveness through patient-specific guidance development and services equity through feedback, from both patient/consumers and providers, on consultative services. The informed consent and shared decision making process would establish a platform for discussion of needs related to safety and cost efficiency because of the opportunity for patient/consumers to document their values and preferences as process requisites.

In order to accomplish quality improvement in the domains recommended by U.S. Health and Human Services, MLP need to understand the ethical requirements of human subjects

research as well as privacy and patient confidentiality as defined under the Health Insurance Portability and Accountability Act (HIPAA) with subsequent amendments in the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted under Title XIII of the American Recovery and Reinvestment Act of 2009. In addition to these federal laws regulating data collection and use, states generally have separate, sometime more stringent, laws governing these aspects of data protection, as well. Some private certification bodies, such as The Joint Commission, have rules governing data collection and use in their subscribing facilities. HIPAA sets the "floor" for these data protections. Clinical activities, such as clinical and quality improvement interventions or informed consent and shared decision making consultations, must be evaluated by an approved institutional review board (IRB) by criteria defining human subjects research, reanalysis of clinical samples, and limited and deidentified data sets (HIPAA, 1996, rev. 2019; HITECH, 2009; Leibach, 2014).

Patient-centered quality in MLP EBP. Clinical laboratories (CL), those laboratories producing information guiding diagnostic, screening, monitoring, prognostic, and therapeutic decision making in healthcare, vary in annual test volume, menu of services offered, levels of testing provided, types and complexity of instrumentation, numbers, and skill level of staff, and patient populations served. Regardless of these variations, the primary goal of the CL is to provide high quality services at the lowest possible cost (Procop et al, 2019). Therefore, operational theories about factors influencing CL quality and/or cost are relevant to every laboratory size and structure.

The Diagnostics Consultation Model© Operational Theory Synthesis

Organizational theory. Macro-level, external pressures influence the quality of healthcare services delivery. These relationships are graphically represented in Figure 7. Quality theories that explore relationships among community structures and processes, variabilities in access, and patient populations, though contributing to CL operations and policy, exert their main influences on the CL indirectly (Siemieniuch & Sinclair, 2014; Yang, 2007; Yang, 2016). These theories identifying external constructs describe CL connections through the primary organizational level. Therefore, theories describing healthcare system organization could be influenced by those proposing, first, more macro-level linkage among characteristics of the external healthcare environment, e.g., community structures, access issues, and characteristics of populations (Blokland & Reneirs, 2020). At a second level, then, those theories defining relationships among external factors could influence the development of organizational characteristics that vary with measurements of patient outcomes, patient safety, and cost-efficient services delivery, i.e., internal environment measures.

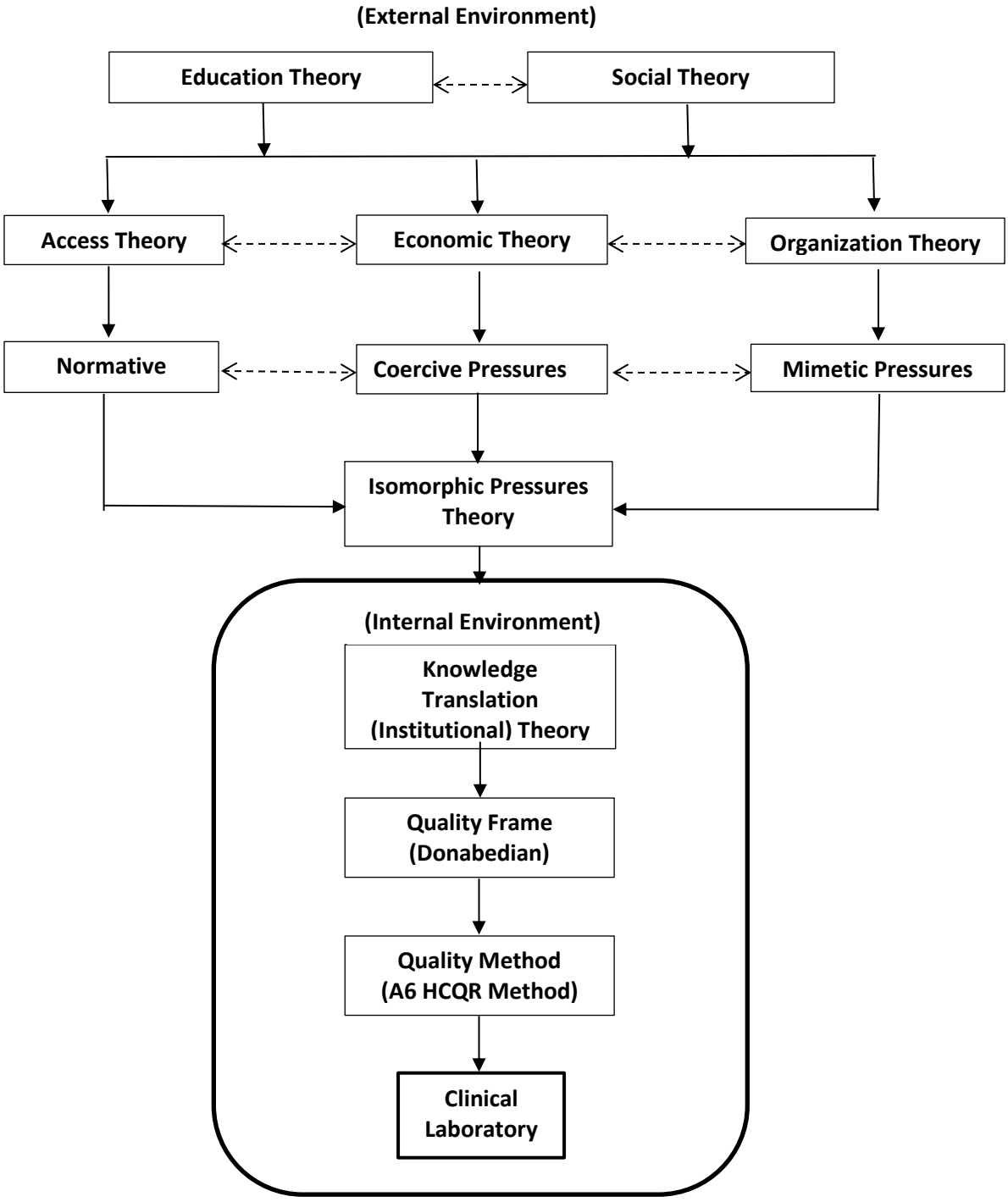


Figure 7. Relationships among Healthcare Environmental and Organizational Theories Influencing Clinical Laboratory Clinical and Quality Systems

Health services research theory. Health services research (HSR), that is, research focused on the contributions of the various constituents of the healthcare delivery system to patient outcomes, can be directed at internal characteristics of patients and their living and work environments which greatly influence their reactions to healthcare experiences, giving rise to social system-based research investigations of individual characteristics and social networks influencing healthcare choices (Applebaum & Robbins, 2016; Bradley, 2002; Carayon et al, 2018; Ospina et al., 2020; Putera, 2017; Shortell & Rundall, 2003). In addition, HSR can be directed at external characteristics like different hierarchical levels of the delivery system, e.g., community, system, or organization, or even toward assessment of contributory influences to access (Aday & Andersen, 1974; Del Mas et al, 2020; Lewanczuk et al., 2020; Modica, 2020; Pelaccia et al., 2020; Porter et al., 2020; Rabi, 2020; Schrijvers, 2012;).

Quality theory. The 2001 NAM report, *Crossing the Quality Chasm*, has challenged the health care delivery system to refocus on appropriate use of healthcare services. Following from this, accreditors of clinical laboratories have taken up the challenge and are actively reviewing progress toward this "new quality" of appropriate use of laboratory information relative to an improvement in health outcomes, increase in patient safety, and decrease in medical errors (TJC, 2021a). The need for interpretation of laboratory information related to appropriate patient assessment is a growing concern world-wide (Amaral et al., 2020; BBC News, 2008).

To identify, describe, measure, provide for, and improve the ordering, dissemination, and utilization of medically effective and cost-efficient clinical laboratory information define the quality objectives among the MLP and these quality objectives are also the focus of evidence

based medical laboratory practice (MLP EBP) (Leibach, 2008a). The larger evidence based medicine (EBM) movement, from which MLP EBP tenets are derived, is driven by computerization and information synthesis, the need for cost-efficiency, and public demand for best treatment options (Crews et al., 2020; Delahanty et al., 2019; Feeley et al., 2020; Gupte et al., 2016; McQueen, 2001). By extension, MLP EBP should consider not only findings from randomized clinical trials, but also clinical observational studies. Triangulating findings from these quasi-experimental and qualitative methods in practice guidelines development, cost-efficiency analysis, and diagnostics outcomes studies will better approximate the broader patient/consumer context (Hill et al., 2020; Kavsak, 2019; Lewanczuk et al., 2020). These mixed methods studies also provide designs through which to compare effectiveness of protocols in a broader patient/consumer context with associated process improvements related to particular patient/consumer populations in various healthcare delivery settings. The goal of the MLP EBP effort, in summary, is to provide quality healthcare in the most cost-effective way, which should be proven and documented through these clinical and quality studies (Lewanczuk et al., 2020; Price & St. John, 2019; Porter et al., 2020).

This emerging view of evidence based practice (EBP) in MLP is one with patient-centered focus and interaction. In venues in which the impact of laboratory information is determined to impact patients' well-being, MLP, functioning at levels of practice appropriate to their professions and education in clinical research, will collate, interpret, and summarize clinical laboratory information and consult with patients and other healthcare providers to optimize

services delivery and desirable health outcomes (Education Statement, ASCLS, 2007; Church & Naugler, 2020; Leibach, 2008b; Rubinstein et al., 2018).

Most research and practice treatments of quality issues rely on Donabedian's classical theoretical model proposing relationships among healthcare structures, processes, and outcomes (Donabedian, 1988). In fact, CL quality processes employed to control the analytic phase of testing are derived from Donabedian theory and operationalized under the rules of Westgard (2006). However, since most medical laboratory errors with significant clinical outcomes occur in non-analytic systems like ordering and utilization of information (results), new practices to address this non-analytic quality gap in medical laboratory services delivery are being proposed (Laposata & Cohen, 2016). These practices will be defined, first, in the healthcare institutional setting where most supply-sensitive care, to include diagnostics testing, is provided (Fisher & Wennberg, 2003). It will be this environment, producing the greatest volume of laboratory information and consuming the largest amount of resources, which will be the most sensitive to changes in practices addressing non-analytic quality gaps. It can be argued that the isomorphism theory operationalized by Yang et al. (2016) is also derived from Donabedian's seminal work if clinical laboratories and resources are considered structures, isomorphic pressures considered processes, and CL and patient health measures considered outcomes. The isomorphism constructs of Yang et al. (2007, 2016) accommodate propositions, i.e., quality questions, from all organizational and systems levels thus allowing for the system-wide expansion of CL quality measurement necessary to control non-analytic performance measures and patient outcomes.

Evidence based practice theory. In the prior theoretical discussion, aspects of environmental factors impacting institutional knowledge creation were discussed and theories were identified that serve to frame clinical questions guiding quality improvement studies (Craig et al., 2020). Unlike quality assessment in the analytic phase, the laboratory medicine field has only recently begun to implement pre-analytic and post-analytic performance measures appropriate for evaluation of quality services delivery by measuring impact of diagnostic information on health outcomes (Christenson, et al., 2011; Rubinstein et al., 2018; Provost, 2011; Smith & Valenta, 2018). Findings from quality studies augmenting analytic laboratory quality measures with health outcomes indicators can directly support clinical decision making regarding best treatments, effective interventions, optimal health outcomes, and effective cost management (Baird, 2014; Christenson et al., 2011; Kratz & Laposata, 2002; Procop et al., 2019; Shah et al., 2021; Theparee et al., 2018).

Deming is credited with first observing the limitations of statistical analysis of dynamic systems similar to healthcare delivery. And later, he designed a quality framework to assess these dynamic systems (Deming, 1986). Building on the concepts of Deming, Rosenberg and Sackett developed an epistemology related to analysis of healthcare delivery outcomes to inform practice improvement (Rosenberg & Donald, 1995; Sackett et al., 1996). Understanding the cycle of identifying best evidence from the healthcare literature, integrating this evidence with individual patient findings to formulate an action plan, evaluating outcomes relative to the individual and the literature, and creating population-based practice guidelines from the interaction is fundamental to the EBP process. This epistemology has been designated evidence based

medicine (EBM), or when applied to healthcare professions other than medicine, evidence based practice (EBP). EBP epistemology is being developed in the CL, as in other health professions, as the framework through which to evaluate operational processes, i.e., all phases of the testing process, directly supporting clinical decision making (Christenson et al, 2011; Leibach, 2011; Leibach & Russell, 2010; Procop et al., 2019; Smith & Valenta, 2018). MLP EBP development also includes studies exploring the interactions between analytic and non-analytic testing phases (Westgard, 2006; Westgard, 2013). Figure 7 graphically represents these theoretical associations.

The EBP paradigm represents a new direction in quality improvement for the CL (Dickerson et al., 2017; Hill et al., 2020; Plebani et al., 2019a; Plebani et al, 2019b). Therefore, to complete the theoretical discussion, consideration must be given to preparation of clinical researchers who will need different skills sets to assess quality issues impacting the total diagnostics testing and care process. In other words, practitioners will be required to integrate evidence with practice outside the experimental, statistical model of analytic phase quality control (Sapatnekar et al., 2021). Education in clinical and quality research methodology must be directed to practitioners as well as student learners (Maness et al., 2020). Didactic coursework, clinical internships, post-doctoral fellowships, and continuing professional education must be designed to inform practice and expose students and practitioners alike to clinical experiences providing the greatest opportunity to develop research skills necessary not only to utilize evidence in clinical decision making but also to generate and communicate data-supported practice guidelines, to monitor patients' clinical paths, to evaluate and introduce new technology, to develop quality indicators, and to create and analyze testing algorithms. Not only will health

outcomes evidence be used in clinical decision making, but these ordering and utilization data can be analyzed to support evidence for practice improvement across all healthcare delivery systems, public and private (Aita, et al., 2019; Leibach, 2008a; Leibach, 2008b; Plebani et al., 2017; Plebani et al., 2019; Siemieniuch & Sinclair, 2014).

Yang et al. (2007, 2015, 2016), Donabedian (1988), Westgard (2006, 2013), Christenson et al. (2011), Leibach and Russell (2010), and Leibach (2011), have provided robust theoretical frames for the design and operationalization of substantive CL quality improvement (i.e., clinical and quality research) programs. Left to fit into the quality improvement (and/or clinical research) agenda for investigation of the impact of MLP EBP are specific hypotheses related to CL quality measurements in the various healthcare system components and pre-intervention (pre-change) baseline studies for comparison. These aspects of the CL clinical and quality research agenda will be considered next.

Diagnostics Consultation Model© theory and methods summary. More and more, health services delivery is guided by evidence of medical effectiveness and cost efficiency (Laposata & Cohen, 2016; Porter, 2010; Procop et al., 2019). Coercive, normative, and mimetic pressures (e.g., regulatory healthcare reform; normative accreditation standards adoption; and mimetic competitive cost-reduction and quality enhancement, respectively) have converged with emerging informatics infrastructure and capability to create conditions favorable for the development of evidence based quality improvement (QI) and clinical decision support in clinical laboratory science as well as all other health professions (IOM/NAM, 2015).

These evidence based QI methodologies provide the clinical research strategies and structure to evaluate efficacy and effectiveness of CL services and provide evidence based benefit/cost analyses for provider and consumer decision support (Bombard et al., 2018; Heyer et al., 2012; Liebow et al., 2012; Snyder et al., 2012a; Snyder et al., 2012b; Yang, 2015; Yang, 2016;). Also inherent in this capability is possible methodology for determining the medical effectiveness of emerging pharmacogenomics and other molecular testing options through longitudinal observational studies of predictions and actual health outcomes (Bandeiras, 2020; Caudell-Feagen & Thompson, 2021).

From a theoretical perspective, this emerging evidence based clinical research capability allows for the investigation of the impact of isomorphic pressures on the delivery of quality CL services, and alternatively, the capability of evidence based best practice recommendations to modify these isomorphic pressures. The research structures now exist to document the quality impact of all aspects of CL services delivery, analytic and practitioner-effectuated, for purposes of optimizing medical effectiveness and cost efficiency for every patient/consumer in real time.

The practice emerging to direct these QI clinical research strategies, i.e., evidence based (MLP) practice, must be cultivated and applied among students and practitioners alike (Chen et al., 2021). The integration of evidence into practice requires research skills in addition to technology-based heuristics. And these new competencies must be identified, unbundled to foundational knowledge concepts and ordered in complexity, and curriculum prepared for communication to and uptake by practitioners in both hierarchical formal education settings and

through continuing professional education venues. These EBP clinical research methodologies also provide strategies for both education and clinical QI program evaluation.

CL information underlies medical decision making in all professions of healthcare providers (NAM, 2015). Therefore, the communication and uptake of CL EBP clinical research methodologies as well as the understanding of and compliance with evidence based laboratory recommendations must be integrated into the practice of all healthcare providers. Any useful, descriptive, and forward-thinking evidence based research agenda must include provision for multi- and inter-disciplinary healthcare provider collaborations (Bartman et al., 2021).

In the broadest sense, any evidence based research agenda for CL would not be comprehensive and effective without the participation of all stakeholders, including MLP, patients/consumers, and customer healthcare providers. In summary, the isomorphism theory of Yang et al. (2007, 2016) and the SEIPS work system design model developed by Carayon and colleagues (2006, 2014, 2018) provide a robust and broad theory base for future development and implementation of the CL research agenda that incorporates quality and knowledge creation/translation frameworks operationalized through EBP methodology.

The Diagnostics Consultation Model©: The Communications Portal for CDS

The NAM (2001) defined six domains for the referencing and measuring of health care quality, the STEEEP typology: Safety, Timeliness, Effectiveness, Efficiency, Equitable, and Patient-centeredness. Healthcare communications failures can impact services delivery in each of these domains (Ballard et al., 2014 ; Craig et al., 2020). Therefore, each of these domains should

be considered in the design, implementation, and evaluation of all healthcare communication systems.

Though the impact of communications errors on quality of health services delivery has been well documented for many years, nearly two-thirds of all sentinel events continue to be related to communication failures (Burns et al., 2021). Further, information handoffs/handovers are implicated in more than half these errors (Burns et al., 2021; Killin et al., 2021).

Recognizing the quality risks involved in healthcare communications, The Joint Commission (TJC) has established patient safety goals for safe communications to include structures for: (1) provision of interactive communications between the giver(s) and receiver(s), (2) identification of priority information related to the patients' continuity of care, treatment, services, and changes in condition, (3) validation of information exchanged between givers and receivers to assure a shared mental model, and (4) documentation that receivers can review historical data with limited interruptions (Applebaum et al, 2021; TJC, 2021a).

A communications standard (NPSG.02.03.01) is also a National Patient Safety Goal® for 2021 in the TJC Clinical Laboratory Program (TJC 2021b). The overall goal of the NPSG.02.03.01 standard is to "improve the effectiveness of communication among caregivers." The focus of guidance for performance measurement is the reporting of critical diagnostics results: (1) "Collaborate with organization leaders to develop written procedures for managing critical results" by defining critical results and procedures, tracking the recipients of critical results, and setting and monitoring turnaround times for reporting, (2) implement procedures for managing critical results, and (3) evaluate the timeliness of these procedures (TJC, 2021b). The

College of American Pathologists (CAP, a clinical laboratory accrediting body) has adopted a communication standard in the General Checklist that more specifically addresses information handoffs:

> GEN.61750: Handoff Communication
>
> The laboratory implements a procedure for effective "handoff" communication.
>
> NOTE: The laboratory should have a procedure for communicating information about pending specimens, tests and patient care issues when responsibility is 'handed off' from one person to another, such as at a change in shift, or when the responsibility for a case is transferred from one pathologist to another. The procedure should include provision for asking and responding to questions.
>
> Evidence of compliance: Logs or message boards showing communication between shifts (Veri, 2021, p. 8).

In this standard, a systems view of healthcare communications, embodied in the STEEEP aims and implied in the TJC standard, is largely ignored, the focus being interlaboratory operations (i.e., Safety I).

Since the establishment of TJC communication goals for healthcare institutions, many approaches to improve communications have been reported (Veterans Administration, 2003). In 2021, Abraham and colleagues (2021) published a systematic review of standardized handoff intervention studies between operating rooms (ORs) and intensive care units (ICUs) that were reported between 2011 and 2019. Most of the studies included in the review compared "bundled" interventions, using process-based protocols and information transfer/communication checklists,

to existing baseline, non-standardized handoff procedures. All baseline and comparator processes were manual and documented in the EHR only *post hoc* and to varying degrees. Abraham and colleagues (2021) reported meta-analyses of process outcomes (technical errors, information omissions, information sharing, handoff duration, transition and ordering time) and clinical outcomes (time to analgesia dosing, antibiotic administration delays, ventilator time, realized errors). Meta-analyses were performed on measures of technical errors, information omissions, information sharing, and time to analgesia dosing. The overall effect sizes of each measure favored the standardized handoff intervention. However, there was little standardization among studies regarding inclusion of outcome measures within the handoff phases, e.g., selection of priority patient care information to report during handoff, and within protocol/checklist construction, e.g., self-report impressions and measures of satisfaction (Arsoniadis, 2020).

Carayon and colleagues (2006) reported an expansion of the Donabedian framework, the Systems Engineering Initiative for Patient Safety (SEIPS) model, that integrates human factors and ergonomics into traditional (Safety I) quality models. The detail of the SEIPS model has been used to develop standardized approaches to interprofessional team (IPT) interactions within and among institutions that address the interface of structures and process with human attitudinal and behavioral (performance) factors. In 2018, Cao and colleagues reported a structured process for IPT rounds in the medical ICU. Later, the design and implementation of IPT processes for "mixed" rounding covering neurosurgery, neurology, cardiothoracic surgery, colorectal surgery, general surgery, pediatrics, and medicine service lines were reported (Abraham et al., 2021; Blazin et al., 2020; Brown et al., 2020). None of these processes address completely the SEIPS

model construction, however. For instance, the SEIPS model includes measurement of patient outcomes involving patient safety and quality of care (Carayon et al, 2006). To date, standardized handoff and rounding efforts have focused on processes for sending and receiving patient information and some measures of patient safety, e.g., medication errors, time to treatment, but have not evaluated the impact of these processes on patient clinical outcomes (Amaral, 2020; Blazin et al., 2020; Desmedt et al., 2020).

A primary contributor to the lack of information on the clinical effectiveness of standardized communication tools is not only the heterogeneity of the tools themselves but also the manual nature of the data collection systems supporting the tools (Arsoniadis, 2020). The repository, transactional structure of EHRs has been reported as a major factor not only in medical errors involving patient misdiagnosis, but also in provider burnout and moral injury (Adler-Milstein et al., 2020; Ellis et al., 2020; Williams, 2021). Health informatics methodology, designed to identify, capture, and analyze relevant data from the electronic health record (EHR), is needed to compare medical effectiveness of algorithm variations and generate evidence on which to base recommendations regarding best practices in communications (Casey et al., 2020; Caudell-Feagen & Thompson, 2021; Glaser, 2020; Strizich & Kim, 2021). Researchers have reported the utility of transactional EHR data, e.g., dashboards, in the improvement of diagnostics test utilization and screening test follow-up (Krasowski et al., 2015: Shanbhag & Bender, 2020; Sivashanker et al., 2021). However, much developmental work remains to be done in clinical research and IT methodology before the integration of clinical outcomes with the

transactional record to create electronic, searchable clinical summaries for care continuity (Safety II) becomes feasible (Arsoniadis, 2020; Glaser, 2020; Weiskopf & Weng, 2013).

Non-MLP healthcare providers have signaled the need for assistance in navigating all phases of the diagnostics testing process, i.e., pre-analytic, analytic, and post-analytic (Hickner et al., 2014; Laposata & Cohen, 2016; Procop et al., 2019; Schmidt et al., 2014; Strizich & Kim, 2021). With the increasingly frequent application of business operations dashboard structure to quality indicator tracking, application programming interfaces and middleware have been developed to support consultation modules within pathology practice (Church & Naugler, 2020; Rashidi et al., 2019; Schmidt et al., 2014; Stendhl et al., 2021; Theparee et al., 2018). Most of these modules are designed for anatomic pathology practice and involve artificial intelligence/machine learning approaches to image interpretation (Church & Naugler, 2020; Rashidi et al., 2019). Some however, address Safety II aspects of diagnostics consultation questions. The CL-based consultation modules reviewed are a blend of manual and digital processes; addressed convenience samples of post-analytic questions only; provided no guidance on IPT reporting, tracking, or work process analyses; and involved pathologists and pathology residents only (Schmidt et al., 2014; Stendhl et al., 2021; Theparee et al., 2018).) The design of these CL-based consultation modules, though commendable initial efforts, do not incorporate the other error reporting, mitigating, and feedback functions of the CL, e.g., incident report follow-up, evaluation of reference test requests, optimization of test orders. Much of this additional CL consultation work is conducted by MLP non-physicians and provides the CDS evidence base for the majority of health providers (Hickner et al., 2014; Procop et al., 2019). In order to fully

achieve the goals of the NAM Quality Aims and TJC and CAP communications standards, a more robust CL-based consultation system is needed to address both interlaboratory and system-wide communications.

Documenting and characterizing the consultations of all medical laboratory professionals (MLP, i.e., physicians and clinical laboratory scientists associated with the clinical laboratory) with other healthcare practitioners could contribute significantly to Safety II objectives by providing real time evidence for the types of clinical issues consuming substantial human and material clinical laboratory resources, i.e., DCM© Arm 1 of the Clinical and Quality Research Program. DCM© components associated with Arm 1 of the DCM© Research Program are outlined in Figure 8.

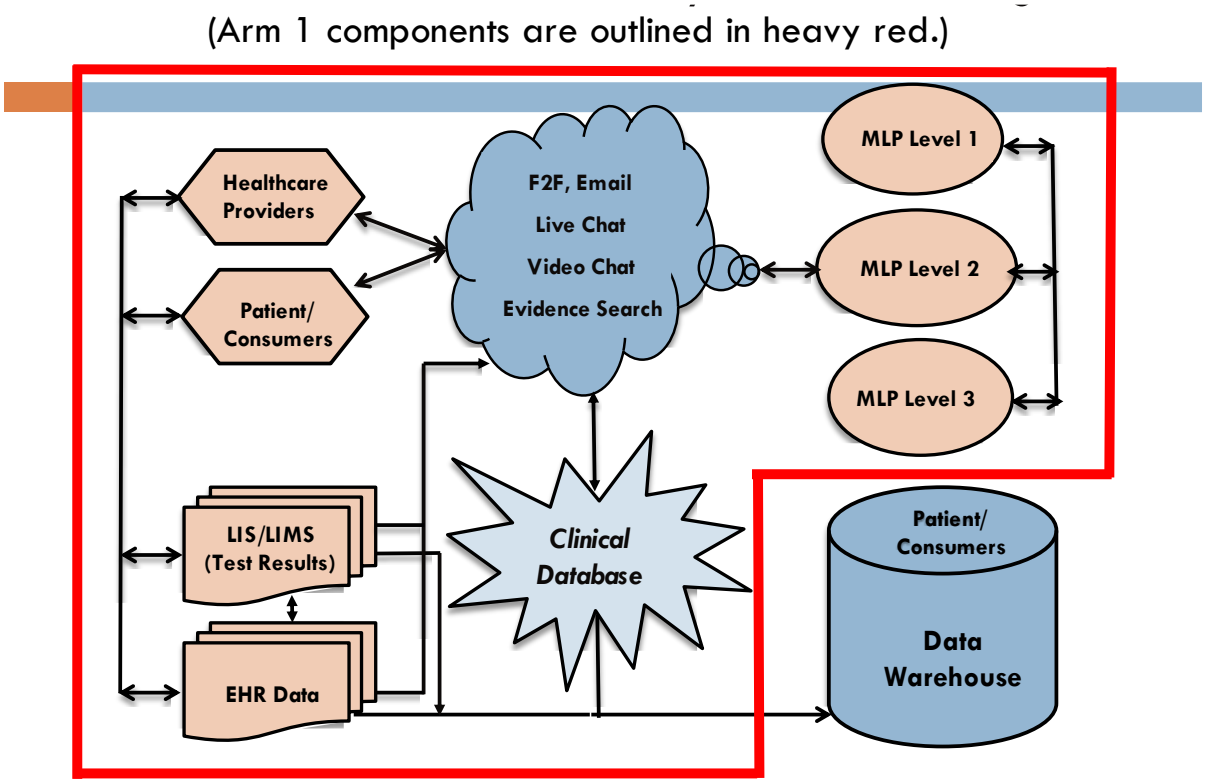


Figure 8. DCM© Components of Arm 1 of the DCM© Clinical and Quality Research Program. Information flows through component work processes linking analytic and clinical data for purposes of evidence based clinical and quality improvement.

Analysis of these data, addressed in Arm 2 of the DCM© Clinical and Quality Research Program, could identify priority, resource-intensive diagnoses and conditions from the vantage point of the clinical laboratory. DCM© components associated with Arm 2 of the DCM© Research Program, i.e., the clinical database and patient/consumer data warehouse, are outlined in Figure 9. The order of priority of these diagnoses (Arm 1) could then be compared to priority diagnoses and chronic diseases documented enterprise-wide (Arm 2). Quality improvement studies targeted toward development of diagnostics algorithms could then be designed for the priority diagnoses in common to both of the DCM© Research Arms.

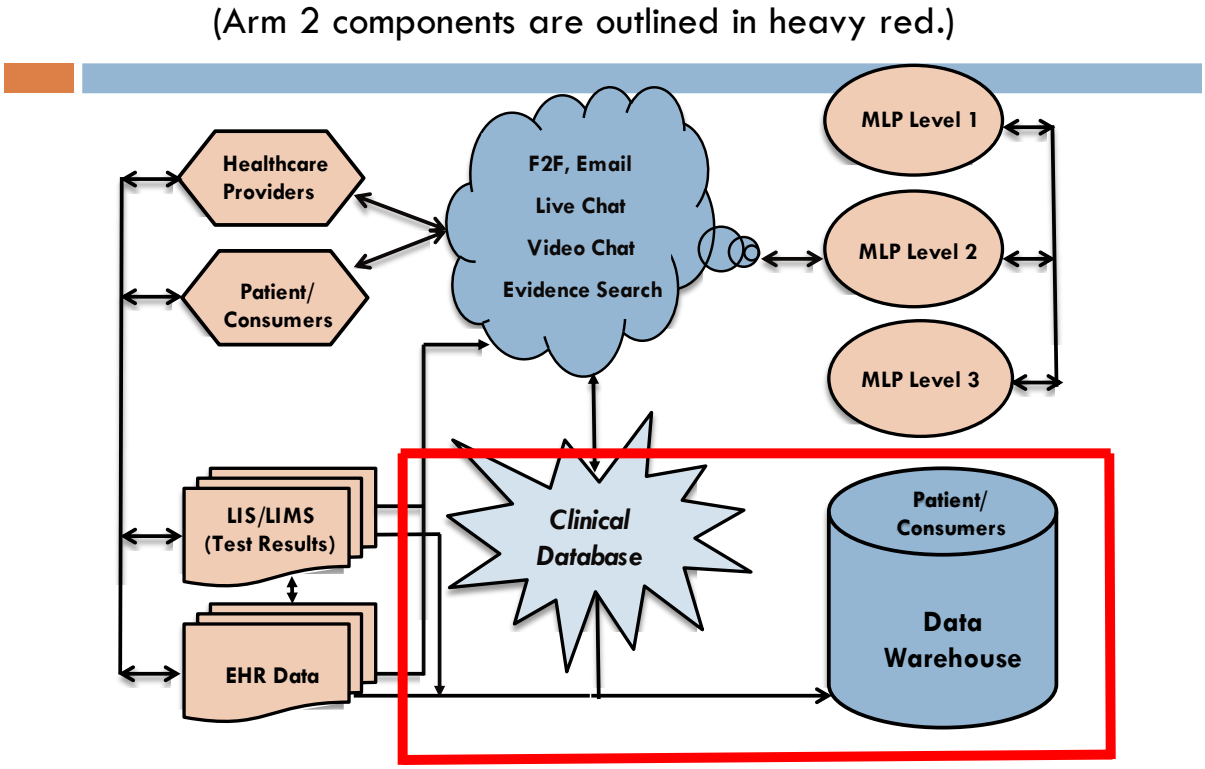


Figure 9. DCM© Components of Arm 2 of the DCM© Clinical and Quality Research Program. Information flows through component work processes linking analytic and clinical data for purposes of evidence based diagnostics algorithm development

Once developed, these ordering algorithms could be applied to the real time monitoring of patients with priority diagnoses. If ordering patterns in individual patients differ significantly from documented "standard" clinical pathways (test ordering algorithms derived from EHR-mined utilization data), MLP would investigate analytic and non-analytic circumstances contributing to the variances, intervening when appropriate to address emergent patient safety and care concerns. Recently, collection and warehousing of clinical information extracted from the EHR for digital analysis has been accomplished through the use of clinical dashboards (Kudler & Pantanowitz, 2010; Lippi et al., 2015; Luo et al., 2016; Mashinchi et al., 2020; Mercer

et al., 2018; Naugler & Church, 2019; ONC, 2020; Plebani et al., 2019; Procop et al., 2014; Rosenbaum & Baron, 2018; Rudolf & Dighe, 2019; Stockbine et al., 2020; Whitehead et al., 2019b). This monitoring and patient safety activity would become standard of care for the laboratory (Leibach, 2011).

Evidence based practice (EBP), and the operationalization of MLP EBP, has emerged as the applied methodology guiding clinical and quality studies identifying priority diagnoses for value-based improvement (Leibach, 2010; Leibach, 2011). Documenting and characterizing MLP consultations through a communications portal interfacing with other healthcare practitioners should be designed, implemented, evaluated, and maintained as a foundational part of these institutional quality plans.

The Diagnostics Consultation Model©: The Framework of the Study

The overarching goal of this work is to describe the Diagnostics Consultation Model© (DCM©), a clinical laboratory (CL) communications portal, designed and proposed to support clinical decision making (CDM) within interprofessional teams, providers, and institutions. The DCM© frames the theoretical and applied constructs of quality, clinical research, evidence based practice, and clinical decision support necessary to address the associated diagnostics communications workflow. The study's research questions address the probability of developing an accurate diagnostics workflow prediction model, i.e., the complexity index (CI), to direct consultation requests to MLP practice levels with requisite education, CT competencies, and experience to resolve consultations accurately, thoroughly, and efficiently. The data involved in developing and evaluating the CI were gathered from real world consultation experiences of

various levels of MLP practitioners in the clinical laboratory. These data will be analyzed to determine the MLP levels of education, CT competencies, and work experiences best suited to address consultations of differing complexities. Further, the DCM© framework suggests workflow pathways for CDS communications among IPT members, individual healthcare providers, and among institutions that accommodate various complexities encountered in diagnostics consultation processes.

CHAPTER 3

RESEARCH DESIGN AND METHODOLOGY

The study's research questions address the probability of developing an accurate diagnostics workflow prediction model, i.e., the complexity index (CI), to direct consultation requests to MLP practice levels with requisite education, CT competencies, and experience to resolve consultations accurately, thoroughly, and efficiently. The data involved in developing and evaluating the CI were gathered from real world consultation experiences of various levels of MLP practitioners in the clinical laboratory. Data were collected describing consultation characteristics as well as workflow processes involved in consultation resolution. Initial analyses, proffered in the pilot study, answered broad research questions addressing documentation of CL consultation occurrence, consultation characteristics, and the association of these characteristics with different MLP practice levels. The dissertation study built on pilot study findings with focused research questions related to prospective prediction of MLP practice levels best suited to address consultations of differing complexities using consultation characteristics available upon consultation initiation.

The Pilot Study Summary

Pilot and dissertation study analyses were conducted on the same dataset with development of the dissertation study research questions guided by findings from the pilot study. The full and complete pilot study report is included as Appendix B; a summary is presented here.

Pilot study purpose. To begin to address the CL knowledge and practice gap related to diagnostics consultation, an exploratory pilot study, the "Clinical Laboratory Performance Measures Project," was conducted to document and characterize MLP involvement in consultation with other healthcare providers. From analysis of these consultation interactions, the impact of laboratory information in clinical decision making was measured and thus evidence was provided regarding the role of MLP consultations in clinical decision support (CDS). The project addressed research questions regarding aspects of the role of MLP in CDS through the implementation of an electronic (and also paper) data collection log for capturing important aspects of consultations among MLP. Characterizing these consultative interventions and analyzing their complexity and medical subject focus led to the identification of consultations that impact (and vary with) CDS.

Pilot study research questions. The following research questions were investigated:

(1) What are the characteristics of MLP consultations with other healthcare providers as categorized by area of the clinical laboratory involved; time of day requested; medical service/hospital location; urgency; healthcare provider type initiating the consultative event; consultation type (i.e., phase of test cycle in question); number of handoffs/logic steps; and medical subject area?

(2) Which consultation characteristics, i.e., area of the clinical laboratory involved; time of day requested; medical service/hospital location; urgency; healthcare provider type initiating the consultative event; test cycle phase involved); number of handoffs/logic steps; and medical subject/hospital location, are associated with MLP practice level involved in final

consultation disposition? The related hypothesis is that some conditions and levels of the independent variables are associated with the MLP practice level involved in the final disposition of consultations.

Pilot study design and methods.

Clinical laboratory data collection log development. MLP managers and clinical pathology section chiefs (also considered MLP) were asked to participate in study instrument design, piloting, implementation, analysis, and evaluation.

Population definition and sample characteristics. The study population was defined as all documented interventions (consultations) between MLP and other healthcare providers (hospital-based users of laboratory information) in a 600-bed, tertiary care hospital affiliated with an academic medical center. Both electronic and face-to-face interactions were considered as consultations. Data on 325 consultation events, i.e., N=325 consultation cases, were recorded during the 11-week data collection period.

The CL data collection log (Appendix A) was completed by participating MLP during the normal workday (24 hours per day, 7 days a week) as consultations occurred. MLP consultations were described demographically by CL area, date/time, medical service/hospital location, urgency status, type of provider initiating the consultation intervention, number of handoffs/logic steps, and testing cycle phase, i.e., pre-, post-, and analytic, to which they related.

Data abstraction procedure. Algorithms for variable recoding to increase power for analyses were developed from granular data as defined in Table 2. The original categories are

shown in Figure 10. Further, a data abstraction table was created for recording additional assessments derived from the statistics data table.

Table 2

Summary of Category Transformation Algorithms in the Pilot Study

Variable	Initial Number of Levels	Transformed (Recoded) Number of Levels
CL Area	12	0 = Professional Knowledge (non-specimen receiving areas)
		1 = General Knowledge (specimen receiving area)
Provider Type	7	0 = Non-RN
		1 = RN
Test Cycle Phase	7	1 = Pre-analytic (test select, place order, collect/ID/transport)
		2 = Analytic (specimen analysis)
		3 = Post-analytic (obtain result, results logic, other)
Handoffs/logic steps	5	1 = One logic step, no handoffs
		2 = Two hand-offs/logic steps
		3 = Three or greater handoffs/logic steps
MLP Practice Level Consultation Disposition	6	1 = MLP Level 1 (MLP complete, one logic step and no handoff)
		2 = MLP Level 2 (Referred to MLP/MLP Manager)
		3 = MLP Level 3 (Referred to physician to include pathology resident, pathologist, and medical resident/attending physician)

These additional assessments, i.e., number of handoffs/logic steps, MLP practice level disposition, and medical subject categories, were qualitatively derived from "consultation summary," "forward," and "reviewer comments" entries in the consultations data collection log (Appendix B). Resultant definitions of handoffs/logic steps and MLP practice level disposition

categories are given in Table 3. Medical subject categories were derived from a thematic analysis of consultation topics as reported in the consultation summary and reviewer comments sections, also shown in Table 3.

Table 3

Pilot Study Original Categories and/or Non-recoded Consultation Characteristics Summary

Original Categories and/or Non-recoded Consultation Characteristics (IV) N = 325	IV Frequency	IV Percent
Clinical Laboratory Area Involved	n = 278	100
Chemistry	63	23
Clinical Pathologists/ Residents	42	15
Immunology/Send Outs	35	13
Outpatient (Medical Office Building)	3	1
Point of Care Testing	40	14
Receiving	95	34
Missing Data: % = (1.00 – n/N) x 100	47	14
Time of Day Initiated	n = 182	100
8 a.m. – 12 p.m.	37	37
1 p.m. – 4 p.m.	37	37
Other	26	26
Missing Data: % = (1.00 – n/N) x 100	143	44
Medical Service/Location Origin	n = 270	100
Emergency Department	28	10
Chemistry (Clinical Laboratory)	23	9
Other	219	81
Missing Data: % = (1.00 – n/N) x 100	55	17
Urgency	n = 278	100
Routine	191	69
STAT	87	31
Missing Data: % = (1.00 – n/N) x 100	47	14
Healthcare Provider Type	n = 289	100
RN	143	51
Other (administrators, MLP, medical students, pharmacists, physicians, respiratory therapists)	135	49
Missing Data: % = (1.00 – n/N) x 100	47	14
Consultation Type (Test Cycle Phase Involved)	n = 278	100
Pre-analytic: Test Select, Place Order, Collect/ID/Transport	137	49
Analytic: Test Parameters	86	31
Post-analytic: Obtain Result, Results Logic, Other	55	20
Missing Data: % = (1.00 – n/N) x 100	47	14
Medical Subject	n = 278	100
Education	3	1
Genetics/Molecular	6	2
Technology Decisions	16	6
IT Ordering	96	35
Pediatric Genetics/Molecular	5	2

Results Resolution	75	27
Patient Safety/Identification	36	13
Test Integration/Evaluation	19	7
Proficiency Testing	3	1
Specimen Referral/Send Out	19	7
Missing Data: % = (1.00 – n/N) x 100	47	14

Each of the 325 recorded consultation events was assigned to a medical subject category defined as either: (1) education, (2) genetics/molecular, (3) technology decisions, (4) information technology/ordering, (5) pediatric genetics/molecular, (6) analytic results resolution, (7) patient safety/identification, (8) test methodology integration/evaluation, (9) proficiency testing, or (10) specimen referral/send out. The "comments" field was used to record free-form comments related to issues arising from the consultation CDS process itself, or documentation from it.

Pilot study results.

Characterization of consultation requests (question 1). Data were collected on seven characteristics (independent variables, IV): (1) CL area involved, (2) date/time, (3) medical service/hospital location, (4) urgency, (5) healthcare provider initiating the consult, (6) consultation type, i.e., testing cycle phase related to the consultation, and (7) number of handoffs/logic steps. Consultation characteristics are reported in Table 3.

Definition of MLP practice level consultation disposition. Consultation disposition was defined as the MLP practice level involved in final consultation resolution and was originally assigned into one of four categories. Most consultations, 77% (214/278), were completed at the time of initial contact with a MLP, e.g., by phone or in person, without the need for further investigation; further investigation is defined as additional handoffs or logic steps

requiring additional consultation with MLP practice levels 1-3 (MLP, MLP manager/technical specialist, and/or MD/PhD/DCLS. Non-MLP practitioner consults were documented but non-MLP practitioners were not considered a MLP practice level because workflow processes demonstrated that clinical information from non-MLP practitioners supported decision making by MLP Practice Level 3. Therefore, for further future analyses, these non-MLP consult frequencies were combined with MLP practice level 3 frequencies for a final total of three MLP practice levels. Frequencies for all disposition categories are shown graphically in Figure 10.

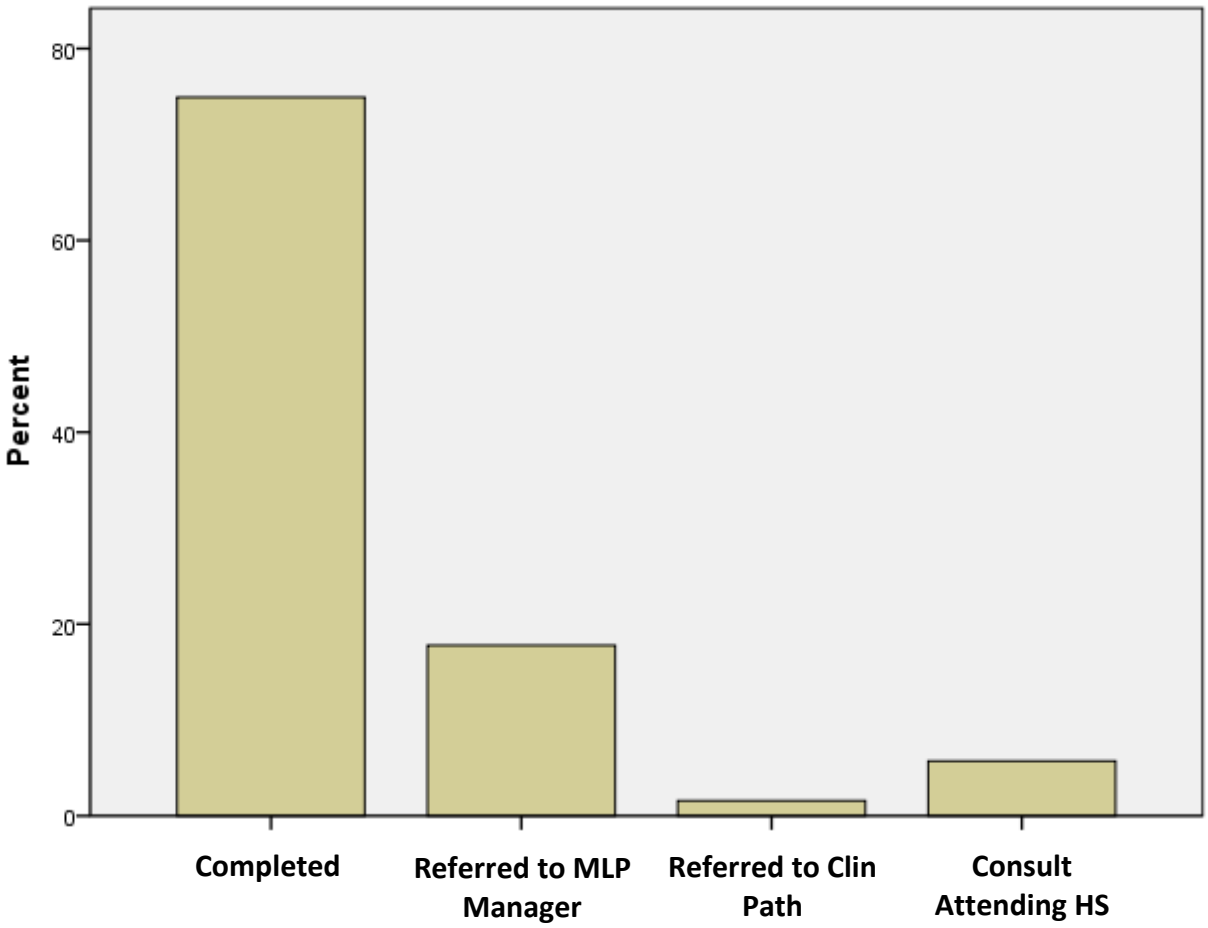


Figure 10. Frequency of Consults by MLP Final Disposition Category:
MLP Practice Level 1: "Completed" = 77% (214/278 consults)
MLP Practice Level 2: "Referred to MLP Manager" = 15% (41/278 consults)
MLP Practice Level 3: "Referred to Clin Path" = ≤1% (2/278 consults)
Non-MLP Practitioner: "Consult Attending/HS" = ≤2% (6/278 consults)

Definition of consultation handoffs/logic steps. Pilot study data indicated that even though consultation resolution could require multiple handoff/logic steps among multiple individuals within each MLP practice level (i.e., up to 5), most consultations were resolved with three or less handoffs/logic steps. Because of the low numbers of handoffs/logic steps in

categories 4 and ≥ 5 handoffs/logic steps, variable values were recoded into three categories: category 1, 1 logic step; category 2, 2 handoffs/logic steps; and category 3, ≥ 3 handoffs/logic steps. See Table 2.

Consultation characteristics related to consultation disposition (question 2).

Transformation of medical service area data resulted in 11 medical services to be used in analyses on this variable. See Table 4. In addition, two of the seven variables, i.e., date/time and urgency, did not correlate with MLP practice level disposition. Analyses using date/time and urgency were, therefore, not considered as potential predictor variables. Provider type was removed from consideration as a predictor of MLP practice level consultation disposition because missing data analysis resulted in significant mean differences between all cases and cases with missing data eliminated. The variable, clinical laboratory area, was also excluded from consideration as a predictor of MLP practice level consultation disposition due to data collection limitations rather than missing data. Major CL areas for consultation, e.g., transfusion service, microbiology, and hematology/coagulation, did not participate in the pilot study due to work force shortages. Though data from the remaining participating CL areas is informative from methodology and processes perspectives, conclusions drawn related to MLP practice level and resources utilized in these areas would not be generalizable to the larger CL and potentially misleading if reported.

Table 4.

Summary of Medical Service Transformation Algorithms

Original Medical Service Areas	Consultation Number (Original Areas)	Medical Service Area Transformations	Transformed Medical Service Areas	Consultation Number (Transformed Areas)
1, Allergy	1	37, Other		
2, Cardiology	14		1, Cardiology	14
3, Cardiac CCU	0			
4, Dermatology	0			
5, Endocrinology	0			
6, ENT (Otolaryngology)	0			
7, Emergency/ Trauma	58		2, Emergency/ Trauma	58
8, Family Medicine	9		3, Family Medicine	9
9, Gastroenterology	0			
10, Geriatrics	0			
11, Gynecology	0			
12, Hematology	1	10, Oncology		
13, Infectious Disease	0			
14, Medicine (Gen)	0			
15, Medicine (Other)	0			
16, Med ICU	3		4, ICU:	30
			3 (Medicine)	
			6 (Neurology)	
			4 (Nursery)	
			10 (Pediatrics)	
			7 (Surgery)	
17, Nephrology	0			
18, Neurology	2	37, Other		
19, Neuro ICU	6	16, Med ICU		
20, Nursery	0			
21, Nursery ICU	4	16, Med ICU		
22, Obstetrics (L&D)	34		5, Obstetrics	34
23, Oncology	10		6, Oncology	10
24, Ophthalmology	0			
25, Orthopedics	0			
26, Pediatrics	24		7, Pediatrics	24
27, Pediatrics ICU	10	16, Med ICU		
28, Pulmonology	1	37, Other		
29, Rheumatology	0			
30, Surgery (Gen)	18		8, Surg Gen	18

31, Surgery (Other)	13		9, Surg Other:	21
			13 (Other)	
			8 (Transplant)	
32, Surgery ICU	7	16, Med ICU		
33, Telemedicine	0			
34, Transplant	8	31, Surgery (Other)		
35, Urology	0			
36, Clin Lab	59		10, Clin Lab	59
37, Other	40		11, Other:	44
			40 (No Service Noted)	
			1 (Allergy)	
			2 (Neurology)	
			1 (Pulmonology)	

The remaining potential predictor variables, i.e., consultation type (test cycle phase), number of handoffs/logic steps, medical service/hospital location, and medical subject were then assessed for their association with MLP practice level consultation disposition. A series of crosstabulations were conducted using the potential predictor variables against the DV, MLP practice level, i.e., levels 1-3, resolving the consultation case. The resulting contingency table gives both the significance (Pearson's Chi-square) as well as strengths (Cramer's V) of the relationships among variables. The results of these crosstabulations are given in Table 5.

Table 5.

Statistical Inferences Among Variables Predicting MLP Practice Level Consultation Disposition

Crosstabulation	Inferential Statistics							
MLP Practice Level Disposition (3 Levels) by:	Pearson Chi-Square			Likelihood Ratio			Cramer's V	
	Value	df	Sig[a]	Value	df	Sig[a]	Value	Sig[a]
Test Cycle Phase[b]	32.387	4	≤ .01	28.533	4	≤ .01	.227	≤ .01
Medical Subject[c]	98.390	18	≤ .01	74.838	18	≤ .01	.396	≤ .01
Medical Service[d]	30.733	20	.059	39.479	20	.006	.218	.059
Handoffs/Logic Steps[e]	97.166	4	≤ .01	122.713	4	≤ .01	.393	≤ .01

[a] Asymptotic significance
[b] Test cycle phase = Consultation type, 3 levels (Pre-analytic, Analytic, Post-analytic)
[c] Medical Subject = 10 levels (Education, Genetics/Molecular, Technology Decisions, IT Ordering, Peds Genetics/Molecular, Results Resolution, Safety/ID, Test Integration/Evaluation, Proficiency Testing, Specimen Referral/Transport)
[d] Medical Service/Hospital Location = 11 Levels (Cardiology; Emergency/Trauma; Family Medicine; ICUs; Obstetrics; Oncology; Pediatric; Surgery, General; Surgery, Other; Clinical Laboratory; Other)
[e] Handoffs/Logic Steps = 3 levels (completed with one logic step, no handoff; two handoffs/logic steps; ≥3 handoffs/logic steps)

Findings from these crosstabulations corroborated that four predictor variables, test cycle phase, medical service/hospital location, medical subject, and handoffs/logic steps, were significantly associated with MLP practice level resolving consultations (Pearson's Chi-square and likelihood ratio statistics) and that the strengths of the relationships were strong (Cramer's V statistics). Medical service, though not significantly correlated (p=.059) with MLP practice level disposition with 95% confidence, nevertheless, showed potential enough (likelihood ratio=.006)

to be tested further in the CI regression model with test cycle phase. In addition, not all 11 medical service areas were found to be significant in the model. Further analyses determined which medical services did not contribute to the model; those were removed and correlation significance increased.

Diagnostics Consultation Model© research program construction. In the pilot study, MLP consultation characteristics, e.g., test cycle phase, CL area, other health professionals involved, medical service, medical subject, were described for the first time. Then correlations of these characteristics with final consultation disposition by MLP practice type were considered. The dissertation study builds on these correlations to question if certain characteristics correlating with disposition by MLP practice type can predict workflow to the correlated MLP practice types and suggest a communication strategy for consultation response both within the clinical laboratory (intralaboratory/interlaboratory) and among health providers throughout the health system.

The Study

Analyses from crosstabulations of pilot study data indicate that MLP practice level consultation disposition can be predicted by test cycle phase, medical subject, medical service, and number of handoffs/logic steps required to resolve the consultation clinical question. These findings suggested the opportunity for further explorations in focusing laboratory information for targeted clinical decision support (CDS) in patient/consumer care. Specifically, direction of resources to appropriately prepared MLP practice level for consultation disposition could be based on some combination of the four predictor variables correlated with MLP practice level

disposition. Thus, a prediction model for allocation of appropriate resources based on consultation characteristics was developed. These linkages also suggested the design of evidence based operational processes, e.g., workflow direction through a communications portal, for optimization of consultation resolution assessed by improvement in clinical and quality outcomes.

Study design. The study was designed to further characterize consultations by developing methodology to predict the MLP practice level most appropriate to resolve a consultation case by using consultation descriptors available at the point of consultation initiation. Pilot study findings suggested, further, that MLP practice levels resolving consultation cases were correlated with other descriptors available only after consultation completion. The descriptors available after consultation completion were used to test the predictive performance of the methodology developed using descriptors collected at the point of consultation initiation, i.e., pre-consultation.

Study aims. The study explored relationships among consultation case data and the MLP practice levels resolving those consultations by investigating patterns in consultation resolution that were hypothesized to predict the appropriately skilled MLP practice level most prepared to address the consultation case. Findings from these analyses advance the capabilities of clinical laboratory scientists to implement evidence based practice efficiently and effectively through consultation.

Research question 1. Can the MLP practice level resolving consultations be predicted by an index derived from the variables test cycle phase and medical service/hospital location?

H_1: MLP practice level resolving consultations can be predicted by an index derived from the variables test cycle phase and medical service/hospital location. The CI adjusted to different variance contributions of the two individual predictors and described the MLP practice level resolving the consultation more consistently than the individual predictor variables alone.

Aim 1. Three MLP practice levels have been associated with consultation final disposition: (a) MLP Level 1, MLP; (b) MLP Level 2, MLP/MLP Specialist/Manager; and (c) MLP Level 3, clinical pathologist/resident/MD. Using data from consultation events occurring in a variety of clinical settings, consultation cases were characterized by MLP practice level resolving consultations using test cycle phase and medical service/hospital location as predictors. A complexity causal model was developed from these two predictor variables to represent the composite variable, complexity index (CI).

Research question 2: Can MLP practice levels resolving consultations be predicted by number of handoffs/logic steps and medical subject associated with consultation cases?

H_2: MLP practice levels resolving consultations can be predicted by number of handoffs/logic steps and medical subject associated with consultation cases. These variable values, available only after consultation completion, defined a typology of increasing scope of knowledge and professional responsibility represented by MLP practice levels, 1-3.

Aim 2: Analyses of relationships among MLP practice levels and number of handoffs/logic steps required for consultation resolution and medical subject involved were

undertaken, also. These variable values, number of handoffs/logic steps and medical subject, were available only after consultation resolution and predicted the same or similar MLP practice level resolving consultations as the prediction model using IVs available at the point of consultation initiation, i.e. pre-consultation. A comparison of the pre-consultation completion and post-completion models was used to validate the prospective predictive performance of the CI.

Study method. Study analyses progressed guided by these steps:

1. The consultation cases sample size (N=325) was considered large enough to power analyses supporting the research questions of the study. Data were cleaned by evaluating missing data, outliers, normality, and linearity. In preparation for regression analyses, homoscedasticity and independence of residuals were also assessed. Power analyses were performed from the determination of the ratio of cases to IVs.
2. MLP practice levels responsible for consultation resolution were defined in the pilot study by analyses of final consultation disposition/resolution. MLP practice levels defined are (a) MLP Level 1, MLP; (b) MLP Level 2, MLP/MLP Specialist/Manager; and (c) MLP Level 3, clinical pathologist/resident/MD.
3. A diagnostics workflow prediction model, the complexity index (CI), was developed using the independent variables, test cycle phase and medical service/hospital location, and dependent variable, MLP practice level. The predictive performance of the complexity index was then evaluated against variable values available after consultation completion, i.e., numbers of handoffs/logic steps and medical subject, that also correlated with MLP practice

levels involved in consultation final disposition, i.e., MLP Levels 1-3. The CI predicted similar MLP practice levels from both datasets, i.e., the independent variables available at the point of consultation initiation and those available after consultation completion.

4. These findings formed the basis of methodology to identify work processes optimizing workflow through the Diagnostics Consultation Model© communication portal. The methodology described the development of a complexity index that is intended to function, at the point of consultation initiation, to direct work orders to the MLP practice level with the competency and experience skill set most closely aligned with the resources required for resolution of the consultation case.

In summary, a complexity index was developed from consultation case data related to test cycle phase and medical service/hospital location from which the consultation request originated. Then MLP practice levels were described by number of handoffs/logic steps and medical subject involved in consultation resolution. These MLP practice level descriptors, documented after consultation completion, defined a typology of increasing scope of knowledge and professional responsibility represented by MLP practice levels 1-3. The complexity index predicted the same or similar MLP practice levels from the variables collected at the point of consultation initiation (pre-consultation) as from those available after consultation completion.

Research question 1: study analyses. The research question related to the first aim is: Can the MLP practice level resolving consultations be predicted by an index derived from the variables test cycle phase and medical service/hospital location? Index variables (test cycle phase and medical service area, i.e., independent variables, IV) were modeled with the MLP practice

level involved in final consultation disposition (dependent variable, DV) to create the composite predictor variable, complexity index.

1. Research question 1, qnalysis 1: Analysis 1 defined the complexity index by predicting the relationship among the predictor variables, test cycle phase and medical service/hospital location, and the dependent variable, MLP practice level (levels 1-3) involved in consultation disposition. There were 2 IVs for this analysis: (1) test cycle phase (3 levels: pre-analytic, analytic, post-analytic) and (2) medical service area (11 levels, see Table 4 for medical service/hospital location categories). These IVs entered the regression model together to distinguish the DV, MLP level involved in consultation disposition. The regression equations follow:
    a. Modeling with Test Cycle Phase:

       MLP practice level = Test Cycle Phase (cyclic phases treated as continuous variables).
    b. Modeling with Medical Service/Hospital Location:

       MLP practice level = Test Cycle Phase + Medical Service/Hospital Location (add each service, one by one).
2. Research question 1, analysis 2: The full regression model defined the complexity index. Candidate IVs included those categories of medical service/hospital location found statistically significant with 95% confidence in the last step of the analysis. The model is:

   MLP practice level = Test Cycle Phase + Medical Service/Hospital Location (best predictors).

All the regression models were evaluated using Multiple R^2 and its associated p value along with standardized beta weights for each of the IVs in the models.

Research question 2, study analyses. Handoffs/logic steps and medical subject were the variables documented after consultation completion that correlate with MLP practice level. These variables were tested to develop a model predicting the level of human resources required to resolve consultation queries (i.e., MLP practice level) using these variable values available after consultation completion.

1. Research question 2, analysis 1: Define the post-consultation completion predictive model by testing the relationship among the IVs, handoffs/logic steps and medical subject, and the dependent variable, MLP practice level (levels 1-3) involved in consultation disposition. There were 2 IVs for this analysis: (1) handoffs/logic steps with 3 levels (completed with one logic step, no handoff; two handoffs/logic steps; ≥3 handoffs/logic steps) and (2) medical subject (10 levels). See Table 3 for medical subject categories. These IVs entered the regression model together to distinguish the DV, MLP level involved in consultation disposition. The regression equations follow.
    a. Modeling with Handoffs/Logic Steps:

       MLP practice level = Handoffs/Logic Steps (add each level, one by one).
    b. Modeling with Medical Subject:

       MLP practice level = Medical Subject (add each level, one by one).
3. Research question 2, analysis 2: The full regression equation defined the post-completion prediction model. Candidate IVs included those categories of handoffs/logic steps and

medical subject found statistically significant with 95% confidence in the last step of the analysis. The model is:

MLP practice level = Handoffs/Logic Steps (best predictors) + Medical Subject (best predictors).

All of the regression models were evaluated using Multiple R^2 and its associated p value along with standardized beta weights for each of the IVs in the models.

Study method summary. In summary, methods for continuous clinical and quality improvement of CL CDS consultation services were described in this study. Methods are proposed that, first, describe processes for documentation of characteristics of consultation events occurring in CL operations. Then methodology to develop processes directing workflow (i.e., consultation requests) to appropriately prepared MLP is described that is derived from analyses of these consultation characteristics. This methodology describing processes that direct workflow, i.e., the complexity index, is intended to be incorporated into workflow processes at consultation initiation to increase the efficiency and medical effectiveness of the consultation process by directing consultations to the appropriately prepared MLP. The quality of the workflow direction process can be continuously improved by refining the CI with additional consultation outcomes data.

CHAPTER 4

Results

Study Development, Implementation, and Evaluation Process

Development, implementation, and evaluation of the dissertation study followed the steps of the A6 HCQR Method. In Steps A1-A3 (ASK, ACQUIRE, APPRAISE), assessment of the body of findings from the pilot study detailed in Appendix B led to the refinement of two research questions and study methods formulated to frame analyses to address them. In Step A4 (ANALYZE), analyses were developed that determined the strength of the contribution of consultation characteristics available at the point of consultation initiation to MLP practice level consultation disposition. From these analyses, a diagnostics workflow prediction model, the complexity index (CI), was designed and developed. In Steps A5 (APPLY) and A6 (ASSESS), analyses were conducted and evaluated.

A6 HCQR Steps A1-A3: ASK, ACQUIRE, and APPRAISE

The two research questions investigated were: (1) Can the MLP practice level resolving consultations be predicted by an index derived from the variables test cycle phase and medical service/hospital location? and (2) Can MLP practice levels resolving consultations be predicted by number of handoffs/logic steps and medical subject associated with consultation cases?

The independent variables, test cycle phase and medical service/hospital location, were documented at the point of consultation initiation and thus are meaningful as contributors in a prospective workflow predictive model (i.e., complexity index, CI). The independent variables

handoffs/logic steps and medical subject involved in consultation resolution were documented after consultation completion and define a typology of increasing scope of knowledge and professional responsibility represented by MLP practice levels 1-3, the dependent variable in the analyses.

The complexity index predicts the same or similar MLP practice levels from the variables collected at the point of consultation initiation (research question 1) as MLP practice levels predicted from those available after consultation completion (research question 2). Therefore, the predictive model developed from post-consultation descriptors served to test the predictive performance of the model (CI) developed using descriptors collected at the point of consultation initiation.

Assessment of data fitness. The appraisal of findings included an evaluation of the fitness of the data to support conclusions from analyses addressing the research questions. The dataset was prepared by evaluating accuracy/coding errors, missing data, normality, linearity, and outliers. In preparation for regression analyses, homoscedasticity (homogeneity of variance) and independence of residuals (multivariate normality) were also assessed when appropriate. Power was evaluated *post hoc* by the determination of the ratio of cases on each variable to each IV or DV, also, to further assess statistical conclusion validity. The analytic variables assessed are test cycle phase, medical service/hospital location, medical subject, handoffs/logic steps, and MLP practice level. Medical service/hospital location and medical subject are categorical variables and will be analyzed as such through a binary transformation of each level of the variable. Test cycle phase, handoffs/logic steps, and MLP practice level are ordinal level

measurements but will be analyzed as interval level justified by the relatively large number of cases (N=325) and the assumptions of the central limit theorem (Tabachnick & Fidell, 2007).

Aim 1 analytic predictor variable: medical service/hospital location (categorical level variable). Medical service/hospital location, a categorical variable, was collected in 37 categories or groups, i.e., from 37 medical service areas. Considering major service area divisions and cases in each, these levels were subsequently recoded into 11 levels. Table 4 tracks each step in the transformation from 37 to 11 levels. Two coding errors were resolved, and no missing data were found in the recoded cases after review for accuracy. There are no univariate outliers as all variables are discrete. One of the 11 levels, "other," is comprised of cases with either no medical service unit recorded or represented by less than three cases. Reasoning that none of the cases in this level would prove significant in analyses, the 44 cases in the "other" category were eliminated from further analysis but still considered in the total 325 cases as not originating from one of the other 10 medical services/hospital locations. After elimination of this category, the 10 categories remaining for analysis for aim 1 were represented by cases received from medical services not in this "other" variable category for a total computational number of 325 cases. Homogeneity of variance and normality were then evaluated by examining cell case counts. The smallest number of cases in any category is nine and the largest is 60. According to Tabachnick & Fidell (2007), the smallest cell of a normally distributed categorical variable should be at least 10% the size of the largest cell. Using this criterion for interpretation, the distribution of medical service/hospital location variable can be assumed to be normal in further analyses for aim 1.

Aim 1 analytic predictor variable: test cycle phase (ordinal/interval level variable).

Test cycle phase, an ordinal variable, was collected in seven levels then recoded into three levels for analysis: pre-analytic, analytic, and post-analytic. The pre-analytic level includes activities occurring before analyte testing, i.e., test selection; order placement; and specimen collection, identification, and transport. The analytic level encompasses analytic activities most commonly performed using instrumentation and evaluating computerized outputs. The post-analytic level includes activities occurring after analyte measurement related to documentation and communication of testing results, i.e., obtaining a valid test result, explaining the context of the result, and apprising the end user of additional information needed for interpretation and CDS.

No entry inaccuracies or missing data were found upon review; 325 cases were analyzed. The test cycle phase variable, was found to be both skewed and kurtotic. See Figure 11. The skew was slightly negative, -.703 (with a standard skew error of .135 resulting in a ratio of 5.21), and kurtotic (-1.196 with a standard kurtosis error of .270 resulting in a ratio of 4.43). Normal skew and kurtosis are both defined for this analysis as 3.3. or less (p=.001). The histogram suggested, however, that the distribution was reasonably normal with slight negative skew that might be improved by transformation.

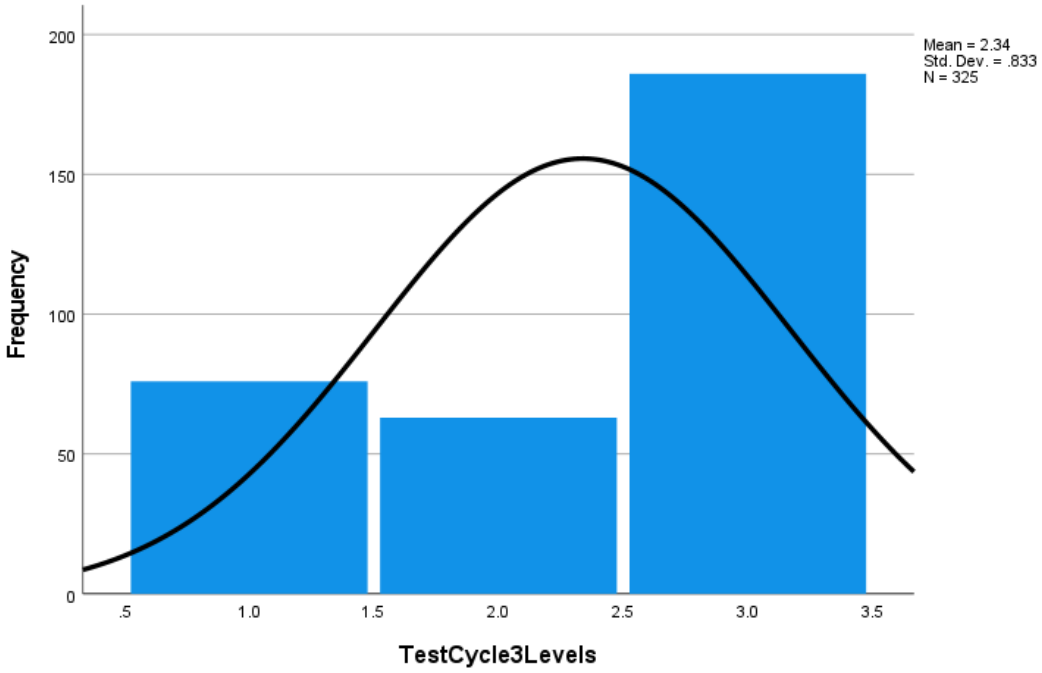


Figure 11. Non-transformed Histogram for the Test Cycle Phase Variable

Square root transformation produced a more symmetric histogram, meaning that skew is closer to 0 (more values closer to the mean), though flatter (more negative kurtosis with less values closer to the mean). Because skew was improved, the square root transformation was adopted for use in the regression model even though the distribution remains non-normal. The square root transformation histogram for the test cycle phase variable is shown in Figure 12.

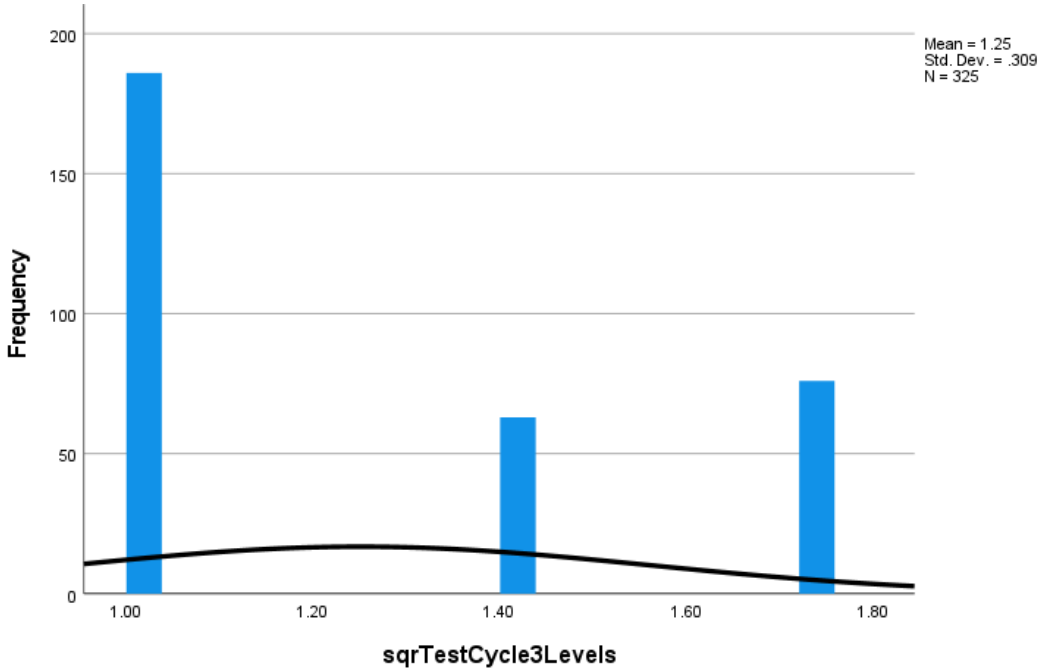


Figure 12. Square Root Transformation Histogram for the Test Cycle Phase Variable

Aim 2 analytic predictor variable: medical subject (categorical level variable). Data on medical subject, a categorical variable, were collected into ten levels defined in Table 3**.** A frequency distribution was reasonable and revealed no coding errors; there are no missing data. There are no univariate outliers as the only values possible for the levels were between one and ten, where each level was transformed into its own binary variable. Homogeneity of variance was evaluated by comparing the category case counts. The medical subjects of "education" and "proficiency testing" had insufficient number of cases to assume a predicted cell size less than or equal to 5 (i.e., 10% or more of the largest cell number) in keeping with the homogeneity of variance and normality assumption (Tabachnick & Fidell, 2007).

Each of the ten category levels was transformed into a binary variable with a code of 1, if the case fit into that category, and a code of 0 otherwise. The number of cases in each of the resulting 10 binary variables was checked against total medical subject cases to verify the accuracy of the transformations. These variables are distributed binomially (bimodally) by definition and, with a sample size of 325, can be assumed to meet the normality assumption vis-à-vis the central limit theorem. In addition, with only two data points, 0 and 1, binary variables are linear by definition. The binary variables in each level were used in regression analyses.

Aim 2 analytic predictor variable: handoffs/logic steps (ordinal/interval level variable). Handoffs/logic steps, an ordinal variable, was collected in five levels then recoded into three levels for analysis: one logic step, no handoffs; two handoffs/logic steps; and three or greater handoffs/logic steps. Because of the low numbers of cases with handoffs/logic steps in the original 4 and ≥ 5 handoffs/logic steps levels, variable values in these two levels were recoded into level three, i.e., three or greater handoffs/logic steps, to conform with the assumptions of homogeneity of variance and normality.

No entry anomalies or missing data were found upon review; 325 cases were analyzed. The handoffs/logic steps variable, was found to be both skewed (-.586 with a standard skew error of .135 resulting in a ratio of 4.34) and kurtotic (-1.034 with a standard kurtosis error of .270 resulting in a ratio of 3.83). Normal skew and kurtosis are both defined for this analysis as 3.3. or less (p=.001). The histogram showed the skew was positive with the statistics and histogram both suggesting a distribution significantly different from normal. The non-transformed histogram for the handoffs/logic steps variable is shown in Figure 13.

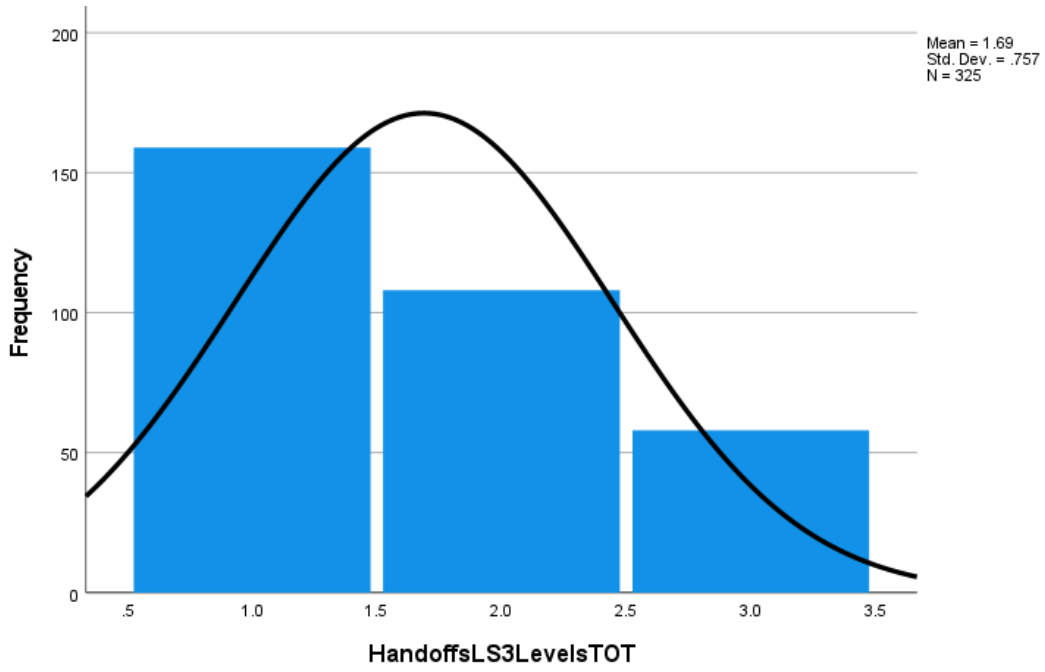


Figure 13. Non-transformed Histogram for the Handoffs/Logic Steps Variable

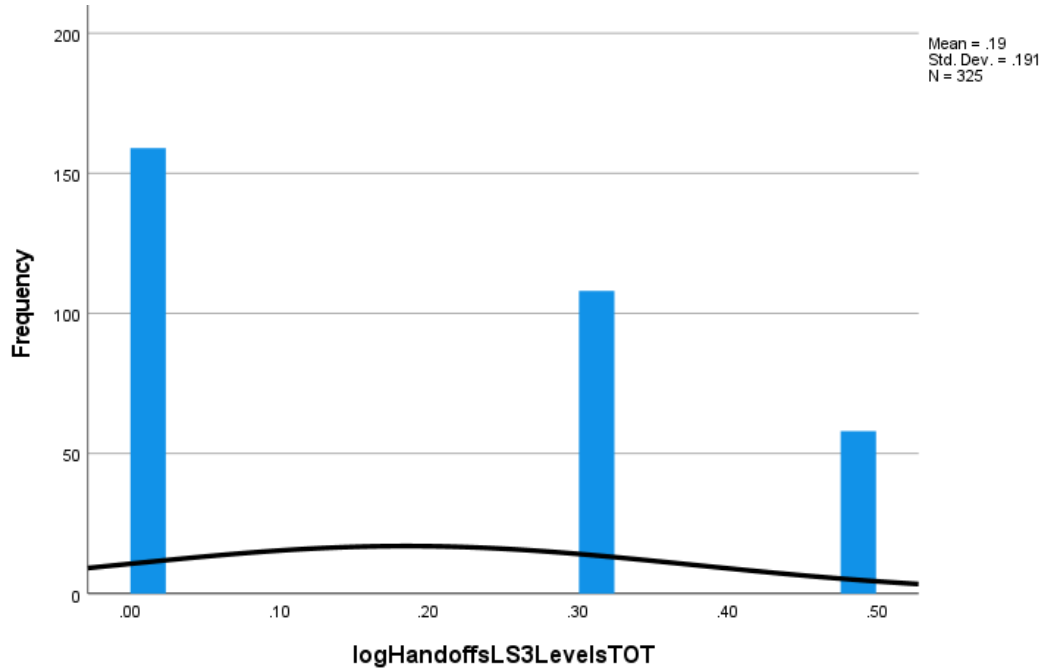
Several methods to improve normality of the distribution of the handoffs/logic steps variable, i.e., log, inverse, and square root transformations, were undertaken (Tabachnick & Fidell, 2007). All of the transformations exhibited increased kurtosis but the log and inverse transforms are the least skewed. Transformation statistics are shown in Table 6. Of these two, the log transformation was the least kurtotic and was adopted for further regression analysis, even though the distribution remains significantly non-normal.

Table 6

Handoffs/Logic Steps Normality Distribution Transformation Statistics

Transform Method	Skewness			Kurtosis		
	Std. Error	Statistic	Ratio	Std. Error	Statistic	Ratio
Square Root	-.782	.135	5.79	-704	.270	2.61
Inverse	-.081	.135	-.60	-1.835	.270	6.79
Log	.267	.135	1.98	-1.551	.270	5.74

The log transformation histogram for the handoffs/logic steps variable is displayed as Figure 14.



Aim 1

Figure 14. Log Transformation Histogram for the Handoffs/Logic Steps Variable

Aim 1 and aim 2 analytic outcome variable: MLP practice level (ordinal/interval level variable). MLP practice level variable, the ordinal dependent variable for both aim 1 and aim 2 analyses, was collected in four levels then recoded into three levels for

analysis: MLP 1 (MLP bench practitioner), MLP 2 (MLP manager or technical specialist), and MLP 3 (MD, PhD specialty scientist, DCLS). Non-MLP practitioner consults were documented and combined with MLP Practice Level 3; workflow processes demonstrated that clinical information from these non-MLP practitioners supported decision making by MLP Practice Level 3. A final total of three MLP practice levels were structured that conformed to the assumptions of homogeneity of variance and normality.

No entry inaccuracies or missing data were found upon review; 325 cases were analyzed. The MLP practice level variable, was found to be both skewed (1.751 with a standard skew error of .135 resulting in a ratio of 12.97) and kurtotic (1.896 with a standard kurtosis error of .270 resulting in a ratio of 7.022). Figure 15 displays the non-transformed histogram for this variable.

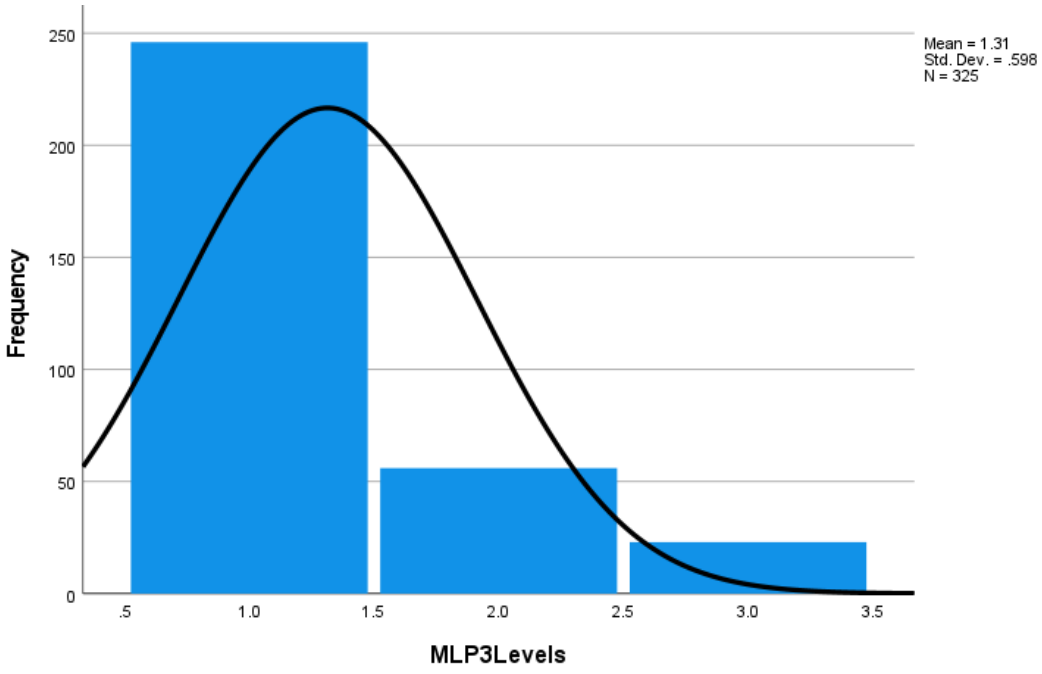


Figure 15. Non-transformed Histogram for the MLP Practice Level Variable

The non-transformed histogram curve is both L-shaped and positively skewed. To address these skewed and kurtotic presentations, both log and inverse transformations were calculated (Tabachnick & Fidell, 2007). Transformation statistics are shown in Table 7.

Table 7

MLP Practice Level Normality Distribution Transformation Statistics

Transform Method	Skewness			Kurtosis		
	Std. Error	Statistic	Ratio	Std. Error	Statistic	Ratio
Inverse	-.081	.135	-.60	-1.835	.270	6.79
Log	.267	.135	1.98	-1.551	.270	5.74

The transformation most approaching normal is the inverse, though the distribution remains significantly non-normal, and was adopted for further regression analysis. The histogram for the inverse transformation of the MLP practice level variable is shown in Figure 16. To be noted, inverse transformations reverse the direction of the scale and, therefore, impact the interpretation of the beta weights in regression analyses.

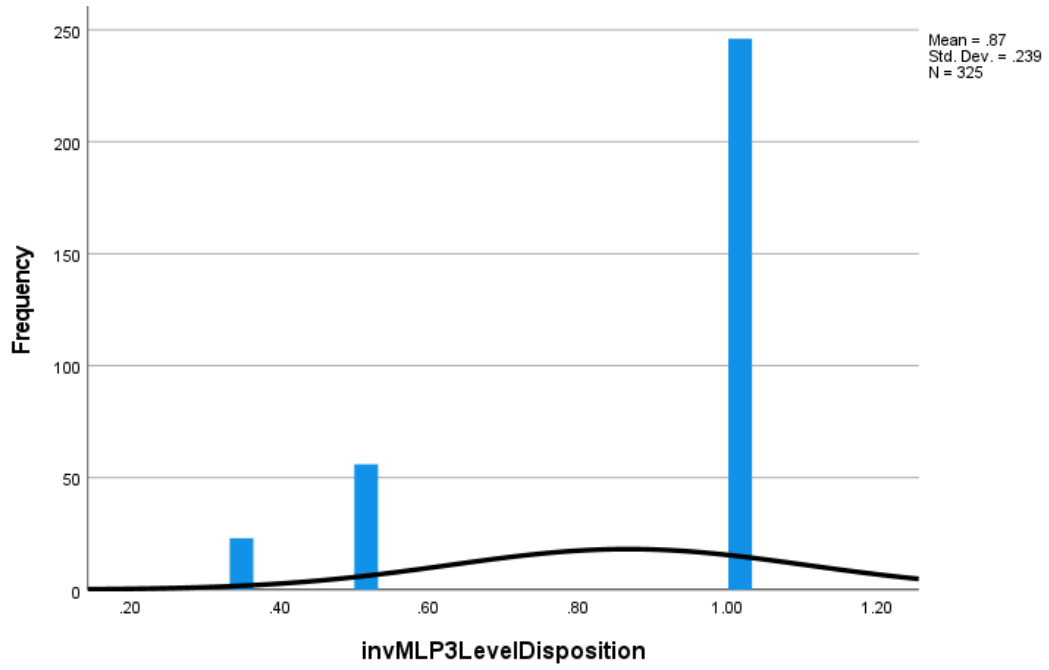


Figure 16. Inverse Transformation Histogram for the MLP Practice Level Variable

A6 HCQR Steps A4-A6: ANALYZE, APPLY, and ASSESS

In Steps A4-A6, first, analyses were developed to determine the strength of the contribution of consultation characteristics available at the point of consultation initiation to the DV, MLP practice level resolving the consultation (aim 1). From these analyses, a diagnostics workflow prediction model, the complexity index (CI), was designed and assessed for its ability to direct consultation workflow in clinical settings to appropriately prepared health professionals. Also, analyses were developed to validate the predictive performance of the CI by assessing the relationship among consultation characteristics available after consultation completion to the three levels of MLP practice (aim 2).

Aim 1 research question 1: step A4 ANALYZE. The research question related to the first aim was: Can the MLP practice level resolving consultations be predicted by an index

derived from the variables test cycle phase and medical service/hospital location? Index variables (test cycle phase and medical service area, i.e., independent variables, IV) were modeled with the MLP practice level involved in final consultation disposition (dependent variable, DV) to create the composite predictor variable, complexity index (CI).

Aim 1 regression analyses assumptions testing. For assumptions testing of the categorical variable, medical service/hospital location, each of the 10 category levels was transformed into a binary variable with a code of 1 if the case fit into that category and a code of 0 otherwise. The resulting 10 binary variables were checked against total medical service/hospital location cases to show that the transformations were accurate. These variables are distributed binomially (bimodally) by definition and, with only two data points, 0 and 1, binary variables are linear by definition. These binary variables were used in subsequent analyses.

Aim 1 regression variables: frequencies. Frequencies for cases in each of the aim 1 analytic variables and variable levels are summarized in Table 8. Consultation requests from family medicine and oncology services did not meet minimum numbers for analysis against each level of the dependent variable MLP practice level and were not included in further regression analyses.

Table 8

Aim 1 Analytic Variables: Frequencies (N = 306, Missing = 0 Cases)

Variable	Variable Levels	N (Cases)	Percent (%)
MLP (3 Levels)[a]	MLP 1	231	75.5%
	MLP 2	53	17.3%
	MLP 3	22	7.2%
Test Cycle Phase (3 Levels)	Pre-analytic	70	22.9%
	Analytic	54	17.6%
	Post-analytic	182	59.5%
Cardiology	Cardiology (No = 0)	292	95.4%
	Cardiology (Yes = 1)	14	4.6%
Emergency Medicine	Emerg Med (No = 0)	248	81.0%
	Emerg Med (Yes = 1)	58	19.0%
Family Medicine[b]	Fam Med ((No = 0)	306	97.1%
	Fam Med (Yes = 1)	9	2.9%
Intensive Care Units (ICUs)	ICUs (No = 0)	276	90.2%
	ICUs (Yes = 1)	30	9.8%
Obstetrics	Obstet (No = 0)	272	88.9%
	Obstet (Yes = 1)	34	11.1%
Oncology[c]	Oncol (No = 0)	306	96.7%
	Oncol (Yes = 1)	10	3.3%
Pediatrics	Peds (No = 0)	282	92.2%
	Peds (Yes = 1)	24	7.8%
Surgery, General	Surg Gen (No = 0)	288	94.1%
	Surg Gen (Yes = 1)	18	5.9%
Surgery, Other	Surg Oth (No = 0)	284	92.8%
	Surg Oth (Yes = 1)	22	7.2%
Clinical Laboratory	Clin Lab (No = 0)	244	79.7%
	Clin Lab (Yes = 1)	62	20.3%

[a] Dependent (outcome) variable = MLP (3 Levels)
[b] All Family Medicine cases were multivariate outliers and deleted from the dataset for further analysis.
[c] All Oncology cases were multivariate outliers and deleted from the dataset for further analysis.

Aim 1 regression variables: descriptive statistics. Descriptive statistics for the categorical regression variable, medical service/hospital location, are summarized in Table 9.

Table 9

Aim 1 Analytic Variables: Descriptive Statistics (N = 306, Missing = 0 Cases)

Statistic	Variables and Variable Levels of Medical Service/Hospital Location[a]									
	Inv MLP[b]	Test Cycle[c]	Card	Emerg Med	ICUs	OB	Peds	Surg Gen	Surg Oth	Clin Lab
Mean	1.32	2.37	.0458	.1895	.0980	.1111	.078	.059	.072	.2026
Std. Dev.	.601	.832	.2093	.3926	.2979	.3148	.269	.236	.259	.4026
Skew[d]	1.737	-.773	4.369	1.592	2.717	2.487	3.15	3.77	3.33	1.487
Skew Std. Error	.139	.139	.139	.139	.139	.139	.139	.139	.139	.139
Std. Skew	12.50	-5.56	31.43	11.45	19.55	17.89	22.7	27.1	24.0	10.70
Kurtosis[d]	1.842	-1.12	17.20	.538	5.416	4.213	7.99	12.3	9.16	.213
Kurtosis Std. Error	.278	.278	.278	.278	.278	.278	.278	.278	.278	.278
Std. Kurtosis	6.623	-.401	61.87	1.94	19.48	15.15	28.7	44.2	32.9	0.77

[a] Medical Services/Hospital Location (categorical predictor variable levels):
Card = Cardiology; Peds = Pediatrics;
Emerg Med = Emergency Medicine; Surg Gen = Surgery, General;
ICUs = Intensive Care Units; Surg Oth = Surgery, Other;
OB = Obstetrics; Clin Lab = Clinical Laboratory
All Family Medicine cases were multivariate outliers and deleted from the dataset for further analysis.
All Oncology cases were multivariate outliers and deleted from the dataset for further analysis.
[b] InvMLP = inverse MLP3Levels (ordinal outcome variable)
[c] Test cycle = square root of test cycle phase (ordinal predictor variable)
[d] Normal statistic for both skew and kurtosis is defined as 3.3 or less at p=.001.

The formula for calculation of the standard statistic for skew and kurtosis, both measures of the degree to which the distributions differ from normal, is the ratio of the skew or kurtosis measure over the skew or kurtosis standard error. Both the standard skew and standard kurtosis statistics indicate significant non-normal distributions on all variable categories. All variable categories show a positive skew (greater than 3.3) and most show positive kurtosis (leptokurtic,

greater than 3.3). Two kurtosis statistics, on emergency medicine and clinical laboratory categories, are substantially less than 3.3 indicating non-normal platykurtic (negative) distributions. Binary transformations were undertaken on all medical services/hospital location categorical variables to improve normality. However, using measurements from these non-normal distributions for CDM increases the chance of type 1 error, threatening statistical conclusion validity. This limitation could be addressed by collecting more cases in each variable level in future research studies. However, if distributions remain naturally non-normal after additional data collection, then non-parametric techniques, e.g., the examination of contingency tables for outliers, should be employed to improve normality for subsequent analysis.

Descriptive statistics for the ordinal/interval regression variables, i.e., MLP, 3 levels, and test cycle phase, 3 levels, are shown in Table 9, also. Both measures were significantly skewed and kurtotic as compared to the standard parameters for a normal distribution, 3.3 at p=.001. Inverse transformation for the MLP variable (Figure 16) and square root transformation for the test cycle phase (Figure 12) variable were undertaken to improve normality. However, the transformed distributions of both these variables remain non-normal. To be noted again, using measurements from these non-normal distributions for CDM threatens statistical conclusion validity and should be addressed by collecting more cases in each variable level in future research studies.

Analysis of regression residuals, or error in the model, was used to test for multivariate normality and equality of variance (homoscedasticity) (Tabachnick & Fidell, 2007). The test for multivariate normality is Shapiro-Wilk's test and the statistic suggest a statistically significant

difference from multivariate normal (S=.795, df=306, p=.000). This increases the chance of type 1 error and threatens statistical conclusion validity, also.

In the aim 1 model, there are 10 potential predictors, derived from the 10 levels of the medical service/hospital location variable, that entered into the model with test cycle phase and were regressed against MLP practice level (DV). Aim 1 regression variables were examined for multivariate outliers using the Mahalanobis D statistic and the chi square critical value of 31.2 (p=.001). Using this statistic, 19 cases, 5.8% of the dataset (19/325 cases), had Mahalanobis D statistics greater than the chi square critical value 31.2 (p=.001) and were removed from further analysis. Deletion of these 19 cases resulted in 306 cases for aim 1 analysis, a large enough sample size remaining to conform to the assumptions of the central limit theorem (Tabachnick & Fidell, 2007).

The test for equality of error variances is Levene's test. For the aim 1 full model, i.e., all 11 medical service/hospital location predictors and test cycle phase, Levene's test is statistically significant (F=9.14, df=26/279, p<.001). This favors the null hypothesis that mean variances are not equal and, therefore, that the assumption of equality of variance is not satisfied.

The lack of equality of variance usually results from small sample sizes in some or all variable categories which increases the chance of type 1 error. Inverse, square root, and log transformations for the ordinal/interval level variables, MLP level and test cycle phase, respectively, were undertaken to improve the distributions of these variables in order to better meet central limit theorem assumptions, decrease the chance of type 1 error, and therefore, improve statistical conclusion validity.

Aim 1 regression model testing. The full regression model for aim 1 is: inverseMLP3LevelDisposition = sqrTestCycle3Levels+ 10 binary medical service/hospital location levels entered one by one against the dependent variable, MLP level. The inverse value for the MLP DV and the square root value for the test cycle IV was used in regression analysis. Binary values for each of the categories of the medical service/hospital location IV were entered into the model one at a time.

A preliminary test of mean differences was undertaken to suggest the direction of the regression findings. This preliminary analysis indicated that mean values of only two of the 11 potential predictors (test cycle phase and surgery, other) differed significantly among MLP levels and, therefore, portend adding significantly to the predictive value of the regression model. For the medical service/hospital location IV, the research hypothesis was that for each variable category, a difference in MLP level mean values for the medical service group and the "not medical service" group binary option are statistically different with 95% confidence. For the test cycle phase independent variable, the hypothesis was that for each test cycle phase category, the difference in MLP mean values for the three test cycle groups is statistically different with 95% confidence. Eta squared or the percent variance explained for srvSurgeryOth was .272/16.084=.017 and for sqrTestCycle3Levels was .488/16.084=.03. Both medical service/hospital location and the test cycle phase variables explained very small amounts of the variance in MLP mean value levels. Table 10 displays the coefficients for the test of mean differences.

Table 10

Aim 1 Regression Variables: Preliminary Test of Mean Differences Among Predictor Variables and Variable Levels (N = 306, Missing = 0 Cases)

Predictor Variable/ Variable Level		Coefficients				
		SumSqr[a]	df[b]	MeanSqr[c]	F[d]	Significance
Predictor (Ordinal): sqrTestCycle3Level[e]	Hypothesis	.488	2	.244	4.472	.012
	Error	16.084	295	.055		
Predictors (Categorical): MedServ/HospLoc Levels[e]						
Cardiology	Hypothesis	.002	1	.002	.039	.843
	Error	16.084	295	.055		
Emergency Medicine	Hypothesis	.014	1	.014	.250	.618
	Error	16.084	295	.055		
Family Medicine[f]	Hypothesis	.000	0			
	Error					
Intensive Care Units	Hypothesis	.023	1	.023	.425	.515
	Error	16.084	295	.055		
Obstetrics	Hypothesis	.015	1	.015	.282	.596
	Error	16.084	295	.055		
Oncology[g]	Hypothesis	.000	0			
	Error					
Pediatrics	Hypothesis	.025	1	.025	.456	.500
	Error	16.084	295	.055		
Surgery, General	Hypothesis	.000	1	.000	.002	.966
	Error	16.084	295	.055		
Surgery, Other	Hypothesis	.272	1	.272	4.986	.026
	Error	16.084	295	.055		
Clinical Laboratory	Hypothesis	.090	1	.090	1.643	.201
	Error	16.084	295	.055	.039	.843

[a] SumSqr = Type III (partial) sum of squares
[b] df = degrees of freedom
[c] MeanSqr = Squares of the sample (level) means
[d] F = F statistic
[e] MedServ/HospLoc Levels = Medical Service/Hospital Location variable, 10 levels
[f] All Family Medicine cases were multivariate outliers (missing correlations) and deleted from the dataset.
[g] All Oncology cases were multivariate outliers (missing correlations) and deleted from the dataset.

Table 11 summarizes the coefficients for the full regression model: invMLP3LevelDisposition = sqrTestCycle3Levels + medical service categories entered one at a time. The t statistic values indicate that three variables/variable levels were significant predictors of MLP level disposition (DV variable = invMLP3LevelDisposition) at p≥.020: test cycle phase (p=.001); surgery, other (p=.008); and clinical laboratory (p=.020). Test cycle phase and the medical service area "surgery, other" were predicted by the test of means differences. One additional medical service area, clinical laboratory, emerged as a significant predictor in the regression, explaining variance in the MLP DV not already accounted for by test cycle phase. All remaining predictors, i.e., medical service/hospital location levels/areas, were eliminated from further analyses since they resulted in no change to the model.

Table 11

Aim 1 Regression Variables: Full Model Coefficients (N = 306, Missing = 0 Cases)

Model[a,b]	Coefficients					
	Beta	t	Significance	Zero Order	Partial	Part
1 Test Cycle Phase Sqr.[c]	.185	3.277	.001	.185	.185	.185
2 Cardiology	.004	.068	.946			
3 Emergency Medicine	.033	.589	.557			
5 ICUs	.028	.491	.624			
6 Obstetrics	.028	.495	.621			
8 Pediatrics	-.056	-.994	.321			
9 Surgery, General	-.007	-.118	.906			
10 Surgery, Other	.148	2.650	.008	.157	.151	.148
11 Clinical Laboratory	-.133	-2.341	.020	-.164	-.133	-.131

[a] Full model is: inverseMLP3LevelDisposition = sqrTestCycle3Levels + 8 binary medical service/hospital locations variable categories entered one by one against the dependent variable, MLP level

[b] Each model displays the beta weight for the predictor after adjusting for the variance of sqrTestCycle3Levels.

[c] Square root value of variable Test Cycle Phase, 3 levels = sqrTestCycle3Levels

The final regression model testing independent variable contributions to MLP level disposition is: invMLP3LevelDisposition = sqrTestCycle3Levels + srvSurgeryOther + srvClinLab. Table 12 summarizes the coefficients for the final model. A positive beta weight for an inverse scale measure for MLP means that the predictor is associated with a lower practice level of MLP; likewise, a negative beta weight is interpreted as indicating a higher level of MLP practice.

Table 12

Aim 1 Regression Variables: Final Model Coefficients (N = 306, Missing = 0 Cases)

Final Model[a]	Coefficients					
	Beta	t	Significance	Zero Order	Partial	Part
1 Test Cycle Phase Sqr.[b]	.185	3.277	.001	.185	.185	.185
Test Cycle Phase Sqr.[b]	.178	3.178	.002	.185	.180	.177
2 Surgery, Other	.148	2.650	.008	.157	.151	.148
Test Cycle Phase Sqr.[b]	.156	2.758	.006	.185	.157	.153
Surgery, Other	.133	2.369	.018	.157	.135	.132
3 Clinical Laboratory	-.115	-2.020	.044	-.164	-.115	-.112

[a] Final model is:
invMLP3LevelDisposition= sqrTestCycle3Levels+ srvSurgeryOth+ srvClinLab
[b] Model 1 is:
invMLP3LevelDisposition = sqrTestCycle3Levels
[c] Model 2 is:
invMLP3LevelDisposition = sqrTestCycle3Levels + srvSurgeryOth
[d] Model 3 is:
invMLP3LevelDisposition = sqrTestCycle3Levels + srvSurgeryOth + srvClinLab
[e] Predictor: Square root value of variable Test Cycle Phase, 3 levels = sqrTestCycle3Levels
[f] Predictor: Surgery, Other = srvSurgeryOth
[g] Predictor: Clinical Laboratory = srvClinLab
[h] Dependent Variable: inverse value of variable MLP, 3 levels = invMLP3LevelDisposition

Aim 1 regression model testing summary. Table 13 summaries important statistical descriptors of the final regression model. The predictor influencing MLP practice level

disposition the most is test cycle phase, explaining 3.4% of variance (R square change=.034, p=.001). Test cycle beta weight is also significant at .178, p=.008; the positive beta weight, for an inverse scale, indicates that the test cycle phase (1-3) is inversely associated with MLP practice level (1-3); as the test cycle phase level measure increases, the MLP practice level (1-3) decreases.

Table 13

Aim 1 Regression Variables: Final Model Summary (N = 306, Missing = 0 Cases)

Model[a]	R	R Square Δ	F	df1	df2	Sig. of F
1[b] Test Cycle Phase Sqr.[e]	.185	.034	10.740	1	304	.001
Test Cycle Phase Sqr.[e]	.185	.034	10.740	1	304	.001
2[c] Surgery, Other	.237	.056	7.022	1	303	.008
Test Cycle Phase Sqr.[e]	.185	.034	10.740	1	304	.001
Surgery, Other[f]	.237	.056	7.022	1	303	.008
3[d] Clinical Laboratory[g]	.262	.069	4.082	1	302	.044

[a] Final model is:
invMLP3LevelDisposition= sqrTestCycle3Levels+ srvSurgeryOth+ srvClinLab
[b] Model 1 is:
invMLP3LevelDisposition = sqrTestCycle3Levels
[c] Model 2 is:
invMLP3LevelDisposition = sqrTestCycle3Levels + srvSurgeryOth
[d] Model 3 is:
invMLP3LevelDisposition = sqrTestCycle3Levels + srvSurgeryOth + srvClinLab
[e] Predictor: Square root value of variable Test Cycle Phase, 3 levels = sqrTestCycle3Levels
[f] Predictor: Surgery, Other = srvSurgeryOth
[g] Predictor: Clinical Laboratory = srvClinLab
[h] Dependent Variable: inverse value of variable MLP, 3 levels = invMLP3LevelDisposition

The next most influential predictor of MLP practice level was the measure associated with the aggregation of surgical service areas other than general surgery, i.e. srvSurgeryOth. These other surgery areas accounted for 2.2% of the variance (R square change=.022, p==.008) in MLP level after adjusting for test cycle phase beta weight. The positive beta weight (.148,

p=.008) for an inverse MLP3LevelDisposition scale, indicates here, also, that the other surgical services measure is inversely associated with MLP practice level (1-3)); as the srvSurgeryOth measure increases, the MLP practice level (1-3) decreases. The clinical laboratory medical service (srvClinLab) was the last of the predictors that explained significant variance in the model. This service area explains 1.7% of the variance (R square change=.017, p=.020) left in the DV invMLP3LevelDisposition, after adjusting for sqrTestCycle3Levels, and 1.3% of the variance (R square change=.013, p=.044) after adjusting for both sqrTestCycle3Levels and srvSurgeryOth. The negative beta weight (-.115, p=.044) for an inverse MLP3LevelDisposition scale, indicates that the srvClinLab measure varies directly with MLP practice level (1-3); as the srvClinLab measure increases becoming more negative, the MLP practice level (1-3) increases.

The three statistically significant predictors explained a total of 6.9% variance (i.e., test cycle phase, 3.4%; srvSurgeryOth, 2.2%; and srvClinLab, 1.3%) in the DV, invMLP3LevelsDisposition. p=.044. Their beta weights varied as the model grew in complexity suggesting that explained variance in invMLP3LevelDisposition was shared among the predictors. Beta weights are shown in Table 13. The beta weight for sqrTestCycle3Levels was .185 by itself, .178 when considering srvSurgeryOth and .156 in the full model. Similarly, the beta weight of srvSurgeryOth dropped from .148 to .133 when srvClinLab was added to the model. Again, the negative beta weight suggests that if srvClinLab is the service category, the MLP level goes up as the inverse value of MLP reverses the scale. A Bonferroni correction applied to revise the alpha level to account for the simultaneous testing of three models, did not

change the interpretation of significance, i.e., critical value of p<.05/3 tests = .017, for any of the test models.

The interpretation of aim 1 regression findings was limited by these small explained variances and the violations of regression assumptions which have been discussed previously. As a consequence, these limitations should be considered when interpreting study findings. However, a *post hoc* power calculation, where N=306, R Square Δ=.069, and number of predictors is 3, returned a power estimate of .987 which mitigates, to some extent, the violation of regression assumptions.

Aim 1 pre-consultation complexity index (CI) structure. Aim 1 regression modeling against the MLP practice level outcome variable confirmed that a workflow prediction index, the complexity index (CI), can be constructed from the values of three predictor characteristics collected at the point of consultation initiation, i.e., test cycle phase and two medical services, surgery, other and clinical laboratory. Using the beta weights from the final regression model, a simple matrix was constructed to explain the logic for predicting the most appropriate MLP practice level for consultation resolution. Positive beta weights for test cycle phase (.156, p=.006) and surgery, other (.133, p=.018) indicated that these measures vary inversely with an inverse MLP practice level. The negative beta weight (-.115, p=.044) of the clinical laboratory predictor for an inverse MLP3LevelDisposition scale, indicated that the srvClinLab measure varies directly with MLP practice level (1-3); as the srvClinLab measure increases becoming more negative, the MLP practice level (1-3) increases. The matrix conceptualizing the logic in the use of the CI for workflow prediction is shown in Table 14.

Table 14

Aim 1 Complexity Index Definition Matrix

MLP Practice Level	Consultation Point of Initiation Predictors		
	Test Cycle Phase	Surgery, Other	Clinical Laboratory
1[a]	3	3	1
2[b]	2	2	2
3[c]	1	1	3

[a] MLP practice level 1 = test cycle phase beta weight highest >.156 + surgery, other beta weight highest >.133+ clinical laboratory beta weight lowest >-.115

[b] MLP practice level 2 = test cycle phase beta weight high but <.156 + surgery, other beta weight high but <.133 + clinical laboratory beta weight low but >-.115

[c] MLP practice level 3 = test cycle phase beta weight lowest <.156 + surgery, other beta weight lowest <.133+ clinical laboratory beta weight highest >-.115

Interpreting the conceptual logic matrix, MLP practice level 1 would be indicated for consultation resolution if the test cycle beta weight is high (>.156); surgery, other beta weight is high (>.133); and clinical laboratory beta weight is low (<-.115). MLP practice level 2 would be indicated for consultation resolution if beta weight for test cycle phase were high but less than .156; beta weight for surgery, other high but less than .133; and beta weight for clinical laboratory were low but greater than -.115. Continuing to follow this logic, MLP practice level 3, then, would be indicated for consultation resolution if beta weight for test cycle phase were lowest; beta weight for surgery, other were lowest; and beta weight for clinical laboratory were highest.

In order to operationalize the CI in the future, the logic of the conceptual changes in beta weights as presented in Table 14 were translated into values associated with predictor variables that can enter into an algorithm describing the logic of the beta weight changes. The algorithm would take the general form of the regression model: MLP practice level predicted = test cycle

phase + surgery, other + clinical laboratory. More specifically, the MLP practice level to receive the presenting consultation request would be indicated by a combination of values related to test cycle level (pre-analytic, analytic, or post-analytic), presence/absence of surgery, other origin, and presence/absence of clinical laboratory origin. The values entered into this algorithm were a combination of beta weights of each of the variable levels calculated from the aim 1 dataset (N=306 cases) and the associated intercept value. This more specific algorithm was developed by using the actual beta weights from the regression equations and became: MLP practice level (predicted) = beta weight (test cycle 1, 2, or 3) + 0 or beta weight (surgery, other) + 0 or beta weight (clinical laboratory) + intercept (i.e., variance not explained by predictors). The MLP practice level values derived from these algorithms can then be used to predict the MLP practice level assigned for consultation resolution from the trendline plotted using the means for each MLP practice level in the aim 1 dataset. Figure 17 displays the practice levels means trendline plot for the aim 1 dataset.

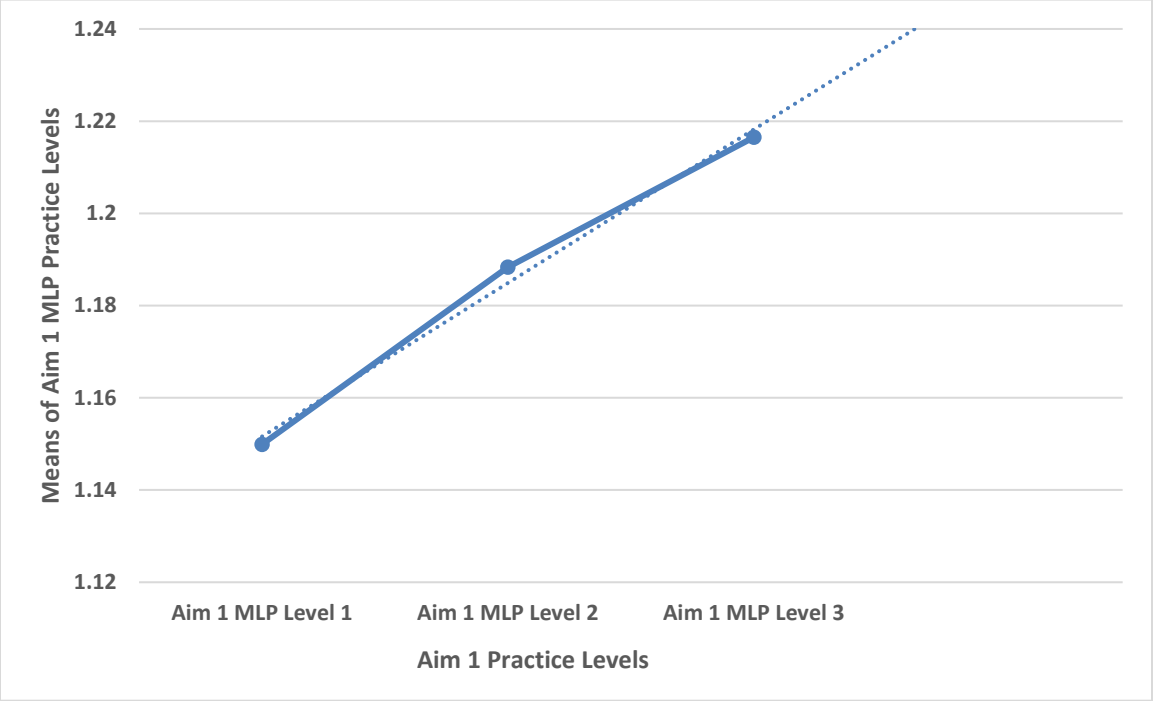
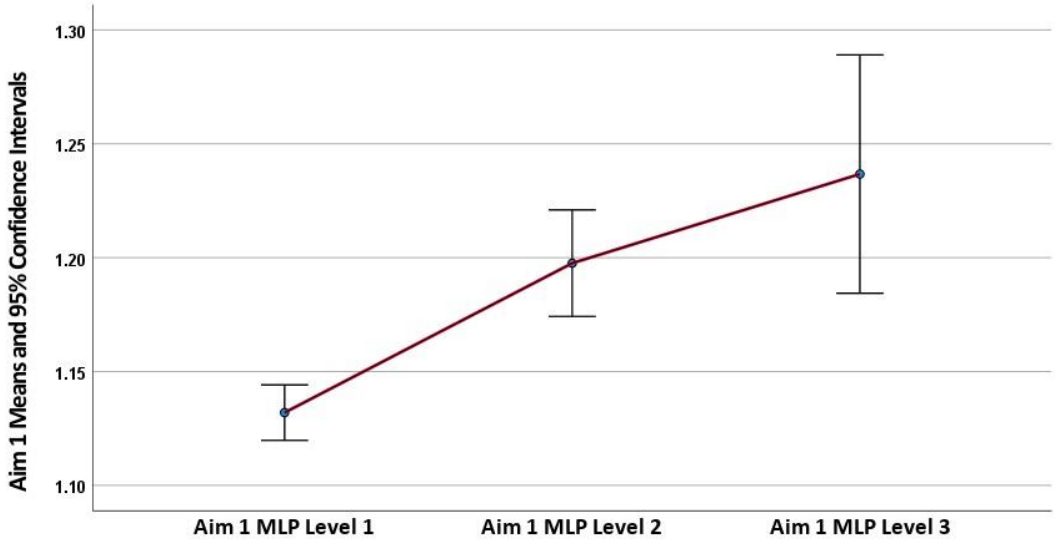


Figure 17. Aim 1 MLP practice level means trendline plot

Means for each MLP practice level in the aim1 dataset represent the average number of consultation cases resolved by each practice level. In practice, ideally, the value generated from the predicted MLP practice level algorithm would fall on the trendline within the confidence limits of the mean of one of the MLP practice levels. Thus, the consultation request would be directed to the MLP practice level with associated mean value closest to that predicted by the algorithm.

Figure 18 summarizes and graphically displays the mean values and confidence limits for each MLP practice level. While the means of all three practice levels were found to be statistically significantly different, not all MLP practice levels can be clearly differentiated when confidence intervals are examined. MLP level 1 values were clearly distinct from the other two

levels and predicted MLP algorithm values falling between lower and upper confidence limits, 1.1388 and 1.1611, respectively, can be assigned as MLP practice level 1 with 95% confidence. However, the confidence intervals of MLP practice levels 2 and 3 overlap to the extent that predictions can only be estimated. Predicted algorithm values falling within the lower bound of MLP 2 (1.1752) and the lower bound of MLP 3 (1.1861) can be assigned to MLP 2 with 95% confidence. Likewise, predicted algorithm values above the upper limit of MLP 2 (1.2013) and below the upper limit of MLP 3 (1.2470) can be assigned to MLP 3 with 95% confidence. However, predicted algorithm values falling between the lower limit of MLP 3 (1.1861) and the upper limit of MLP 2 (1.2013) could be either MLP 2 or 3. More precise assignment awaits the identification of predictors explaining more variance in the CI model and/or more MLP level 2 and 3 assigned consultations, i.e., larger number of MLP level 2 and 3 data points.



MLP Practice Level	Mean	Lower Limit 95% Confidence	Upper Limit 95% Confidence
MLP 1	1.1499	1.1388	1.1611
MLP 2	1.1883	1.1752	1.2013
MLP3	1.2165	1.1861	1.2470

Figure 18. Aim 1 MLP practice level means with 95% confidence intervals

Aim 2 research question 2: step A4 ANALYZE. The research question related to the second aim is: Can MLP practice levels resolving consultations be predicted by number of handoffs/logic steps and medical subject associated with consultation cases? Index variables (handoffs/logic steps and medical subject, i.e., independent variables, IV) were modeled with the MLP practice level involved in final consultation disposition (dependent variable, DV) to define a typology of increasing scope of knowledge and professional responsibility represented by MLP practice levels 1-3.

Aim 2 regression analyses assumptions testing. For assumptions testing of the categorical variable, medical subject, each of the 10 category levels was transformed into a binary variable with a code of 1 if the case fit into that category and a code of 0 otherwise. The resulting 10 binary variables were checked against total medical subject cases to show that the transformations were accurate. These variables are distributed binomially (bimodally) by definition and, with a sample size of 308 for aim 2, can be assumed to meet the multivariate normality and homoscedasticity assumptions invoked in the central limit theorem. In addition, with only two data points, 0 and 1, binary variables are linear by definition. These binary variables were used in preliminary regression analyses.

In the aim 2 model, there are 10 potential predictors, derived from the 10 levels of the medical subject variable, that entered into the model with handoffs/logic steps and were regressed against MLP practice level (DV). Aim 2 regression variables were examined for multivariate outliers using the Mahalanobis D statistic and the chi square critical value of 29.6 (p=.001). Using this statistic, 17 cases, 5.2% of the dataset (17/325 cases), had Mahalanobis D statistics greater than the chi square critical value 29.6 (p=.001) and were removed from further analysis. Deletion of these 17 cases resulted in 308 cases for aim 2 analysis, a large enough sample size remaining to conform to the assumptions of the central limit theorem (Tabachnick & Fidell, 2007).

Aim 2 regression variables: frequencies. Frequencies for cases in each of the aim 2 analytic variables and variable levels are summarized in Table 15. Consultation requests regarding the subjects of education, genetics/molecular, pediatrics genetics/molecular, and

proficiency testing did not meet minimum numbers of cases for analysis against each level of the dependent variable MLP practice level and were not included in further regression analyses.

Table 15

Aim 2 Analytic Variables: Frequencies (N = 308 Missing = 0 Cases)

Variable	Variable Level	N (Cases)	Percent (%)
MLP (3 Levels)	MLP 1	237	76.9
	MLP 2	56	18.2
	MLP 3	15	4.9
Handoffs/Logic Steps (3 Levels)	1 Logic Step; No Handoffs	151	49.0
	2 Handoffs/Logic Steps	102	33.1
	≥3 Handoffs/Logic Steps	55	17.9
Education[a]	(No = 0)	308	
	(Yes = 1)	0	
Genetics/Molecular[a]	(No = 0)	308	
	(Yes = 1)	0	
Technology Decisions	(No = 0)	292	94.8
	(Yes = 1)	16	5.2
IT Ordering	(No = 0)	192	62.3
	(Yes = 1)	116	37.7
Peds Genetics/Molecular[a]	(No = 0)	308	
	(Yes = 1)	0	
Results Resolution	(No = 0)	206	66.9
	(Yes = 1)	102	33.1
Safety ID	(No = 0)	272	88.3
	(Yes = 1)	36	11.7
Test Integration/Evaluation	(No = 0)	289	93.8
	(Yes = 1)	19	6.2
Proficiency Testing[a]	(No = 0)	308	
	(Yes = 1)	0	
Specimen Referral/Transport	(No = 0)	289	93.8
	(Yes = 1)	19	6.2

[a] All cases from each subject category were multivariate outliers and deleted from the dataset for regression testing.

Aim 2 regression variables: descriptive statistics. Descriptive statistics for the categorical regression variable, medical subject, and for the ordinal/interval variables MLP level and handoffs/logic steps are summarized in Table 16.

Table 16

Aim 2 Analytic Variables: Descriptive Statistics (N = 308, Missing = 0 Cases)

Statistic	Variables and Variable Levels of Medical Subject[a]							
	invMLP 3Level	logHoff /LS	Tech Decisions	IT Order	Results Resolve	Safety/ ID	Test Integrate /Eval	Spec Refer/ Trans
Mean	.8766	1849	.0519	.3766	.3312	.1169	.0617	.0617
Std. Dev.	.22814	.19130	.2223	.4853	.47140	.32180	.24098	.24098
Skew	-1.367	.271	4.058	.512	.721	2.397	3.662	3.662
Skew Std. Error	.139	.139	.139	.139	.139	.139	.139	.139
Std. Skew	.022	-1.551	14.56	-1.75	-1.490	3.768	11.481	11.481
Kurtosis	.277	.277	.277	.3766	.3312	.1169	.0617	.277
Kurtosis Std. Error	.8766	1849	.0519	.4853	.47140	.32180	.24098	.0617
Std. Kurtosis	.22814	.19130	.2223	.512	.721	2.397	3.662	.24098

[a] Medical subject (categorical predictor variable levels):
Tech Decisions = Technology Decisions; Safety/ID = Patient Safety and ID Issues;
IT Ordering = Order Entry Issues; Test Integrate/Eval = Testing Upgrade/Eval issues;
Results Resolve = Results Resolution; Spec Refer/Trans = Specimen Referral Issues.
All cases from the medical subject categories education, genetics/molecular, pediatrics genetics/molecular, and proficiency testing were multivariate outliers and deleted from the dataset for regression testing.
[b] InvMLP = inverse MLP3Levels (ordinal outcome variable)
[c] Test cycle = square root of test cycle phase (ordinal predictor variable)
[d] Normal statistic for both skew and kurtosis is defined as 3.3 or less at p=.001.

The formula for calculation of the standard statistic for skew and kurtosis, both measures of the degree to which the distributions differ from normal, is the ratio of the skew or kurtosis

measure over the skew or kurtosis standard error. Both the standard skew and standard kurtosis statistics indicate significant non-normal distributions on all variable levels except test integration/evaluation which can be considered normally distributed (skew=3.662; kurtosis=3.662). All other variable levels were skewed, i.e., positive skew greater than or negative skew less than 3.3, p=.001. Seven of the 8 variable levels showed platykurtic (negative) distributions (kurtosis statistic less than 3.3, p=.001); Using measurements from the non-normal distributions for clinical decision making (CDM) increases the chance of type 1 error, threatening statistical conclusion validity.

Analysis of regression residuals or error in the model was used to test for multivariate normality and equality of variance (homoscedasticity) (Tabachnick & Fidell, 2007). The test for multivariate normality is Shapiro-Wilk's test and the statistic suggests a statistically significant difference from multivariate normal (S=.825, df=308, p=.000). This increases the chance of type 1 error and threatens statistical conclusion validity, also.

The test for equality of error variances is Levene's test. For the aim 2 full model, i.e., all 10 medical subject predictors and handoffs/logic steps, Levene's test was statistically significant (F=11.846, df=17/290, p<.001). This favors the null hypothesis that mean variances are not equal and, therefore, that the assumption of equality of variance is not satisfied. The lack of equality of variance usually results from small sample sizes in some or all variable categories which increases the chance of type 1 error.

Aim 2 regression model testing. The full regression model for aim 2 is: inverseMLP3LevelDisposition = logHandoffsLS3LevelsTOT + 10 binary medical subject levels

entered one by one against the dependent variable, MLP level. The inverse value for the MLP DV and the log value for the handoffs/logic steps independent variable (IV) were used in regression analysis. Binary values for each of the levels of the medical subject IV were entered into the model one at a time.

A preliminary test of mean differences was undertaken to suggest the direction of the regression findings. This preliminary analysis indicated that mean values of six of the 10 potential medical subject predictors differed significantly among MLP levels and, therefore, portend adding significantly to the predictive value of the regression model. The four variable levels that were excluded from regression analysis are sbjEducation, sbjGeneticsMolecular, sbjPedsGeneticsMolecular, and sbjProficiencyTesting. None of the remaining six medical subject levels was significant at $p<.05$, but all were significant at $p<.052$. The six significant medical subject levels were sbjTechnologyDecisions ($p<.052$), sbjITOrdering ($p<.050$), sbjResultsResolution ($p<.051$), sbjSafetyID ($p<.051$), sbjTestIntegrationEvaluation ($p<.052$), sbjSpecimenReferralTransport ($p<.052$) and logHandoffsLS3LevelsTOT ($p<.050$). For the medical subject IV, the research hypothesis was that for each variable level, a difference in MLP level mean values for the medical subject group and the "not medical subject" group binary option were statistically different with 95% confidence. For the handoffs/logic steps IV, the hypothesis was that for each handoffs/logic steps level, the difference in MLP mean values for the three handoff/logic steps groups was statistically different with 95% confidence. Eta Squared, or the percent variance explained, for logHandoffsLS3LevelsTOT was .724/15.978=.045 (4.5%)

but substantially lower for the medical subject variable levels. Table 17 displays the coefficients for the ANOVA tests of mean differences.

Table 17

Aim 2 Regression Variables: Preliminary Test of Mean Differences Among Predictor Variables and Variable Levels (N = 308, Missing = 0 Cases)

Predictor vs. Outcome Variable/ Variable Level		Coefficients				
		SumSqr[a]	df[b]	MeanSqr[c]	Eta	Eta Sqr[d]
Predictor (Ordinal): invMLP3LevelDisposition[e] vs. logHoffsLS3LevelsTOT	Combined	.724	2	.362	.213	.045
	Within	15.254	305	.050		
	Total	15.978	307			
Predictors (Categorical): Medical Subject Levels						
invMLP3LevelDisposition[e] vs. sbjTechnologyDecisions	Combined	.189	1	.189	.109	.012
	Within	15.789	306	.052		
	Total	15.978	307			
invMLP3LevelDisposition[e] vs. sbjITOrdering	Combined	.808	1	.808	.225	.051
	Within	15.170	306	.050		
	Total	15.978	307			
invMLP3LevelDisposition[e] vs. sbjResultsResolution	Combined	.404	1	.404	.159	.025
	Within	15.575	306	.051		
	Total	15.978	307			
invMLP3LevelDisposition[e] vs. sbjSafetyID	Combined	.051	1	.051	.057	.003
	Within	15.927	306	.052		
	Total	15.978	307			
invMLP3LevelDisposition[e] vs. sbjTestIntegratEvaluation	Combined	.154	1	.154	.098	.010
	Within	15.825	306	.052		
	Total	15.978	307			
invMLP3LevelDisposition[e] vs. sbjSpecimenReferTrans	Combined	.006	1	.006	.019	.000
	Within	15.973	306	.052		
	Total	15.978	307			

[a] SumSqr = Type III (partial) sum of squares
[b] df = degrees of freedom
[c] MeanSqr = Squares of the sample (level) means
[d] Eta Sqr. = Eta squared, the percent DV variance explained by the variable/variable category
[e] DV = invMLP3LevelDisposition (inverse value of MLP Levels 1-3 disposition)

Table 18 summaries the coefficients for the aim 2 full regression model: invMLP3LevelDisposition = logHandoffsLS3LevelsTOT + 6 medical subject categories entered one at a time. The t statistic values indicated that four variables/variable levels were significant predictors of MLP level disposition (DV variable = invMLP3LevelDisposition) at p≤.016: logHandoffsLS3LevelsTOT (p=.000); sbjITOrdering (p=.000); sbjSafetyID (p=.016); and sbjResultsResolution (p=.000). The Eta squared values (i.e., percent variance explained) from the test of means differences suggested the significance of these variables, also. All remaining medical subject level predictors were eliminated from further analyses since they resulted in no significant change to the model.

Table 18

Aim 2 Regression Variables: Full Model Coefficients (N = 308, Missing = 0 Cases)

Model[a]	Coefficients					
	Beta	t	Significance	Zero Order	Partial	Part
1 sbjITOrdering	.225	4.038	.000	.225	.225	.225
2 logHandoffsLS3LevelsTOT	-.203	-3.633	.000	-.203	-.203	-.203
3 sbjResultsResolution	-.241	-4.311	.000	-.159	-.204	-.200
4 sbjSafetyID	.143	2.412	.016	.057	.137	.134
5 sbjTechnologyDecisions[b]		-1.644	.101		-.094	
6 sbjTestIntegratEvaluation[b]		-1.419	.157		-.081	
7 sbjSpecimenReferTransport[b]		.537	.591		.031	

[a] Full model is: inverseMLP3LevelDisposition = logHandoffsLS3LevelsTOT + 6 binary medical subject levels entered one by one against the dependent variable, MLP level.

[b] Medical subject category did not significantly change the full model and were removed from the final model.

The final aim 2 regression model testing IV contributions to MLP level disposition is: invMLP3LevelDisposition = sbjITOrdering + logHandoffsLS3LevelsTOT + sbjSafetyID +

sbjResultsResolution. The significant model variables, i.e., sbjITOrdering, logHandoffsLS3LevelsTOT, sbjSafetyID, and sbjResultsResolution together explain 15.0% of the variance in invMLP3LevelDisposition. The variable level sbjITOrdering explained 5.1%, logHandoffsLS3LevelsTOT explained 4.1%, sbjResultsResolution explained 4.0%, and sbjSafetyID explained 1.8%. The model was statistically significant at p=.001.

Table 19 summarizes the coefficients for the aim 2 final model. Even though the medical subject level, results resolution, was a significant predictor by itself and explained 4.0% of the variance in the MLP DV, it did not significantly add to the prediction model after adjusting for IT ordering, handoffs/logic steps, and safety/ID (p=.540). The final model was thus reduced to three predictors of MLP practice level: IT ordering, handoffs/logic steps, and safety/ID.

Table 19

Aim 2 Regression Variables: Final Model Coefficients (N = 308, Missing = 0 Cases)

Final Model[a]	Coefficients					
	Beta	t	Significance	Zero Order	Partial	Part
1[b] sbjITOrdering[e]	.225	4.038	.000	.225	.225	.225
sbjITOrdering	.185	3.258	.001	.225	.183	.180
2[c] logHandoffsLS3LevelsTOT[f]	-.157	-2.752	.006	-.203	-.156	-.152
sbjITOrdering	.226	3.937	.000	.225	.220	.214
logHandoffsLS3LevelsTOT	-.212	-3.623	.000	-.203	-.203	-.197
3[d] sbjSafetyID[g]	.193	3.263	.001	.057	.184	.177

[a] Aim 2 final model is:
invMLP3LevelDisposition = sbjITOrdering + logHandoffsLS3LevelsTOT + sbjSafetyID
[b] Model 1 is:
invMLP3LevelDisposition = sbjITOrdering
[c] Model 2 is:
invMLP3LevelDisposition = sbjITOrdering + logHandoffsLS3LevelsTOT
[d] Model 3 is:
invMLP3LevelDisposition = sbjITOrdering + logHandoffsLS3LevelsTOT + sbjSafetyID
[e] Predictor: Medical subject level IT Ordering = sbjITOrdering
[f] Predictor: Handoffs/Logic Steps, 3 levels = logHandoffsLS3LevelsTOT
[g] Predictor: Medical subject level Safety/ID = sbjSafetyID
[h] Dependent Variable: inverse value of variable MLP, 3 levels = invMLP3LevelDisposition

A positive beta weight for an inverse scale measure for MLP means that the predictor is associated with a lower practice level of MLP; likewise, a negative beta weight is interpreted as indicating a higher level of MLP practice.

Aim 2 regression model testing summary. Table 20 summarizes important statistical descriptors of the final regression model. The aim 2 predictor influencing MLP practice level disposition the most was medical subject IT ordering, explaining 5.1% of variance (R square change=.051, p=.000). Handoffs/logic steps was also significant with 4.1% variance explained (R square change=.041, p=.000) after adjusting for the contribution of IT ordering. The third

significant predictor in the model was medical subject safety/ID explaining 1.8% (R square change=.018, p=.016) of the variance in MLP practice level after adjusting for the contributions of both IT ordering and handoffs/logic steps variables. Positive beta weights for an inverse MLP3LevelDisposition scale, indicate that the associated measure is inversely associated with MLP practice level (1-3); as the measure increases, the MLP practice level (1-3) decreases. On the other hand, negative beta weights for an inverse MLP3LevelDisposition scale, as seen with the log value of the handoffs/logic steps variable, indicate that the measure varies directly with MLP practice level (1-3); as the handoffs/logic steps measure increases becoming less negative, the MLP practice level (1-3) increases.

Table 20

Aim 2 Regression Variables: Final Model Summary (N = 308, Missing = 0 Cases)

Model[a]	R	R Square Δ	F Δ	df1	df2	Sig. of F Δ
1[b] sbjITOrderingf	.225	.051	16.304	1	306	.000
sbjITOrdering	.225	.051	16.304	1	306	.000
2[c] logHandoffsLS3LevelsTOTg	.271	.023	7.573	1	305	.006
sbjITOrdering	.225	.051	16.304	1	306	.000
logHandoffsLS3LevelsTOT	.271	.023	7.573	1	305	.006
3[d] sbjSafetyIDh	.324	.031	10.647	1	304	.001

[a] Aim 2 final model is:
invMLP3LevelDisposition = sbjITOrdering + logHandoffsLS3LevelsTOT + sbjSafetyID
[b] Model 1 is:
invMLP3LevelDisposition = sbjITOrdering
[c] Model 2 is:
invMLP3LevelDisposition = sbjITOrdering + logHandoffsLS3LevelsTOT
[d] Model 3 is:
invMLP3LevelDisposition = sbjITOrdering + logHandoffsLS3LevelsTOT + sbjSafetyID
[f] Predictor: Medical subject level IT Ordering = sbjITOrdering
[g] Predictor: Handoffs/Logic Steps, 3 levels = logHandoffsLS3LevelsTOT
[h] Predictor: Medical subject level Safety/ID = sbjSafetyID
[i] Dependent Variable: inverse value of variable MLP, 3 levels = invMLP3LevelDisposition

The three significant predictors of MLP practice level, logHandoffsLS3LevelsTOT, sbjITOrdering and sbjSafetyID, together explained 10.5% of the variance in the invMLP3LevelDisposition DV. The predictor accounting for the most variance was sbjITOrdering at 5.1%, followed by logHandoffsLS3LevelsTOT at 2.3%, and sbjSafetyID at 3.1%. The model was statistically significant at p=.001. The medical subject level sbjResultsResolution dropped from the final model because the predictor did not significantly contribute to the model after adjustment for the other predictors accounting for more variance. Beta weights of the three predictors varied as the model grew in complexity suggesting that explained variance in invMLP3LevelDisposition was shared among the predictors. The beta weight for sbjITOrdering was .225 by itself, .185 when considering handoffs, and .226 in the final model (Table 19). Similarly, the beta weight of handoffs increased from -.157 to -.212 when sbjSafetyID was added to the model. The beta weight for sbjSafetyID alone was .193. A Bonferroni correction applied to revise the alpha level to account for the simultaneous testing of three models, did not change the interpretation of significance, i.e., critical value of $p<.05/3$ tests = .017, for any of the test models.

The interpretation of aim 2 regression findings is limited by the small explained variances and the violations of regression assumptions which have been discussed previously. As a consequence, these limitations should be considered when interpreting study findings. However, a post-hoc power calculation, where N=308, R Square Δ=.105, p=.05, and number of predictors is 3, returned a power estimate of .9996 which mitigates, to some extent, the violation of regression assumptions.

Aim 2 post-consultation prediction index structure. Aim 2 regression modeling against the MLP practice level outcome variable confirmed that a workflow prediction index can also be constructed from the values of three post-consultation predictor characteristics only available after consultation completion, i.e., handoffs/logic steps and two medical subject level variables, IT ordering and safetyID. Using the beta weights from the final regression model, a simple matrix was constructed to predict the most appropriate MLP practice level for consultation resolution. Positive beta weights for IT ordering (.226 p=.000) and safetyID (.196, p=.001) indicate that these measures vary inversely with an inverse MLP practice level. The negative beta weight (-.212, p=.000) of the handoffs/logic steps predictor for an inverse MLP3LevelDisposition scale, indicates that the handoffs/logic steps measure varies directly with MLP practice level (1-3); as the handoffs/logic steps measure increases becoming more negative, the MLP practice level (1-3) increases. A preliminary matrix defining the logic in the use of the post-consultation workflow prediction index is shown in Table 21.

Table 21

Aim 2 Post-Consultation Workflow Predictive Index Definition Matrix

MLP Practice Level	Post-Consultation Workflow Predictors		
	IT Ordering	SafetyID	Handoffs/Logic Steps
1[a]	3	3	1
2[b]	2	2	2
3[c]	1	1	3

[a] MLP practice level 1 = IT ordering beta weight highest >.226+ safetyID beta weight highest >.196+ handoffs/logic steps beta weight lowest <-.212

[b] MLP practice level 2 = IT ordering beta weight high but <.226 + safetyID beta weight high but <.196 + clinical laboratory beta weight low but >-.212

[c] MLP practice level 3 = IT ordering beta weight lowest <.226+ safetyID beta weight lowest <.196+ clinical laboratory beta weight highest >-.212

Interpreting the preliminary logic matrix, MLP practice level 1 would be indicated for consultation resolution if the IT ordering beta weight is high (>.226); safetyID beta weight is high (>.196); and handoffs/logic steps beta weight is low (<-.212). MLP practice level 2 would be indicated for consultation resolution if beta weight for test IT ordering were high but less than .226; beta weight for safetyID high but less than .196; and beta weight for handoffs/logic steps were low but greater than -.212. Continuing to follow this logic, MLP practice level 3, then, would be indicated for consultation resolution if beta weight for IT ordering were lowest; beta weight for safetyID were lowest; and beta weight for handoffs/logic steps were highest.

Aim 1 and aim 2 regression models comparison: step A5 APPLY. Both workflow prediction indices, i.e., the aim 1 CI and the aim 2 post-consultation index, categorize the same DV, MLP practice level, into one of three levels. The models were covaried against each other to validate the predictive performance of the CI using measures available only after consultation completion. In other words, two competing predictor datasets were utilized to categorize levels of MLP practice and the results compared.

Covariance analysis measures and removes the influence of joint variability of predictors on the DV MLP measure. The analysis identified the variance in model 1 after adjusting for model 2 and the variance in model 2 after adjusting for model 1. In preparation for these regressions, the multivariate outliers were eliminated from both the aim 1 model and the aim 2 model leaving 290 (N=308-18) cases for the analysis. Next the final models of each aim were analyzed using the shared dataset. The final model comparison summaries for each aim are given in Table 22

Table 22

Aim 1 and Aim 2 Final Model Comparison Summary (N=290 Cases)

Comparison Models[a]	R	R Square Δ	F Δ	df1	df2	Sig. of F Δ
1 Aim 1[b] (added first)	.259	.067	6.883	3	286	.000
Aim 2[c]	.384	.147	8.859	3	283	.000
2 Aim 2[c] (added first)	.353	.124	13.540	3	286	.000
Aim 1[b]	.384	.023	2.550	3	283	.056

[a] Dependent Variable: inverse value of variable MLP, 3 levels = invMLP3LevelDisposition
[b] Aim 1 Predictors: srvClinLab + srvSurgOth + sqrTestCycle3LevelsTOT
[c] Aim 2 Predictors: srvClinLab + srvSurgOth + sqrTestCycle3LevelsTOT + logHandoffsJS3LevelsTOT +sbjSafetyID + sbjITOrdering

Interpreting the summary, the aim 1 model alone was statistically significant with R square of .067 (p=.000). Also, the aim 2 model alone was statistically significant with R square of .124 (p=.000). Adding aim 2 predictors' variances to aim 1, the R square changes from .067 to .147. This .08 R square change (119% = .08/.067; p=.000) indicated the addition of a significant contribution to the variance explained in aim 1. On the other hand, adding aim 1 predictors' variances to aim 2 resulted in a statistically insignificant R square change of .023 (.124 to .147, p=.056). A Bonferroni correction applied to revise the alpha level to account for the simultaneous performance of two tests (aim 1 and aim 2 regressors), did not change the interpretation of significance, i.e., critical value of p<.05/2 tests = .025, for either test model or the comparison.

It can be concluded from the comparison analysis that both the CI (aim 1 workflow predictive model) and the aim 2 post-consultation workflow predictive model were statistically significant and different from one another yet predicted, in general, similar MLP practice levels. When comparing regression models that use the same dependent variable and the same

estimation period, as is the case with aim 1 and aim 2, R square change was used as a criterion for comparing them. Figure 19 graphically demonstrated the similarity of the practice level means trendlines for aim 1 and aim 2 as well as the linearity of their mean plots. Each of the models explained only small amounts of variance in the MLP practice level DV, however.

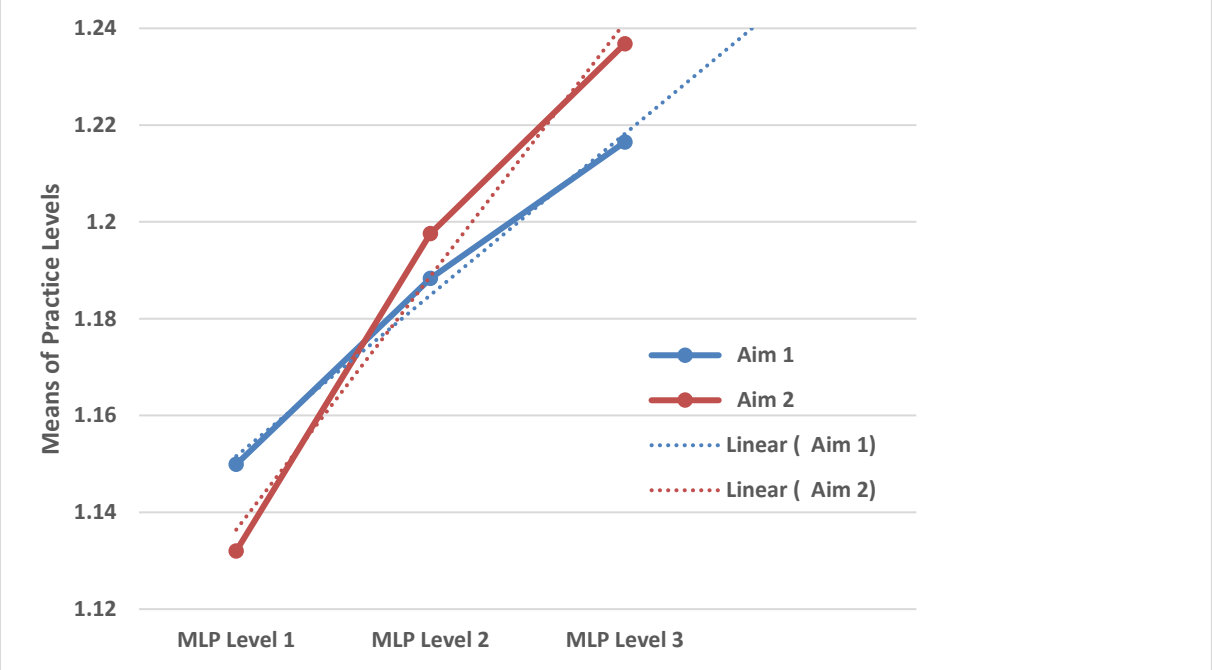


Figure 19. Aim 1 and Aim 2 MLP practice level means trendlines comparison

Aim 1 research question 1 results summary: step A6 ASSESS. Research question 1 was: Can the MLP practice level resolving consultations be predicted by an index derived from the variables test cycle phase and medical service/hospital location? The two variable categories tested in the prediction model, i.e., the complexity index (CI), were test cycle phase (pre-analytic, analytic, and post-analytic levels) and 10 medical service/hospital locations. Crosstabulations and regression modeling were undertaken to determine the contribution of each

of these variables and/or variable levels to the MLP practice level ultimately resolving the consultation case. The final regression model for aim 1 was: invMLP3LevelDisposition= sqrTestCycle3Levels+ srvSurgeryOth+ srvClinLab. Test cycle phase as well as two medical service locations, surgery other than general and clinical laboratory, were significant determinants of MLP practice level consultation resolution. The CI thus created from this discovery provided a numerical value indexed to one of the three MLP practice levels most appropriate for consultation resolution.

Aim 2 research question 2 results summary: step A6 ASSESS. Research question 2 was: Can MLP practice levels resolving consultations be predicted by number of handoffs/logic steps and medical subject associated with consultation cases? To address this question, a different dataset of consultation characteristics was analyzed for the significance of their contributions to the choice of MLP practitioner resolving consultation cases; the characteristics analyzed for this question were available only after consultation completion. The MLP practice level thus generated by the post-completion workflow predictive model serves as a validation method for the CI developed for prospective application.

The variable categories tested in the full post-completion prediction model were handoffs/logic steps (3 levels) and six medical subject categories shown in Table 18. ANOVA and regression modeling were undertaken to determine the contribution of each of these variables and/or variable levels to the MLP practice level ultimately resolving the consultation case. The final regression model for aim 2 was: invMLP3LevelDisposition = sbjITOrdering + logHandoffsLS3LevelsTOT + sbjSafetyID. Handoffs/logic steps as well as two medical subjects,

IT ordering and safety/ID, were significant determinants of MLP practice level consultation resolution. The post-completion workflow prediction model thus created from these analyses also provided a numerical value indexed to one of the three MLP practice levels most appropriate for consultation resolution.

CHAPTER 5

Discussion and Implications

Study Context and Worldview

Following a brief summary of findings from this study, implications and potential significance for practice in healthcare, education, and research will be discussed. Results will be viewed through the lens of current practice in each of these contexts, and heuristics developed from the findings will be proffered as strategies for advancing quality in all these environments. The chapter concludes with suggestions for further studies.

Potential significance of the findings is drawn from the principles put forth in the study assumptions. First, the field of healthcare diagnostics is based in the assumption that there is empirical truth, e.g., accurate results from clinical analyses, reproducible evidence from clinical research, and unbiased curricula developed from educational outcomes tracked to improvement in quality of life measures (Ballard et al., 2014; Carayon et al., 2006, 2014, 2018; IOM/NAM, 2015). The assumption of empirical truth underlies the reliance on diagnostics in CDM as the primary source of objective data. The assumption of truth is also evident in the scientific approach to evidence based clinical and quality studies as well as evidence based practice. The overarching goal of this study was to develop methodology based on empirical truth intended to increase the efficiency and effectiveness of CL communications for the improvement of care for patient/consumers.

Next is the assumption that critical thinking (CT), as the bedrock of ethics, is grounded in truth-seeking and shields against bias and its effects; ethics and evidence based practice are operationalized through CT. Evidence based practice itself is feasible only because of the assumption that quality is desirable, can be improved, and that high quality costs less than poor quality in both material and human resources measures (Carayon et al., 2018; Deming, 1986; Donabedian, 1988; Porter et al., 2013, 2020). The design, implementation, and evaluation of this study illustrated that healthcare practitioners are highly skilled and motivated to provide quality care and critically think in the provision of services. Ethics defining equity, justice, and autonomy as well as privacy and confidentiality were evident in the care given to study training sessions and in data collection tool design and data collection by study participants. The identification and assessment of study bias and limitations, both critical factors in assessing truth in clinical and quality improvement studies, was possible because of the critical thinking and ethical practice of the study participants.

The last study assumption is that patient/consumers should drive healthcare services delivery within the context of truth, critical thinking and ethics, and quality gauged by improvement in health outcomes for individuals and society as a whole (Ballard et al, 2014; IOM/NAM, 2015; Procop et al., 2019; Proctor et al., 2011; Protection of Human Subjects Revised Common Rule, 2018). The specific research questions of this study addressed the development and assessment of a prediction model, the complexity index, intended in practice to direct consultation workflow to appropriate MLP for resolution. CI implementation is the first step in actualization of the DCM© designed as a communications portal “to support clinical

decision making (CDM) within interprofessional teams, providers, and institutions." The assumption of improvement in patient/consumer-centered care as evaluated by the measurement of STEEEP outcomes documented through DCM© and A6 HCQR methodology is preeminent in DCM© design and purpose.

The adoption of a worldview encompassing these four assumptions through implementation of the DCM©, i.e., truth, CT in EBP, quality, and patient/consumer-centeredness, has implications for healthcare delivery, education, and research in macro as well as micro practice environments.

Study Results Redux and Significance

The overarching goal of this work is “to describe the Diagnostics Consultation Model© (DCM©), a clinical laboratory (CL) communications portal, designed and proposed to support clinical decision making (CDM) within interprofessional teams, providers, and institutions." Specific aims supporting the purpose were to design, develop and evaluate a workflow prediction index (the complexity index, CI) that could assign consultation requests for resolution based on an algorithm comprised of consultation characteristics available at the point of consultation initiation. In practice, the CI is intended to function as the entry point into a workflow process directing diagnostics consultation requests, first, to the appropriately qualified MLP for investigation and then branching into processes for tracking medical history and clinical information accumulation, documenting resolution logic and detail, verifying conclusions, and communicating recommendations for clinical decision support to all health professionals involved and the health record.

Data to develop and validate the CI were collected during clinical laboratory (CL) daily activities documented during an institutional review board-approved study conducted in 2011. Data elements collected describe types of consultation requests brought to the CL, types of health professionals requesting consultation, steps and health professionals involved in the request resolution process, and processes involved in results reporting. From analysis of data collected at the point of consultation initiation, test cycle phase and medical service of origin emerged as statistically significant pre-consultation predictors of the MLP practice level best prepared to resolve particular consultations.

A second workflow predictive model was constructed from data collected after consultation completion. Number of handoffs/logic steps and medical subject emerged as statistically significant post-consultation predictors of the MLP practice level best prepared to resolve particular consultations.

Both pre-consultation and post-consultation models predicted one of three MLP levels of practice defined by education, experience, and position responsibilities and were both determined to be statistically significant predictors of MLP practice level appropriate for consultation resolution. The post-consultation predictors, handoffs/logic steps and medical subject, were demonstrated to be more specific predictors of MLP practice level, i.e., post-consultation predictors accounted for more variance in the MLP DV, than pre-consultation predictors, test cycle phase and medical service. Findings from the post-consultation model were employed to assess the predictive performance of the CI.

Study significance for healthcare delivery. Others have reported inadequate healthcare IPT communications and CDM leading to quality gaps in patient/consumer care (Abraham et al., 2021; Cao et al., 2018; Carayon et al., 2006). Though the impact of these communications errors on quality of health services delivery are well documented, nearly two-thirds of all sentinel events continue to be related to communication failures (Burns et al., 2021). Further, information handoffs/handovers are implicated in more than half these errors (Burns et al., 2021; Killin et al., 2021). CL information, as the primary source of objective data for CDS, underlies medical decision making in all professions of healthcare providers (NAM, 2015). Focusing specifically on the role of the CL in providing quality CDS, non-MLP healthcare providers have also signaled the need for assistance in navigating all phases of the diagnostics testing process, i.e., pre-analytic, analytic, and post-analytic (Hickner et al., 2014; Laposata & Cohen, 2016; Procop et al., 2019; Schmidt et al., 2014; Strizich & Kim, 2021). Therefore, any quality and evidence based communications system would not be comprehensive and effective without the participation of all stakeholders, including MLP, patients/consumers, and customer healthcare providers. This study began to address the gap in communication of diagnostics information.

Codifying methodology for development of the CI is the first step in actualization of the DCM© communications portal, i.e., appropriately prepared MLP are identified by the CI and engaged to begin consultation resolution work. Codifying methodology for development of the post-consultation workflow prediction model is a companion step in communications portal actualization. By definition, the post-consultation model analyses describe methods to identify significant predictors of MLP practice level entering into the consultation workflow as steps are

completed or documented at final consultation completion. Using methods similar to those employed to develop the predictive models in this study, models could be developed predicting workflow in an ever expanding communications system related to consultation resolution, e.g., number and level of practice of MLP and other health practitioners involved in handoffs, CT practice competencies utilized in resolution, databases searched for CDS, number and scope of communication tools employed. This scope expansion would become the foundation for the design of the next steps in actualization of the DCM©.

Figure 20 is a diagram of work process steps to be investigated in order to supply the evidence base for completion of the DCM© communications system. DCM© initiation would begin with direction of consultation requests to appropriate MLP by the CI. Direction of each subsequent step in the workflow would require analyses similar to those described in this study to identify significant afferent and efferent predictors guiding further steps in the consultation resolution and communications processes among providers involved in consultation completion. Once predictors are identified at each step, workflow direction could be automated by artificial intelligence (AI) algorithms completed with predictors found to be significant at each step.

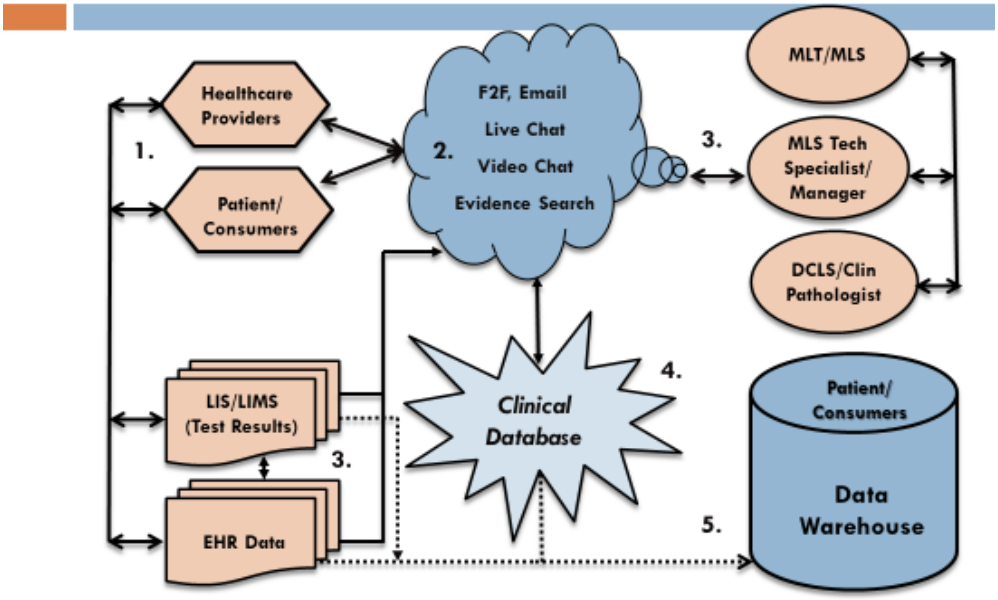


Figure 20. Diagnostics Consultation Model© (DCM©) Work Processes Flow:
1. Consultations are requested by providers as well as patient/consumers.
2. MLP Diagnostics Consultants review applicable evidence from curated databases, e.g., PubMed, through the lens of individuals' health information (i.e., precision medicine).
3. Diagnostics Consultants draw on the expertise and knowledge of other healthcare providers as well as historical diagnostics information from the CL laboratory information systems/laboratory information and management systems in the consultation process.
4. Consultation summaries along with demographic and other PHI (protected health Information) are documented in local clinical databases.
5. With patient/consumer consent, all health record data are sent to the patient/consumer-controlled electronic data warehouse for continuing workflow beyond that would follow from documentation of the practitioners, competences, and databases involved in handoffs/logic steps and the consultation medical subject.

The potential significance of this work for healthcare delivery relates to improvement in decision making not only within departments but also throughout health systems. At the unit level, work can be distributed based on medical complexity directly to practitioners with commensurate competencies. Verification rules establishing release of results and

recommendations for further medical interventions can be designed based on the complexity of the cases and number and types of practitioners and services required beyond the unit level services. Further, stepwise and summary documentation of all medical decisions and evidence supporting them would be maintained in the medical record for all interprofessional team members involved to review to assure continuity of care. Documentation of services in this way could also serve as a basis for reimbursement based on value of practitioners to the healthcare team and provide evidence for justification of hiring decisions. And perhaps most importantly, because data from consultations would be evaluated continuously for impact on health outcomes and maintained in one record, patient/consumers could be brought into care plan planning, evaluation, and decision making even as care environments proceed from community to institution and back to community for post-event follow-up.

Study significance for clinical and quality research. Prior to the widespread adoption of electronic health records (EHR) in health systems and provider practices, clinical data were available only for clinical trials through strict experimental protocols approved by institutional review boards. Data generated through patient care were generally considered to be only for internal quality improvement analysis, examined only in the aggregate, and not to be published outside the institution where gathered (Kudler et al., 2010; Leibach, 2014). Often studies involving clinical data generated through healthcare services delivery were not considered to be research, but rather quality improvement (Leibach, 2014; Protection of Human Subjects Common Rule, 2009; Protection of Human Subjects Revised Common Rule, 2018). EHRs have provided improved and more standardized access to patient/consumer and delivery

processes data while regulations protecting patent/consumer privacy and confidentiality have better defined circumstances under which clinical data may be studied and communicated (IOM/NAM, 2015; Laposata & Cohen, 2016; Leibach, 2008; Porter, 2010; Procop et al., 2019).

Even though access to clinical data has improved, understanding of the informatics techniques required to extract data elements and build the requisite dashboard data displays for clinical research studies is limited in most institutions to a small number of information technology (IT) specialists in institutional level quality and utilization review roles (Adler-Milstein et al., 2020; Ellis et al., 2020; Williams, 2021). Health informatics methodology, designed to identify, capture, and analyze relevant data from the electronic health record (EHR), is needed to compare medical effectiveness of algorithm variations and generate evidence on which to base recommendations regarding best practices in communications (Casey et al., 2020; Caudell-Feagen & Thompson, 2021; Glaser, 2020; Strizich & Kim, 2021). Much developmental work is needed in codifying interoperability among databases and standardization in IT methodology before the integration of clinical outcomes with the transactional record to create electronic, searchable clinical summaries for care continuity becomes feasible (Arsoniadis, 2020; Glaser, 2020; Sivashanker et al., 2021; Weiskopf & Weng, 2013).

On the other side of the clinical and quality research equation, most healthcare practitioners who understand the relationship between clinical and diagnostics interventions and health outcomes lack the IT skills to build EHR based clinical studies at the same time IT specialists lack clinical knowledge and experience. Whereas some application programming interfaces and middleware have been developed to support consultation modules within

pathology practice, most of these modules are designed for anatomic pathology and involve artificial intelligence/machine learning approaches to image interpretation (Church & Naugler, 2020; Rashidi et al., 2019; Schmidt et al., 2014; Stendhl et al., 2021; Theparee et al., 2018). The CL-based consultation modules reviewed that do address aspects of diagnostics consultation questions, however, were a blend of manual and digital processes; addressed convenience samples of post-analytic questions only; provided no guidance on IPT reporting, tracking, or work process analyses; and involved pathologists and pathology residents only (Church & Naugler, 2020; Rashidi et al., 2019; Schmidt et al., 2014; Stendhl et al., 2021; Theparee et al., 2018).) The design of these CL-based consultation modules does not incorporate the other error reporting, mitigating, and feedback functions of the CL, e.g., incident report follow-up, evaluation of reference test requests, optimization of test orders. Many of these additional CL consultation work processes are conducted by MLP non-physicians, are subsumed in DCM© design, and provide the CDS evidence base for the majority of health providers (Hickner et al., 2014; Procop et al., 2019).

The potential significance of this work in forwarding clinical and quality research lies in the development of a structured framework to serve as a guide for continuous quality improvement studies. This framework, the A6 Method for Healthcare Clinical and Quality Research (A6 HCQR), describes methodology for building an evidence base for efficient and effective delivery of patient/consumer-centered care through work processes of the DCM©. The A6 HCQR integrates the rigor of the well-characterized literature synthesis process into the classic Quality Theoretical Framework developed and first reported in 1988 by Donabedian and

detailed more thoroughly in the SEIPS Model (Carayon et al., 2006; Carayon et al., 2014; Carayon et al., 2018; Donabedian, 1988; Reinke, 2017). The A6 HCQR describes a clinical and quality research structure that not only allows for, but requires, the design, development, implementation, and evaluation of clinical studies utilizing clinical outcomes data (evidence of impact) generated through analyses of health services delivery care paths.

The A6 HCQR method is comprised of six steps (ASK, ACQUIRE, APPRAISE, ANALYZE, APPLY, ASSESS) guiding the design, implementation, evaluation, and communication of findings of clinical and quality research studies. Table 23 summarizes the constructs in each step and offers the steps in the progression of this study as exemplars. The A6 HCQR methodology, with adaptations for specific clinical questions, could guide clinical and quality studies in all healthcare settings as illustrated by its application in the study described here.

Table 23

A6 Method for Healthcare Clinical and Quality Research: Steps A1-A6 Definitions and Examples

A6 Method for Healthcare Clinical and Quality Research (A6 HCQR)		
A6 HCQR Step	A6 HCQR Step Definition	A6 HCQR Step Example
A1 ASK	Topic area (EBI, evidence based initiative) is identified that is considered to contribute significantly in performance related to failure, achievement, and/or maintenance of a quality goal.	Data were presented that justify the selection and evaluation of consultation characteristics as predictors of MLP practice level consultation resolution.
A2 ACQUIRE	A1 topic is distilled into a specific and measurable clinical question. Preliminary review of the literature is conducted to determine the strength of the body of evidence supporting the clinical impact	Literature related to major theories influencing the construction of the communications portal of the DCM©, the evidence based

	of the question and to discover seminal reports that could inform further, more extensive literature search strategies.	initiative (EBI) to be investigated, was accumulated
A3 APPRAISE	A pool of candidate practices is generated from the extensive, if not exhaustive, review of literature evaluated on strength of reported evidence as well as relevancy to the clinical situation for which the EBI is being designed. Also, a pool of variables, i.e., measures reported to vary with changes in the EBI-related practice, is accumulated. Literature identified previously will be analyzed in two processes, article abstraction and variable extraction to compile the candidate practices and variable pools.	Literature from theories supporting DCM© design as well as pilot study data were presented that justified the selection and evaluation of test cycle phase, medical service/hospital location, medical subject, and handoffs/logic steps as predictors of MLP practice level consultation resolution. Research questions were refined.
A4 ANALYZE	All the products of previous planning steps are synthesized into an EBI implementation protocol. Details of protocol implementation and variable analysis are identified and described to include IRB and administrative permissions and approvals, personnel participation secured, preparation of training materials, design of data collection tools, schedule of educational sessions, timeline for accomplishment of major milestones, and evaluation methods.	Datasets were evaluated for accuracy and fitness. Analyses were planned to determine if models predicting MLP practice level resolution could be constructed from pre-consultation (research question 1) and post-consultation (research question 2) characteristics. IRB approval was obtained for the study. Evaluation methods were planned.
A5 APPLY	Training, data collection, and analysis begins. Implementation barriers and hurdles are documented and their impacts on study findings considered. Adaptations are considered by the research team and, if feasible, work-arounds developed, documented, and implemented.	Analyses were conducted to determine the significance of contributions of both pre-consultation characteristics (test cycle phase and medical service area) and post-consultation characteristics (handoffs/logic steps and medical subject) to the choice of MLP practitioner resolving the consultation case.
A6 ASSESS	EBI evaluation strategies are conducted. Analysts prepare data for assessment to include pooling of indicators from	Pre-consultation and post-consultation predictive models were evaluated quantitatively

	different collection sources and by different variable types, missing data analyses, sensitivity analyses, and power determinations. Data are then analyzed descriptively by individual variables as well as variable groups. These analyses are then used to assess significant differences between baseline and EBI performance on specific indicators and to perform inferential analyses to determine the contribution of variable combinations to overall EBI path effectiveness.	and qualitatively. Statistical inferences were drawn regarding the strength of evidence predicting MLP practice level in both pre-consultation and post-consultation datasets. Study design and data collection limitations were identified, documented, and assessed for their impact on the internal validity and generalizability of study findings.

Study significance for education in quality. Tracking measures of quality performance and the achievement of quality goals are priorities in health services delivery (TJC, 2021a, 2021b). Not only do licensing and accrediting bodies monitor closely and publish institutional performance metrics but federal payments to providers and reimbursements to institutions are often linked to performance against quality standards (D'Avena, et al.,2020; Cattell et al., 2020; Porter, 2008, 2009, 2010; Porter et al., 2013, 2020). Yang et al. (2007, 2015, 2016), Donabedian (1988), Westgard (2006, 2013), Christenson et al. (2011), Leibach and Russell (2010), and Leibach (2011), have provided robust theoretical frames for the design and operationalization of substantive CL quality improvement (i.e., clinical and quality research) programs. Historically, quality measures have focused on error rates (failures) in process steps or slippage in patient/consumer satisfaction (Blokland & Reniers, 2020; Sapatnekar et al., 2021; Westgard, 2006, 2013). With increased focus on value based care (highest quality/lowest cost), measures are being developed that include health outcomes that can be objectively documented through audits of patient records. However, the capabilities of the current transactional and interoperable

structure of electronic health records inhibits auditing of statistically valid numbers of cases to support evidence based care path design (Del Mas et al, 2020; Lewanczuk et al., 2020; Modica, 2020; Pelaccia et al., 2020; Porter et al., 2020; Procop et al, 2019; Rabi, 2020; Schrijvers, 2012).

The EBP paradigm represents a new direction in education as well as quality improvement for the CL (Dickerson et al., 2017; Hill et al., 2020; Plebani et al., 2019a; Plebani et al, 2019b). Clinical and quality researchers will need different skills sets to assess quality issues impacting the total diagnostics testing and care process. Practitioners will be required to integrate evidence with practice outside the experimental, statistical model of analytic phase quality control (Sapatnekar et al., 2021). Education in clinical and quality research methodology must be directed to practitioners as well as student learners (Maness et al., 2020). Didactic coursework, clinical internships, and continuing professional education must be designed to inform practice and expose students and practitioners alike to clinical experiences providing the greatest opportunity to develop research skills necessary not only to utilize evidence in clinical decision making but also to generate and communicate data-supported practice guidelines, to monitor patients' clinical paths, to evaluate and introduce new technology, to develop quality indicators, and to create and analyze testing algorithms. Not only will health outcomes evidence be used in clinical decision making, but these utilization data can be analyzed to support evidence for practice improvement across all healthcare delivery systems, public and private (Aita, et al., 2019; Leibach, 2008a; Leibach, 2008b; Plebani et al., 2017; Plebani et al., 2019; Siemieniuch & Sinclair, 2014).

Implementation of DCM© methodology would serve to educate practitioners in quality tenets and link them into the institution-wide delivery, measurement, evaluation, and reporting of quality services. The A6 Method for Healthcare Quality and Clinical Research (A6 HCQR), providing the structure for the DCM© quality studies described in this work, would serve as the educational framework for implementation of homologous studies in medical service areas beyond the clinical laboratory. Following the A6 HCQR steps, medical services would collect data related to daily unit activities to analyze, set priorities, and assign workflow on the basis of resources, both material and human, required to resolve consultations most effectively within their scopes of practice. The establishment of this initial data collection and analysis work processes is analogous to development of the CL CI and would follow the same methodology. Past the establishment of this first step in workflow direction, the medical service unit would then become the next step in DCM© actualization, if CL consultation resolution required participation of an IPT member from that medical service. Or if the consultation request were not primarily dependent on diagnostics information for resolution, the CL would become a process step, and a MLP IPT member, in the medical service unit's consultation resolution workflow process. Providers from medical services other than CL would enter the DCM© at step one in Figure 17.

Prior to DCM© implementation, practitioners in all medical and support services and administrative units would be educated as to its institutional structure, related work processes in their areas, and functions required to fulfill their roles in documenting, analyzing, and/or reporting outcomes. The integration of all these DCM© quality functions would be the

foundation of an institutional or system-wide value based quality initiative that would meet and exceed all current reporting requirements; that is, the fully actualized DCM© would provide the evidence for a learning health system based on the measurement and evaluation of health outcomes for both individuals and populations served by the provider system (Ballard et al., 2014). In addition, a curriculum based on DCM© methodology and A6 HCQR clinical and quality research constructs, i.e., health services science, could be developed as a guideline for continuing or formal education certification in health services science earned through participation in quality activities in the learning health system or after completion of formal programs to be developed in health services science (Leibach, 2007, 2008a, 2008b, 2010, 2011; Leibach & Russell, 2010).

Study limitations. The limitations of the study relate to potential bias in the collection and interpretation of data elements, i.e. consultation characteristics. First, the complete and accurate recording of all data cannot be assured. In addition, no attempt was made to standardize individual research participants' perceptions of consultation questions through interrater comparisons. Although interpretations of research participants' were guided by commonly held practice understandings, there was also no strict control on the interpretation of categories into which primary data were assigned; in some instances, data were placed in categories, e.g., test cycle phase assignment, without clear support and documentation for the choice by the research participant.

In addition, the statistically significant CI predictors derived from the aim 1 and aim 2 datasets in this study represent very small variances in the MLP practice level DV. Therefore, the

predictive performance of both the pre-consultation CI and the post-consultation model are subject to increased type 1 error. In addition, generalizability to other clinical settings is limited; findings from data collection and analyses in different clinical settings is expected to vary seasonally, with specific catchment populations, and with clinical services provided.

Limitations of this study defining the complexity index (CI) can be overcome in the future by improved data collection practices, the evaluation of more specific predictors for the CI, greater participation of practitioners throughout the various sections of the CL and automating the DCM© workflow processes.

Study conclusions. Though the study reported here has significant bias introduced in the data collection process and by the exclusion of PHI, it has produced methodology for establishing processes to generate data for streamlining workflow and improving clinical decision support for MLP and other health professionals throughout the health system and for use in the design of data collection processes and collection tools for use in multiple clinical settings. The overarching goal of this work was "to describe the Diagnostics Consultation Model© (DCM©), a clinical laboratory (CL) communications portal, designed and proposed to support clinical decision making (CDM) within interprofessional teams, providers, and institutions." Methodology describing the complexity index developed in this study was the first step in actualizing this overarching goal.

Datasets and analyses described in this study are intended to be utilized as the foundation of continuous, evidence based CL and enterprise clinical and quality improvement studies. Because implementation of the DCM© methodology is predicated on the collection of data

(evidence) related to work processes, findings can also support internal CL job analysis and workflow process improvements as operations structures change. Larger studies, in multiple health system settings, to refine data collection platforms along with continuous analyses of findings at all practice levels will contribute to the refinement of setting-specific algorithms derived from this methodology. Given the goal of methodology development, it can be concluded that the study adequately addressed the research questions posed.

Implementation of DCM© methods and curriculum in health professions' daily practice and formal and continuing education venues has the potential to change health services delivery by the redistribution of care through interprofessional teams (IPT) coordinated by standardized workflow and communication processes (Ballard et al., 2014). IPT membership would be determined by developments necessitating changes in care paths and would follow patient/consumers through all care environments and levels of care. In addition, this care delivery structure portends the capability to follow individuals' medical histories longitudinally and, through regular consultations, to address issues of access, equity, and compliance for the purpose of development of an evidence based, individualized care plan for every patient/consumer.

Future studies. Future studies to refine the DCM© CI should focus, then, on identifying CI predictors explaining more variance in MLP practice level. Identification of more specific CI predictors could be accomplished by collection of more consultation data and reestablishing priority of predictor significance through regression analysis. For instance, diagnosis (ICD) codes are projected to explain significant variance in the CI model because they describe

diagnosis acuity and complexity. However, theses codes were not available at the time of data collection for this study. The collection of ICD codes, including co-morbidities, could be added to the study protocol to increase specificity in consultation characteristics definition and thus increased CI specificity. In addition, only some levels of the medical service variable were significant predictors. If consultation requests originate from a medical service area found to be statistically non-significant, then a value would not be entered into the CI prediction algorithm resulting in compromised MLP level assignment due to the omission of explained variance, albeit small. Future studies should focus on the identification of more "forced choice" predictors, e.g., test cycle phase, that add significantly to the variance in MLP practice level. These "forced choice" variables would fit into one mutually exclusive variable category and would, therefore, always enter a value into the algorithm.

To summarize continuing DCM© expansion, future studies should focus on three more critical next steps: (1) identification of more specific predictors for the CI (the point of entry into the portal) (2) systematic, unbiased collection of afferent and efferent workflow characteristics (i.e., number and types of practitioners, handoffs/logic steps, practice competencies, and databases) as well as communications involved in CDM at each work process step, and (3) DCM© automation.

Results from studies implementing DCM© communications processes among all providers involved in consultation resolution would then become the basis of expansion of the DCM© throughout the healthcare system. With this expansion, the DCM© would grow into full

potential as the conduit for patient/consumer information in all levels of care, i.e., primary, secondary, tertiary, and referral.

Results from studies in DCM© automation should focus on development of AI algorithms to increase the feasibility of implementation. In its current manual form, data collection for study analyses is labor intensive and subject to significant collection bias. Also, workflow processes are manually initiated and dependent on practitioner priority for initiation and follow through. Automation of collection, workflow direction, IPT and EHR communications, and continuous evaluation would increase both the quality and value of DCM© processes through the improvement of process efficiency and assessment of medical effectiveness.

Future studies in healthcare education and clinical and quality research should focus on conducting and reporting findings from services delivery and clinical outcomes quality improvement investigations. A6 HCQR methods and related curriculum are being developed and implemented in CL doctoral training programs for the purpose of objectifying a standardized, reproducible, consistently communicated approach to the generation and incorporation of clinical research findings into daily practice to improve quality and value of services. A6 HCQR-guided curriculum should also be adapted for post-doctoral programs and incorporation into position responsibilities of all CL practitioners with quality and utilization review responsibilities to increase the integration of clinical and quality research methods into practice, focus patient/consumer care on communication of clinical and quality study findings, and promote

EHR research methods innovation to codify approaches to algorithm development guiding individualized patient/consumer care.

The significance of future studies should be evaluated by the extent to which STEEEP aims (i.e., safe, timely, efficient, effective, equitable, patient-centered) are improved by the direction of consultations and consultation information summaries to appropriate MLP at the point of consultation initiation and, subsequently, to all IPT members involved in consultation resolution. Future studies employing DCM© methodology could be structured to identify outcomes measures related to STEEEP aims in all healthcare practices, in all modes of health communications, and in diagnostics algorithm and treatment guideline development and evaluation. DCM© curriculum could be employed in formal and continuing education programs to educate healthcare providers in quality and clinical research tenets as the basis for continuous quality improvement. In this way, the DCM©, employed as a health system approach to evidence based practice, quality improvement, and individualized patient/consumer care (i.e., health services science), could provide the foundation for value based healthcare continuously optimized to address the needs of individuals, populations, and health systems throughout the continuum of care.

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APPENDIX A

Clinical Laboratory Data Collection Log Abstract

IRB #10-12-126; Georgia Regents University
Clinical Laboratory Performance Measures Project
Clinical Laboratory Data Collection Log, v.9/16/11

Pathologist/Manager/Designee: _____
Inclusive Dates: _____
Submitted By, CL Area, and Date: _____

Legend: **AD** = Administrator; **AT** = Attending Physician; **HS** = Housestaff; **MT** = Medical Technologist/Clinical Laboratory Scientist; **RN** = Nurse: **CP** = Pathologist; **OT** = Other Healthcare Provider (define in space provided below); **Test Select** = Test Selection Query (Check); **Place Order** = Order Placement Clarification (Check); **Collect/ID/Tran** = Specimen ID, Collection, Transport Details (Check); **Obtain Result** = Preliminary or Final Results Inquiry (Check); **Results Logic** = Interpretation and/or Reflex Logic (Check); **Test** = Analytic Query (Check); **Other** = Miscellaneous requests, e.g., billing information (check); Forward = Forward to Manager's/Pathologist's Attention (Check)

Date	Time	Service/ Location	Urgent		Healthcare Provider							Consultation Category							Consultation Summary	Forward		Review Comments	Reviewer	Review Date
			Y	N	AD	AT	HS	MT	RN	CP	OT	Test Select	Place Order	Collect/ ID/Tran	Obtain Result	Results Logic	Test	Other		YES	NO			

APPENDIX B

The Pilot Study

Introduction

Neither methods for characterization of MLP consultations nor attribution of MLP consultations to significant diagnoses or health outcomes have been reported. To address these gaps regarding the role of MLP consultations in clinical decision support (CDS), an exploratory study was conducted to document and characterize MLP involvement in consultation with other health providers regarding questions they have about access to and utilization of clinical laboratory (CL) information. Being able to predict the pathway and direction of questions about laboratory information would not only provide the methodology to monitor for and correct patient safety concerns but would also significantly inform efforts to staff laboratories and educate students appropriately for consultation practice (Leibach, 2011).

The exploratory pilot study, the "Clinical Laboratory Performance Measures Project," was conducted to document and characterize MLP involvement in consultation with other healthcare providers regarding the impact of laboratory information in clinical decision making and thus provide evidence regarding the role of MLP consultations in clinical decision support (CDS). The pilot project addressed research questions regarding aspects of the role of MLP in CDS through the implementation of an electronic (and also paper) data collection log for capturing important aspects of consultations among MLP. Characterizing these consultative interventions and analyzing their complexity and medical subject focus led to the identification of consultations that impact (and vary with) CDS. The project (Elizabeth Kenimer Leibach, Ed.D., Principal Investigator) was approved for expedited review March 11, 2011 by the

Institutional Review Board (IRB) of Augusta University (formerly Georgia Regents University) as IRB #10-12-126/IRBNet #611273-2.

Pilot Study Research Questions

The following research questions were investigated:

1. What are the characteristics of MLP consultations with other healthcare providers as categorized by area of the clinical laboratory involved; time of day requested; medical service/hospital location; urgency; healthcare provider type initiating the consultative event; consultation type (i.e., phase of test cycle in question); number of handoffs/logic steps; and medical subject area?
2. Which consultation characteristics, i.e., area of the clinical laboratory involved; time of day requested; medical service/hospital location; urgency; healthcare provider type initiating the consultative event; test cycle phase involved); number of handoffs/logic steps; and medical subject/hospital location, are associated with MLP practice level involved in final consultation disposition? The related hypothesis is that some conditions and levels of the independent variables are associated with the MLP practice level involved in the final disposition of consultations.

Pilot Study Design and Methods

Clinical laboratory data collection log development. MLP managers and clinical pathology section chiefs (also considered MLP) were asked to participate in study instrument design, piloting, implementation, analysis, and evaluation. Between June and October 2011, four meetings were conducted. The first meeting (June 2011) was dedicated to a project overview

and design of the data collection log. During July 2011, the data collection instrument was piloted and a second meeting was conducted with participating MLP to refine the initial data collection log. The CL consultations data collection log, an Excel worksheet, is Appendix A. Instructions regarding completion of the log as well as information regarding goals and objectives of the project were shared with MLP participants during educational sessions conducted prior to the beginning of data collection.

Population definition and sample characteristics. The study population was defined as all documented interventions (consultations) between MLP and other healthcare providers (hospital-based users of laboratory information) in a 600-bed, tertiary care hospital affiliated with an academic medical center. Both electronic and face-to-face interactions were considered as consultations.

The study sample consisted of an 11-week documentation (September 19, 2011 – November 22, 2011) of these electronic and face-to-face interactions among MLP and other healthcare providers. Data logs of consultative events were maintained during the study period by 7 of 13 areas of the clinical pathology laboratory (CL). The sample was a purposeful, convenience sample of descriptions of as many consultative events involving MLP as possible for the 11 weeks of study duration. Sampling was not randomized nor was there any attempt to assess inter-rater bias potentially associated with differences in MLP perceptions or work shift variations in MLP and/or healthcare provider characteristics and position responsibilities. Data on 325 consultation events, i.e., N=325 consultation cases, were recorded.

The CL data collection log (Figure 1a and Appendix A) was completed by participating MLP during the normal workday (24 hours per day, 7 days a week) as consultations occurred. Cumulative data collection logs were submitted electronically to the principal investigator every two weeks; an email reminder prompt was sent before each submission was due. MLP consultations were described demographically by CL area, date/time, medical service/hospital location, urgency status, type of provider initiating the consultation intervention, number of handoffs/logic steps, and testing cycle phase, i.e., pre-, post-, and analytic, to which they related. A statistics data table was then created in SPSS Statistics (v. 22) for manual entry of variable values and subsequent data analysis.

IRB #10-12-126; Georgia Regents University
Clinical Laboratory Performance Measures Project
Clinical Laboratory Data Collection Log, v.9/16/11

Pathologist/Manager/Designee: _____
Inclusive Dates: _____
Submitted By, CL Area, and Date: _____

Legend: **AD** = Administrator; **AT** = Attending Physician; **HS** = Housestaff; **MT** = Medical Technologist/Clinical Laboratory Scientist; **RN** = Nurse: **CP** = Pathologist; **OT** = Other Healthcare Provider (define in space provided below); **Test Select** = Test Selection Query (Check); **Place Order** = Order Placement Clarification (Check); **Collect/ID/Tran** = Specimen ID, Collection, Transport Details (Check); **Obtain Result** = Preliminary or Final Results Inquiry (Check); **Results Logic** = Interpretation and/or Reflex Logic (Check); **Test** = Analytic Query (Check); **Other** = Miscellaneous requests, e.g., billing information (check); Forward = Forward to Manager's/Pathologist's Attention (Check)

Date	Time	Service/ Location	Urgent		Healthcare Provider							Consultation Category							Consultation Summary	Forward		Review Comments	Reviewer	Review Date
			Y	N	AD	AT	HS	MT	RN	CP	OT	Test Select	Place Order	Collect/ ID/Tran	Obtain Result	Results Logic	Test	Other		YES	NO			

Figure 1a and Appendix A. CLPM Pilot Project Consultations Data Collection Log Abstract

Data abstraction procedure. Algorithms for variable recoding to increase power for analyses were developed from granular data as defined in Table 2a. Further, a data abstraction table was created for recording additional assessments derived from the statistics data table.

Table 2a

Summary of Category Transformation Algorithms in the Pilot Study

Variable	Initial Number of Levels	Transformed (Recoded) Number of Levels
CL Area	12	0 = Professional Knowledge (non-specimen receiving areas)
		1 = General Knowledge (specimen receiving area)
Provider Type	7	0 = Non-RN
		1 = RN
Test Cycle Phase	7	1 = Pre-analytic (test select, place order, collect/ID/transport)
		2 = Analytic (specimen analysis)
		3 = Post-analytic (obtain result, results logic, other)
Handoffs/logic steps	5	1 = One logic step, no handoffs
		2 = Two hand-offs/logic steps
		3 = Three or greater handoffs/logic steps
MLP Practice Level Consultation Disposition	6	1 = MLP Level 1 (MLP complete, one logic step and no handoff)
		2 = MLP Level 2 (Referred to MLP/MLP Manager)
		3 = MLP Level 3 (Referred to physician to include pathology resident, pathologist, and medical resident/attending physician)

These additional assessments, i.e., number of handoffs/logic steps, MLP practice level disposition, and medical subject categories, were qualitatively derived from "consultation summary," "forward," and "reviewer comments" entries in the consultations data collection log. Resultant definitions of handoffs/logic steps and MLP practice level disposition categories are given in Table 2a.

Each of the 325 recorded consultation events was assigned to a medical subject category defined as either: (1) education, (2) genetics/molecular, (3) technology decisions, (4) information technology/ordering, (5) pediatric genetics/molecular, (6) analytic results resolution, (7) patient

safety/identification, (8) test methodology integration/evaluation, (9) proficiency testing, or (10) specimen referral/send out. Medical subject categories were derived from a thematic analysis of consultation topics as reported in the consultation summary and reviewer comments sections, also shown in Pilot Study Table 3a. Also, the original and/or non-recoded categories are shown in Table 3a. Lastly, the "comments" field was used to record free-form comments related to issues arising from the consultation CDS process itself, or documentation from it.

Table 3a

Pilot Study Original Categories and/or Non-recoded Consultation Characteristics Summary

Original Categories and/or Non-recoded Consultation Characteristics (IV) N = 325	IV Frequency	IV Percent
Clinical Laboratory Area Involved	n = 278	100
Chemistry	63	23
Clinical Pathologists/ Residents	42	15
Immunology/Send Outs	35	13
Outpatient (Medical Office Building)	3	1
Point of Care Testing	40	14
Receiving	95	34
Missing Data: % = (1.00 – n/N) x 100	47	14
Time of Day Initiated	n = 182	100
8 a.m. – 12 p.m.	37	37
1 p.m. – 4 p.m.	37	37
Other	26	26
Missing Data: % = (1.00 – n/N) x 100	143	44
Medical Service/Location Origin	n = 270	100
Emergency Department	28	10
Chemistry (Clinical Laboratory)	23	9
Other	219	81
Missing Data: % = (1.00 – n/N) x 100	55	17
Urgency	n = 278	100
Routine	191	69
STAT	87	31
Missing Data: % = (1.00 – n/N) x 100	47	14
Healthcare Provider Type	n = 289	100
RN	143	51
Other (administrators, MLP, medical students, pharmacists, physicians, respiratory therapists)	135	49
Missing Data: % = (1.00 – n/N) x 100	47	14
Consultation Type (Test Cycle Phase Involved)	n = 278	100
Pre-analytic: Test Select, Place Order, Collect/ID/Transport	137	49
Analytic: Test Parameters	86	31
Post-analytic: Obtain Result, Results Logic, Other	55	20
Missing Data: % = (1.00 – n/N) x 100	47	14
Medical Subject	n = 278	100
Education	3	1
Genetics/Molecular	6	2
Technology Decisions	16	6
IT Ordering	96	35
Pediatric Genetics/Molecular	5	2

Results Resolution	75	27
Patient Safety/Identification	36	13
Test Integration/Evaluation	19	7
Proficiency Testing	3	1
Specimen Referral/Send Out	19	7
Missing Data: % = (1.00 – n/N) x 100	47	14

Pilot Study Data Analysis

All descriptive and inferential statistical analyses were performed using IBM SPSS Statistics, v. 22; standard formatting conventions, as well as thresholds and significance levels for regression modeling were used. In preparation for descriptive characterization of consultations, data were initially collected into multiple levels of categorical measurements to preserve granularity. However, total number of consultations was insufficient to allow for analysis on all independent variables (IV) at all levels, and for some analyses, data were recoded according to the algorithms given in Table 2a.

Pilot Study Results

Characterization of consultation requests (question 1). During the 11-week pilot study period, 325 consultative events were documented. Data were collected on seven characteristics (independent variables, IV): (1) CL area involved, (2) date/time, (3) medical service/hospital location, (4) urgency, (5) healthcare provider initiating the consult, (6) consultation type, i.e., testing cycle phase related to the consultation, and (7) number of handoffs/logic steps. Data were cleaned and a missing values analysis performed to determine the impact of these missing data. After missing data cases were eliminated, 278 consultative events remained. Percentage of missing data from variable fields was 5% or less except in the parameters healthcare provider type (11%, 36/325) and time of day of consultation (44%, 143/325). Descriptive parameters

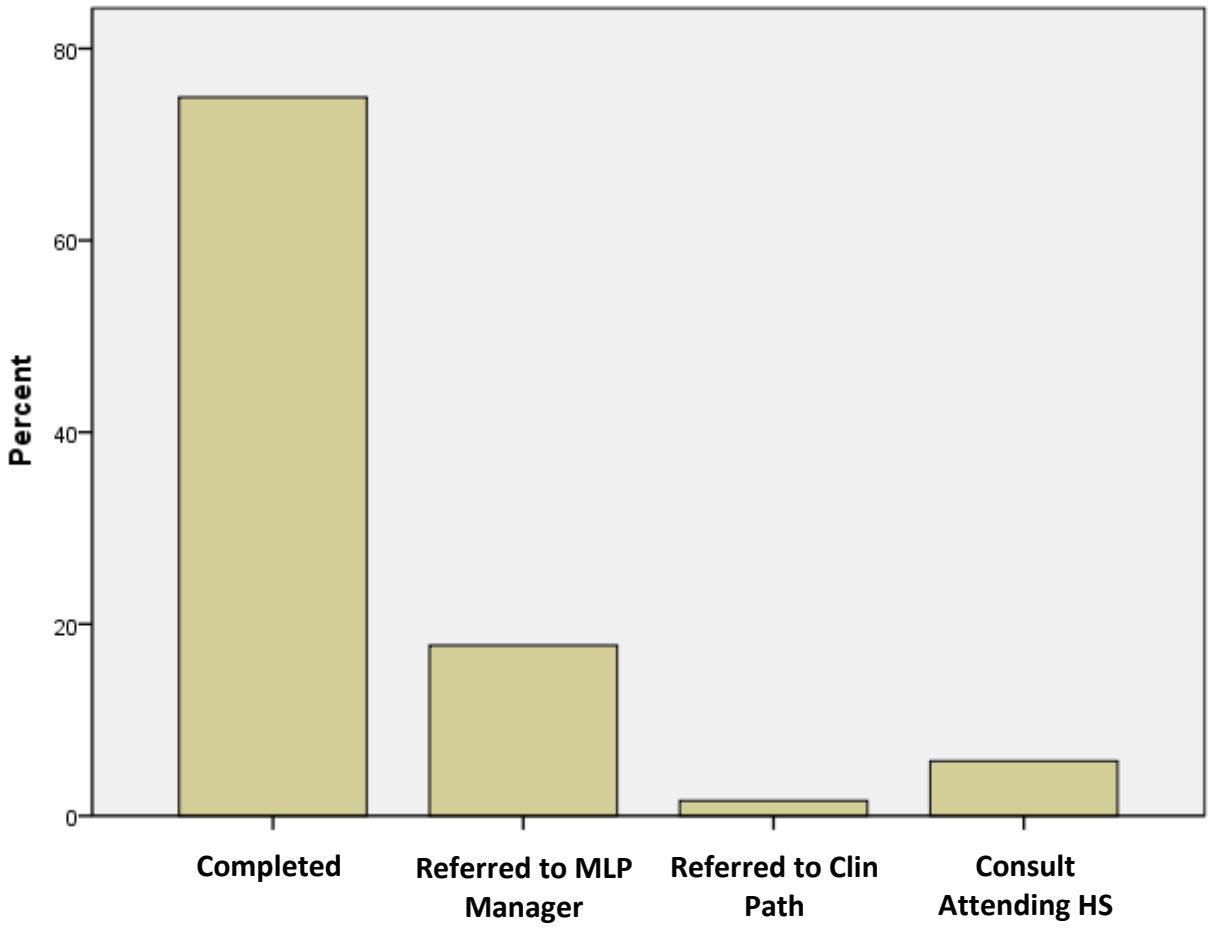
reported were calculated using data with missing values removed unless otherwise indicated. Consultation characteristics are reported in Table 3a.

Comparing means of all cases to means of those with missing data cases eliminated resulted in significant mean differences only in provider type. Therefore, provider type was removed from further consideration as a predictor of MLP practice level consultation disposition.

The variable, clinical laboratory area, was also excluded from consideration as a predictor of MLP practice level consultation disposition due to data collection limitations rather than missing data. Major CL areas for consultation, e.g., transfusion service, microbiology, and hematology/coagulation, did not participate in the pilot study due to work force shortages. Though data from the remaining participating CL areas is informative from methodology and processes perspectives, conclusions drawn related to MLP practice level resources utilized in these areas would not be generalizable to the larger CL and potentially misleading if reported.

Definition of MLP practice level consultation disposition. Consultation disposition was defined as the MLP practice level involved in final consultation resolution. In initial analyses, four (4) MLP practitioner levels were defined in consultation disposition: (1) MLP Practice Level 1 ("Completed" at the time of initial contact by MLP), (2) MLP Practice Level 2 ("Referred to MLP or MLP technical specialist/manager"), (3) MLP Practice Level 3 ("Referred to clinical pathologist/resident/MD"), and (4) "Consult Attending/HS," defined as a request for additional information from the attending physician or resident/house staff. Most consultations, 77% (214/278), were completed at the time of initial contact with a MLP, e.g., by phone or in person, without the need for further investigation; further investigation is defined as handoffs or

logic steps requiring additional consultation with MLP Practice Levels 1-3 (MLP, MLP manager/technical specialist, and/or clinical pathologist/resident). Resolution of some consultation questions involved information from non-MLP health practitioners, for instance, attending physicians or medical residents. Non-MLP practitioner consults were documented but non-MLP practitioners were not considered a MLP practice level because workflow processes demonstrated that clinical information from non-MLP practitioners supported decision making by MLP Practice Level 3. Therefore, for further future analyses, these non-MLP consult frequencies were combined with MLP Practice Level 3 frequencies. Frequencies for all MLP practice level disposition categories are shown graphically in Figure 10a.



Pilot Study Figure 10a. Frequency of MLP Consults by MLP Final Disposition Category:
MLP Practice Level 1: "Completed" = 77% (214/278 consults)
MLP Practice Level 2: "Referred to MLP Manager" = 15% (41/278 consults)
MLP Practice Level 3: "Referred to Clin Path" = ≤1% (2/278 consults)
Non-MLP Practitioner: "Consult Attending/HS" = ≤2% (6/278 consults)

Definition of consultation handoffs/logic steps. In the pilot study, five (5) categories (levels) of handoffs/logic steps were assigned and defined as cognitive processes, requiring either literature (technical manuals, publications, guidelines) review or referral to another MLP level. With the data collection log, consultation workflow was tracked through all cognitive CDS (logic) steps or referrals to other MLP (handoffs). Pilot study data indicated that even though

consultation resolution could require multiple handoff/logic steps among multiple individuals within each MLP practice level (i.e., up to 5), most consultations were resolved with 3 or less handoffs/logic steps. Because of the low numbers of handoffs/logic steps in categories 4 and ≥ 5 handoffs/logic steps, variable values were recoded into three categories: category 1, 1 logic step; category 2, 2 handoffs/logic steps; and category 3, ≥ 3 handoffs/logic steps. See Table 2a.

Consultation characteristics related to consultation disposition (question 2).

Healthcare providers from 97 medical service locations were available to seek consultations during the data collection period. However, the numbers of cases from most of the medical service units were less than numbers required for analysis. The variable, "medical service/hospital location," was recoded, first, from the original number of 97 medical services available, to 37 by eliminating those medical services not consulting with the CL during the pilot study. The resulting 37 medical services were then recoded as appropriate on the basis of commonality among medical specialties, resulting in 11 medical services to be used in analyses on this variable. See Table 4a. In addition, two of the seven variables, i.e., date/time and urgency, did not correlate with MLP practice level disposition; all category levels of these IVs were equally distributed across MLP practice levels (DV) for resolution. (Data not shown.) Analyses using date/time and urgency were, therefore, not considered as potential predictor variables.

Pilot Study Table 4a

Summary of Medical Service Transformation Algorithms

Original Medical Service Areas	Consultation Number (Original Areas)	Medical Service Area Transformations	Transformed Medical Service Areas	Consultation Number (Transformed Areas)
1, Allergy	1	37, Other		
2, Cardiology	14		1, Cardiology	14
3, Cardiac CCU	0			
4, Dermatology	0			
5, Endocrinology	0			
6, ENT (Otolaryngology)	0			
7, Emergency/ Trauma	58		2, Emergency/ Trauma	58
8, Family Medicine	9		3, Family Medicine	9
9, Gastroenterology	0			
10, Geriatrics	0			
11, Gynecology	0			
12, Hematology	1	10, Oncology		
13, Infectious Disease	0			
14, Medicine (Gen)	0			
15, Medicine (Other)	0			
16, Med ICU	3		4, ICU:	30
			3 (Medicine)	
			6 (Neurology)	
			4 (Nursery)	
			10 (Pediatrics)	
			7 (Surgery)	
17, Nephrology	0			
18, Neurology	2	37, Other		
19, Neuro ICU	6	16, Med ICU		
20, Nursery	0			
21, Nursery ICU	4	16, Med ICU		
22, Obstetrics (L&D)	34		5, Obstetrics	34
23, Oncology	10		6, Oncology	10
24, Ophthalmology	0			
25, Orthopedics	0			
26, Pediatrics	24		7, Pediatrics	24
27, Pediatrics ICU	10	16, Med ICU		
28, Pulmonology	1	37, Other		
29, Rheumatology	0			
30, Surgery (Gen)	18		8, Surg Gen	18

31, Surgery (Other)	13		9, Surg Other:	21
			13 (Other)	
			8 (Transplant)	
32, Surgery ICU	7	16, Med ICU		
33, Telemedicine	0			
34, Transplant	8	31, Surgery (Other)		
35, Urology	0			
36, Clin Lab	59		10, Clin Lab	59
37, Other	40		11, Other:	44
			40 (No Service Noted)	
			1 (Allergy)	
			2 (Neurology)	
			1 (Pulmonology)	

The remaining potential predictor variables, i.e., consultation type (test cycle phase), number of handoffs/logic steps, medical service/hospital location, and medical subject were then assessed for their association with MLP practice level consultation disposition. A series of crosstabulations were conducted using the potential predictor variables against the DV, MLP practice level, i.e., levels 1-3, resolving the consultation case. The resulting contingency table, with the significance (Pearson's Chi-square) as well as strengths (Cramer's V) of the relationships among variables, is given in Table 5a.

Table 5a

Statistical Inferences Among Variables Predicting MLP Practice Level Consultation Disposition

Crosstabulation	Inferential Statistics							
MLP Practice Level Disposition (3 Levels) by:	Pearson Chi-Square			Likelihood Ratio			Cramer's V	
	Value	df	Sig[a]	Value	df	Sig[a]	Value	Sig[a]
Test Cycle Phase[b]	32.387	4	≤ .01	28.533	4	≤ .01	.227	≤ .01
Medical Subject[c]	98.390	18	≤ .01	74.838	18	≤ .01	.396	≤ .01
Medical Service[d]	30.733	20	.059	39.479	20	.006	.218	.059
Handoffs/Logic Steps[e]	97.166	4	≤ .01	122.713	4	≤ .01	.393	≤ .01

[a] Asymptotic significance
[b] Test cycle phase = Consultation type, 3 levels (Pre-analytic, Analytic, Post-analytic)
[c] Medical Subject = 10 levels (Education, Genetics/Molecular, Technology Decisions, IT Ordering, Peds Genetics/Molecular, Results Resolution, Safety/ID, Test Integration/Evaluation, Proficiency Testing, Specimen Referral/Transport)
[d] Medical Service/Hospital Location = 11 Levels (Cardiology; Emergency/Trauma; Family Medicine; ICUs; Obstetrics; Oncology; Pediatric; Surgery, General; Surgery, Other; Clinical Laboratory; Other)
[e] Handoffs/Logic Steps = 3 levels (completed with one logic step, no handoff; two handoffs/logic steps; ≥3 handoffs/logic steps)

Findings from these crosstabulations corroborate that four predictor variables, test cycle phase, medical service/hospital location, medical subject, and handoffs/logic steps, are significantly associated with MLP practice level resolving consultations (Pearson's Chi-square and likelihood ratio statistics) and that the strengths of the relationships are strong (Cramer's V statistics). Medical service, though not significantly correlated (p=.059) with MLP practice level disposition with 95% confidence, nevertheless, shows potential enough (likelihood ratio=.006) to

be tested further in the CI regression model with test cycle phase. And not all 11 medical service areas are expected to be significant in the model. Further analyses determined which medical services did not contribute to the model, they were removed, and correlation significance increased.

Medical subject and handoffs/logic steps, the two predictor variables whose values are not known until consultation completion, were tested together in a separate regression model for prediction of MLP practice level disposition after consultation completion. The results of the two regression models, i.e., comparing the model using variables available at the point of consultation initiation to the model using variables after consultation completion, were analyzed to determine the prediction performance of the CI.

Diagnostics Consultation Model© research program construction. From analyses of data from structures, processes, and outcomes collected in the pilot study, a research program was formulated that describes two arms for the collection and analysis of clinical laboratory information required to establish a continuous quality improvement system based on evidence of increased value to patients/consumers. The first arm of the Research Program, Consultation Characterization and Implementation Science, is established to investigate and document characteristics of consultation events in multiple clinical settings. Investigations within the first aim of this arm, Consultation Characterization, utilize data collection tools comprised of measurement elements derived from narrative analysis of encounters with both healthcare providers and patients/consumers alike. Investigations in aim 1 of arm 1 of the Research program will address the general question, “What are the characteristics of healthcare professionals’

consultations?" Research questions in both the pilot study and dissertation study addressed queries and analyses under arm 1, aim 1 of the DCM© Research Program.

In the pilot study, MLP consultation characteristics, e.g., test cycle phase, CL area, other health professionals involved, medical service, medical subject, were described for the first time. Then correlations of these characteristics with final consultation disposition by MLP practice type were considered. The dissertation study builds on these correlations to question if certain characteristics correlating with disposition by MLP practice type can predict workflow to the correlated MLP practice types and suggest a communication strategy for consultation response both within the clinical laboratory (intralaboratory/interlaboratory) and among health providers throughout the health system.

APPENDIX C

DCM© DATA DICTIONARY (DD), v. 8.5.20
DATA DICTIONARY: "20.8-5.DCM Non-transformed Data Dictionary.App.B.EK Leibach.VCU.docx"
DATA SET: "20.8-3.DCM Non-transformed Data.EK Leibach.VCU.sav"

VARIABLE	VARIABLE NAME	DATA TYPE	ALLOWED VALUES	DESCRIPTION
Case ID	CaseID	Numeric	Integers	Assigned accession number in order received
Date	Date(Date Picker)	Numeric	MM/DD/YY	The date the exception case appeared
Medical Record Number	MedRec	Numeric	Integers	Permanent Patient Identifier
Patient Age	PtAge	Alpha-numeric	1=< 30 days 2=1-11 months 3=1-17 years 4=18-44 years 5=45-64 years 6=65-85 years 7=>85 years	The age range of the patient when the exception case was generated
Patient Gender	Gender	Alpha-numeric	1=Male 2=Female 3=Undisclosed 4=Other	Documented gender when the case was received. Define "Other" in "Comments."
Primary Patient Dx	1^{ST}Dx	Alpha	Free Text	The primary diagnosis of the patient when the case was received
Primary Dx ICD-10 Code	PrimICD10	Alpha-numeric	A00.000-Z00.000	The ICD-10 code that correlates with the written primary diagnosis of the patient when the exception case was generated.
Ordering Provider Type	ProvTyp	Alpha-numeric	1=Attending Physician (AP) 2=Resident Physician (RP) 3=Consulting Physician (CP) 4=Nurse (RN/APN) 5=Pharmacy (PharmD) 6=CL Protocol (Prot) 7=Other (O)	Practitioner type placing test order. Define "Other" in "Comments."
Ordering Service / Patient Location	MedServ	Alpha-numeric	1=Allergy 2=Cardiology 3=Cardiac CCU	The location of the patient when exception generated. Define "Other" in

			4=Dermatology 5=Endocrinology 6=ENT (Otolaryngology) 7=Emergency/Trauma 8=Family Medicine 9=Gastroenterology 10=Geriatrics 11=Gynecology 12=Hematology 13=Infectious Disease 14=Medicine (Gen) 15=Medicine (Other) 16=MedICU 17=Nephrology 18=Neurology 19=NeuroICU 20=Nursery 21=NurseryICU 22=Obstetrics (L&D) 23=Oncology 24=Ophthalmology 25=Orthopedics 26=Pediatrics 27=PedsICU 28=Pulmonology 29=Rheumatology 30=Surgery (Gen) 31=Surgery (Other) 32=SurgICU 33=Telemedicine 34=Transplant 35=Urology 36=Other	"Comments."
Clinical Lab Area Associated with Test(s)	CLArea	Alpha-numeric	1=AP/CP 2=Blood Bank 3=Chemistry 4=Coagulation 5=Genetics 6=Hematology 7=Immunology 8=LIS/IT 9=Microbiology 10=Molecular	The primary clinical laboratory area related to the exception case. Define "Other" in "Comments."

			11=POCT 12=Receiving 13=Send out/Referral 14=Toxicology 15=Other	
Test Name(s)	TestName	Alpha	Free Text	The specific test(s) that generated the exception case.
Test CPT Code(s)	TestCPT	Numeric	80000-89999	The Current Procedural Terminology (CPT) code that correlates to the specific test(s) generating the exception case.
Case Exception Trigger Criterion	Trigger	Alpha-numeric	1=Duplicate Order 2=Medically Unnecessary Order 3=Medical Necessity Evaluation 4=Sample Improper Collection (clotted, leaking, tube type, QNS) 5=Sample Hemolyzed / Lipemic 6=Test Cost >$200 7=Order Deferred/Clarification 8=Cost/Insurance Issues 9=Other	The criterion rule violation generating the exception case. Define “Other” in “Comments.”
Case Test Cycle Phase	TestPhase	Alpha-numeric	1=Test Select/Order 2=ID/Collect/Transport 3=Analysis/Assay 4=Result Reporting 5=Interpretation/ Recommendation 6=Other	The test cycle phase associated with the exception. Define “Other” in “Comments.”
Case Treatment Phase	TxPhase	Alpha-numeric	1=Screening 2=Diagnosis 3=Monitoring 4=Prognosis 5=Other	Exception case treatment phase. Define “Other” in “Comments .”
Sequence of Hand-offs/Logic Steps Among	Handoffs	Numeric	1=DCLS (DCLS) 2=MLP (SO/Specialist MLP)	List IPT member number in sequence in order of hand-offs/Logic Steps (delimited

Interprofessional Team in Case Review			3=GC (Genetic Counselor) 4=MIC (Clin Micro) 5=RES (Clin Path Resident) 6=PATH (Pathologist) 7=ADM (CL Admin) 8=PharmD (Clin Pharm) 9=ML (Med Librarian) 10=EPI (Epidemiologist) 11-=Nurse (RN) 12=Mid-level (APN/PA) 13=Other (Other)	by commas). Define "Other" in "Comments." ≥
Total Number of Hand-offs / Logic Steps	#Handoffs	Alpha-numeric	1=I handoff/logic step 2=2 handoffs/logic steps 3=3 handoffs/logic steps 4=4 handoffs/logic steps 5=5 handoff/logic steps 6->5 handoffs/logic steps	The total number of hand-offs / logic steps involved in case resolution. Define "Other" in "Comments."
Case Resolution	ResolveTyp	Alpha-numeric	1=Testing Performed 2=Testing Denied/Canceled 3=Testing Substituted 4=Additional Tests Ordered 5=Testing Deferred 6=New Algorithm Proposed 7=Other	Type of resolution action resulting from case review completion. Define "Other" in "Comments."
Date Resolution Report Sent	NoticeDate (Date Picker)	Numeric	MM/DD/YY	Date provider notified of case resolution
Resolution Report Authority	NoticeAuth	Alpha-numeric	1=CL Protocol 2=CL Med Director 3=DCLS 4=Other	Authority to release notice. Define "Other" in "Comments."
Resolution Report Format	RptForm	Alpha-numeric	1=Phone Call 2=Email 3=Secure Message 4=EHR Note 5=EHR Consultation Report 6=Other	Consultation reporting mechanism. Define "Other" in "Comments."

Provider Type(s) Notified	ProvTypNotif	Alpha-numeric	0=None 1=Attending Physician (AP) 2=Resident (Res) 3=Mid-level (APN/PA) 4=CL Med Director (CL) 5=Nurse (RN) 6=Other	Roles / positions notified of resolution. (List numbers corresponding to all notified.) Define “Other” in “Comments.”
Date of Provider Response	RespDate (Date Picker)	Numeric	MM/DD/YY	Date provider acknowledged case resolution notice. Enter 01/01/01 if “No Response.”
Provider Follow-up Action	ProvAct	Alpha-numeric	1=Order Cancelled, Prov 2=Test Reordered, Prov 3=No response 4=Other	Provider response to resolution notice. Define “Other” in “Comments .”
Length of Stay / Admission to date of consultation request	LOStoCon	Alpha-numeric	1=1 Day 2=2 days 3=3 days 4=4-5 days 5=6-10 days 6=11-15 days 7=16-20 days 8=≥21 days 9=Outpatient (OP) 10=Other	LOS from time of admission to time of consultation. Define “Other” in “Comments.” ≥
Days to Consultation Case Resolution	ResolveDays	Alpha-numeric	1=1 day 2=2 days 3=3 days 4=4-5 days 5=6-10 days 6=11-15 days 7=16-20 days 8=≥21 days 9=Outpatient (OP) 10=Other	Days from case review request to case resolution. Define “Other” in “Comments.”
Mortality During Case Consultation	Mortal	Alpha-numeric	1=Yes 2=No	Patient death during consultation period
Cost (Charges) Change (Delta)	Cost	Currency	$*****.** +/-	The resulting costs or savings related to case resolution (from reference lab charges and charge

				masters).
Comment(s)	AddInfo	Alpha	Free Text	Explanation of “Other” and/or additional information

APPENDIX D

DCM© DATA COLLECTION TOOL (Column Headers Only), v. 8.5.20

Case ID	Date (right click for Date Picker)	Medical Record Number	Patient Age	Patient Gender	Primary Patient Diagnosis	Primary Diagnosis Code (ICD- 10)	Ordering Provider Type

Ordering Service / Location	Clinical Lab Area	Test Name(s)	Test CPT Code(s)	Case Trigger Criterion	Case Test Cycle Phase

Case Treatment Phase	IP Team Handoffs Sequence	Total Handoffs / Logic Steps	Case Resolution	Date Resolution Report Sent to Provider (Date Picker)	Resolution Report Authority

Resolution Report Format	Provider Type(s) Notified (List Corresponding Numbers)	Date of Provider Response (Date Picker)	Provider Follow-up Action	LOS to Case Consultation	Days to Case Resolution

Mortality During Case Consultation	Cost Savings (+/-)	Comment(s)

Vita

Dr. Elizabeth Kenimer Leibach (Ph.D., Ed.D., M.S., MLS^{CM}, SBB^{CM}) is Professor and Chair Emerita at Rutgers University, Department of Clinical Laboratory and Medical Imaging Sciences; Professor and Chair Emerita (tenured) at Augusta University, Department of Medical Laboratory, Imaging, and Radiologic Sciences (College of Allied Health Sciences) and Department of Pathology (Medical College of Georgia); and Principal Officer for Healthcare Management and Education Services (HMES), LLC, consulting in areas related to clinical diagnostics services delivery, clinical and translational research, quality assessment, and education. She has a baccalaureate degree in Medical Technology (MLS^{CM}) and a Master of Science degree in Cell and Molecular Biology from Augusta University, a Specialist in Blood Banking (SBB^{CM}), certification through the University of Texas Health Sciences Center in Dallas (Parkland Memorial Hospital) School of Blood Banking Technology, a Doctor of Education (Ed.D.) in Adult Education from The University of Georgia, and a Ph.D. in Health Related Sciences from Virginia Commonwealth University. Dr. Kenimer Leibach is actively involved in clinical research and publication in evidence based healthcare services delivery related to informatics and clinical decision support, individual and population-level health record data analytics, and quality metrics for evaluation of medical effectiveness and cost efficiency of diagnostics services. Other healthcare activities, founded in quality theory, include development of evidence based educational materials for consumers, healthcare providers, and health educators concerning major chronic diseases of US populations. She has served as Education Editor for Clinical Laboratory Science, Senior Service Fellow and Expert Consultant for the US Centers for Disease Control and Prevention in the Laboratory Medicine Best Practices Initiative, and Rutgers Biomedical Health Sciences Liaison to the New Jersey Veterans Administration Health System. Dr. Kenimer Leibach's unabridged biography appears in the 2022 edition of Marquis Who's Who in America.