PROCESS EFFICIENCY OF DIAGNOSTIC PRACTICES IN PATHOLOGY

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The competitive landscape of the health care sector is changing. Private for-profit, private not-for-profit, and public medical care entities along the value chain are increasingly expanding the scope of their business endeavors. This thesis will discuss the evolution of medical services and the metrics used to measure the quality of those services, with particular attention to specialist diagnostic service players in dermatopathology. Hospitals are increasingly competing with private laboratories on the services side, while competing with biotechnology and pharmaceutical companies on the research and development (R&D) side. It is important to understand the factors that contribute to this increasingly complex market for medically related services. This paper includes a review of the empirical literature on metrics to assess quality of care both on a hospital and specialty practice level, a case discussion of a specific dermatopathology practice, and a discussion of the findings from interviews and field research. While it is important to assess the process efficiency of a firm’s operations in order to explore the levers for improvement, it is equally important to make sure that the levers used align well with the underlying strategy of the firm.
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CHAPTER 1: INTRODUCTION

The Market:

The health care industry is complex and fractured with multiple players. These players range from insurers, to health care providers who treat the ill, to industry firms that develop life-saving drugs and devices, to the patient. Industry firms such as biotechnology and pharmaceutical companies frame their place in the market according to research and development (R&D) of drugs, biological agents, and medical devices. Health care providers, such as hospitals, frame their place in the market according to patient care services and contributions to basic science and clinical practice.

Sharing the R&D, or Service, Space

The theme of this thesis is that many private for-profit industry players are increasingly competing with traditional clinical organizations in the diagnostics area of health care. Such activities in the same service or product space have been described by Lacetera, Murray, and Jeanrenaud in areas of the health care industry other than diagnostic pathology.

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Purpose and Structure

The purpose of this thesis is to assess the processing of tissue specimens at a Boston-area academic medical center in order to

1) Introduce concepts of operations management in order to assess efficiency in health care organizations

2) Analyze the components of the firm's strategy and assess the alignment of firm strategy with internal processes

3) Outline the difficulties of applying such operational frameworks to health care

This research aims to benefit both operations management and health care organizations by providing a discussion of key factors in assessing dermatopathology operations.

The thesis is presented as a series of articles: a literature review, a case-style presentation of a Boston-area academic medical center, a process flow diagram to illustrate, and an accompanying detailed description of the process of diagnosis. It then presents a discussion of diagnostics as they relate to service and manufacturing operations, as well as a discussion of the levers for change at the academic medical center.
CHAPTER 2: A COMPARATIVE REVIEW OF THE LITERATURE ON QUALITY METRICS AND THE DIAGNOSTIC PATHOLOGY MARKET

ABSTRACT

The competitive landscape of the health care sector is changing. Private for-profit, private not-for-profit, and public medical care entities along the value chain are increasingly expanding the scope of their business endeavors. The evolution of medical services and the metrics for quality measurement of those services are the focus of this paper, particularly specialist diagnostic service players and other practices, such as radiology and drug development. Hospitals are increasingly competing with private laboratories on the services side, while competing with biotechnology and pharmaceutical companies on the R&D side. It is important to understand the factors that contribute to this increasingly complex market for medically related services. The first section of this article reviews the empirical literature on metrics used to assess quality of care on the hospital level, then assesses the findings of the differences in quality of care by organization profit and teaching status. The second section of this article reviews studies of specific quality measures in diagnostic pathology practices and then discusses the competitive landscape of the clinical testing market.

INTRODUCTION

The rising cost of health care in the United States is a dominant topic among public policy makers, private advocacy groups, the private life sciences industry, and not-for-profit medical practices. The total health expenditure as a percentage of gross domestic product (GDP) for the United States was 14.6% in 2002, the highest among all countries included in the World Health Organization (WHO) 2002 survey. Biotechnology and pharmaceutical companies have grown to dominate a large part of the market in research and development of new compounds and therapeutic molecules, with the United States being a world leader in drug and medical device development. For-profit or not-for-profit hospitals provide a range of services and products from surgery to diagnostic imaging to acute care. Academic medical centers are a subset of hospitals—they are the nonprofit, medical school–affiliated
organizations that have a three-pronged mission of teaching, clinical care, and research. Thus, academic medical centers compete on a number of fronts with various private health care/life sciences sector players.

This paper synthesizes the current literature in several sections: the first section discusses the metrics used to assess quality of care on the level of the hospital; the second section offers discussion of the literature concerning the differences between private for-profit laboratory/clinical practice versus the private or public not-for-profit practice in relation to patient outcomes; the final section addresses quality-of-care standards and quality metrics for diagnostic pathology procedures and outlines the clinical testing market.

1. HOSPITALS AND QUALITY METRICS

In this section, discussion focuses on the different types of metrics that have been used to assess the quality of services provided by hospitals. I then compare the quality findings for different subsets of hospitals—those that are for-profit versus those that are not-for-profit, and those that are teaching hospitals versus those that are not.

1.1 Metrics for Quality of Care in Hospitals

What metrics for quality should be used when assessing hospitals? There is vast heterogeneity in the metrics used to determine quality. Table 2.1 presents the principal types of metrics used in studies that have been conducted on hospital quality. I then discuss the pros and cons of such sources.
The *Cleveland Health Quality Choice* (CHQC) study assessed quality of care through three metrics: patient satisfaction through surveys of medical, surgical, and obstetrics patients; intensive care unit mortality and length of stay; and mortality and length of stay for conditions other than intensive care. The data was collected through surveys and chart abstraction. A positive outcome of the study was that the initiative triggered quality improvements. The accuracy of the specific risk adjustment methods used to inform quality has been called into question. Risk adjustments are highly controversial since they entail a sophisticated treatment of condition-specific clinical data that is often not routinely collected. The risk adjustment performed for the CHQC study was further obscured by the private and proprietary use of formulas by the consultants performing the analyses.
The *Leapfrog Group*³ used proxies⁴ for quality standards. These proxies were (1) an assessment of the use of computerizing physician order entry (CPOE), (2) whether or not board-certified intensivists manage intensive care units, and (3) the establishment of annual hospital volume standards in several clinical areas. Leapfrog established evidence-based hospital quality and safety standards with a national panel of health-safety researchers before beginning their study. As a result of the study, many of the hospitals included have adopted CPOE, and they have found that the burden of data collection is relatively low. Volume standards as proxies for quality have been somewhat more controversial than CPOE, however, and the study suggests that this may be due to the lack of control hospitals have over this metric relative to the other two included in the analysis. The clarity of some of the data elements included in the study has also been called into question, as has the veracity of the survey responses. All three metrics have the benefit of accessible data collection.

The *Niagara Health and Quality Commission*⁴ (NHQC) used follow-up phone calls with patients after they had been discharged as a proxy for patient satisfaction. Sampling patient experience helped the participating hospitals to improve performance in the areas in which they had been criticized. However, the patient experience only represents a small part of hospital quality.

The *Guidelines for Applied Practice (GAP) Initiative*⁵ focused on processes rather than patient outcomes to determine quality. The physicians in the pilot study (cardiologists) were given a toolkit, which included standard orders, a clinician pocket guide, patient education materials, chart reminders, and examples of how to report performance. The study resulted in improvements to the processes measured and demonstrated that process improvements can yield quality-of-care improvements.

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⁴ Proxy measures for quality as opposed to direct measures of quality

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Other reports, such as *Quality Counts* (QC), have published hospital ratings (through newspapers, postings at supermarkets, etc.) calculated based on mortality and complication rates. Improvements in the areas measured were generated among the hospitals that were publicly rated as opposed to those that were not.

In sum, varying metrics have been used to judge hospital quality: structures (e.g., Leapfrog and CPOE), process (e.g., GAP and the physician toolkit), and/or outcome data (e.g., NHQC and surveys). In addition to great debate over which metrics should be used to assess quality and safety of care in clinical settings, there is debate as to the appropriateness of using these measures. Quality measures are scrutinized partly because they make inferences about the extent of quality failings. While explicit measures have been used to quantify the structures, processes, and outcomes of health care, as described above, they are used to describe wide variability, make inferences about the extent of quality failings, and estimate the consequences of such failings.

### 1.2 Quality According to Profit and Teaching Status

As mentioned in the above section, there are serious concerns as to the usefulness of the metrics developed and used to date in assessing the quality of care in hospitals. In addition, the use of mortality rates to assess quality of care is also problematic since risk adjustments are often inaccurate and not well understood. However, many studies continue to use mortality rates to compare private for-profit hospitals with private not-for-profit hospitals.

In one such meta-analysis, studies were chosen based on a set of criteria, and the results were masked before determining each study’s eligibility. Eligibility criteria included observational studies or randomized controlled trials that compared the two types of hospital status, and the relative risk of
mortality for one group versus the other was calculated. One of the potential confounding factors thought to have obscured the results is the fact that a much higher proportion of not-for-profit hospitals serve as teaching hospitals as compared to their for-profit counterparts. Three studies included in the meta-analysis excluded teaching hospitals and still demonstrated a statistical significance between the mortality rates of the two hospital groups.\textsuperscript{9} There is also suggestion that private not-for-profit hospitals serve a patient population with greater disease severity, which would result in a negative bias for private not-for-profit hospitals' risk of mortality.\textsuperscript{10}

In sum, private not-for-profit hospitals were found to provide better quality of care than private for-profit hospitals, and major teaching hospitals were found to provide better quality of care than nonmajor and nonteaching hospitals. In addition, major teaching hospitals provided better quality of care for common conditions than nonteaching hospitals. The quality-of-care differences assessed looked primarily at mortality rates as a measure of quality. We now address the metrics used to assess quality in diagnostic pathology.

2. QUALITY, PROCESS, AND THE COMPETITIVE LANDSCAPE IN DIAGNOSTIC PATHOLOGY

As with any process analysis, we have to keep in mind the overarching organizational strategy of the firm. What is the intended competitive advantage of this organization? How do the operations of the firm align with their positioning in the marketplace? In the following section, I discuss the different quality measures used in pathology practices, both in academic medical centers and in private for-profit operations. Ultimately though, efficiency as measured through performance on these metrics has to be contextualized with respect to the firm in order to judge the reliance on and use of these metrics to drive performance.
2.1 Metrics for Quality in Pathology Laboratories

The College of American Pathologists (CAP) has performed numerous studies on pathology laboratories in large cohorts from across the United States. These studies address, among others, issues of quality measures, error rates and detection, patient safety, and optimal staffing and turnaround time, either of general pathology laboratories or, more specifically, of anatomic pathology laboratories. As laboratory practices and measures of performance can be expected to vary with the subspecialty, some of the general pathology lab results, as well as the anatomic pathology lab results, cannot be expected to reflect accurately the specific quality and processing measures for the dermatopathology laboratory.

Quality assurance (QA) and quality control (QC) are crucial aspects of a clinical laboratory to ensure standard of care. The CAP Q-Probes, a multi-institutional quality-improvement and benchmarking program, yielded studies from large cohorts of laboratories throughout the 1990s. These studies give a framework for laboratory performance in three phases of the testing process.

The diagnostic process is broken down into three phases: the preanalytic, analytic, and postanalytic phases. The preanalytic phase comprises patient consent, specimen preparation, specimen transportation and handling, and sample accession. The analytic phase comprises all technical and professional diagnostic procedures: testing methods, lab protocols, testing and diagnostic criteria, terminology, diagnostic accuracy, report content, and time to complete the analytic phase. The postanalytic phase deals with report delivery, report format and clarity, and integration of lab and

* The Q-probes program is a subscription service of periodic structured quality assurance studies. The number of laboratories participating in studies each year ranges from 300-700 per study.
clinical information. Metrics that apply to the stages of the diagnostic process are: customer satisfaction, test turnaround times, patient identification, specimen acceptability, critical value reporting, and proficiency testing, among others.

Awards of excellence and performance scales are used in both service and manufacturing firms. For example, expectations for performance excellence are described by the Malcolm Baldrige National Quality Award *Criteria for Performance Excellence*.\(^\text{13}\) One study on quality in pathology has attempted to evaluate laboratory performance with the Six Sigma performance scale.\(^\text{14}\) Six Sigma is a measure of the conformance of process output to customer requirements. Potential use of the Six Sigma performance scale for quality assurance in laboratories was justified by the statement that “many other organizations use the design-measure-assess-improve model to effectively manage their business processes and to drive improvement of organization performance competitiveness.” Data from published Q-Probes reports was compared against a three-lab-group study. The data collected was normalized to parts per million (ppm) errors. This is in contrast to usual laboratory practice, in which the metric for errors is characterized as percentage variance. Percentage variance for both the three-lab group and the Q-Probes appeared low with some exceptions, and the article mentioned that each variance represents a large number, with each error having the potential to affect the patient adversely. The study did not calculate the sigma measures for each quality indicator; rather, it tabulated the ppm errors for each quality indicator and compared it to the Six Sigma measure of 3.4 ppm.

As mentioned above, turnaround times for laboratory test results have been used as a measure when assessing quality and laboratory performance. One such study aimed to determine the base parameters for routine outpatient turnaround time and to identify influential factors.\(^\text{15}\) This is particularly relevant to dermatopathology units when assessing the competitive landscape in anatomic pathology since
these units may choose to expand their outpatient services effort to compete with lucrative, private, for-profit diagnostic labs. In this study, laboratories collected data over a four-week period. Data points included times of day associated with collection of samples, laboratory receipt, result verification of specimens, and blood test–specific measures. Blood test–specific measures were chosen as proxies for three types of tests: (1) those that can be performed rapidly, (2) those that can easily be performed within a workday shift, and (3) those that are performed less frequently. Practice-related information was also included, such as whether the lab was associated with a managed care organization (MCO). Collection of the samples to lab receipt (preanalytic phase), turnaround times, and distribution were found to increase with time of day: 70% of the samples came from outpatients within the institution, and 10% came from local physician offices.

Another study used the following metrics to measure quality at the analytic stage of diagnostic laboratory processing: the frequency of discrepancy, type of discrepancy, vi effect of discrepancy on patient outcome, vii and clarity of report. vi Error detection in anatomic pathology usually occurs through the process of secondary reviews, which are built into some QA practices, for example, the review of a set percentage of cases, intradepartmental “difficult case” conferences, or the review of all malignancies. Study of secondary review methods has been variable. Of the participating institutions in the study, 31% were teaching hospitals, 23% had a pathology residency program, and 54.9% were private not-for-profit institutions. The majority of discrepancies had no effect on patient care, while 5.3% had a moderate or marked effect on patient care. The mean multi-institutional discrepancy frequency was determined to be 6.7%.

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vi Such as change in margin status, change in diagnosis, change in patient information, or typographic error.

vii Recorded as harm, near miss, or no harm.
Other studies have investigated staffing benchmarks for clinical laboratories. One such study assessed information about technical and management staffing and output for four laboratory sections, one of which was anatomic pathology. Benchmarks of labor productivity, defined as output per nonmanagement full-time equivalent, and management’s span of control, defined as nonmanagement full-time equivalent per manager, were found to vary greatly from lab to lab. Higher test volumes correlated with higher productivity for all labs with the exception of histology. Activities included in the study varied across the four laboratories. For example, in anatomic pathology, the metrics used were number of tissue blocks, cytology accessions, and billed procedures, whereas in transfusion medicine, the metrics used were number of crossmatches, type, and screens procedures. Likewise, productivity measures varied across the laboratories: productivity in anatomic pathology was tested for association with specimen complexity by calculating the ratio of different Current Procedure Terminology (CPT) codes. Sections of the laboratories were grouped into comparable “peer groups” by testing volume. Even so, results showed that productivity still varied widely. This data was not correlated with laboratories’ throughput or error rates. Therefore, productivity measures are not recommended as sole measures of quality for several reasons: the different metrics used for each laboratory section were not proven to be comparable, there was no analysis of their correlation to error rates or turnaround time (two metrics that have previously been discussed as potential indicators of quality), and other intangible factors that also contributed to productivity were not measured or adjusted for. Analyses of quality using optimal staffing should also include other metrics.

2.2 The Emerging Competitive Landscape in Dermatopathology Practices

A recent market analysis outlined the size and growth of components of the overall clinical lab-testing market. The total market size for overall clinical lab testing is $36 billion, which comprises
clinical lab testing (82%, $29.5 billion) and anatomic pathology (18%, $6.5 billion). The anatomic pathology division of the market was further broken down into three categories, hospital outpatient, hospital inpatient, and outpatient, which were 14%, 38%, and 48%, respectively. The outpatient segment was further broken down by disease, organ, or test. These were pap smears (37%, $1.13 billion), skin (22%, $680 million), cervical (20%, $620 million), other (9%, $280 million), prostate (7%, $230 million), and gastrointestinal (5%, $170 million). Industry growth of anatomic pathology was estimated at 6% to 7% per annum, with an independent lab-testing market volume growth of 3% to 4% and price growth of 2% per annum. The outpatient segment of the anatomic pathology market is estimated to be growing at 8% to 10% per annum.

Industry growth in clinical testing is projected to continue. Several factors play a role in the assessment of growth prospects for clinical pathology laboratories, such as, among others, the retraction of the managed care threat, an aging population, and the steady rise of cancer incidence. As a result, there have been several recent acquisitions of the top three pure-play anatomic pathology companies. Dianon was acquired by LabCorp for $598.4 million in early 2003, AmeriPath was acquired by Welsh Carson for $792.3 million in early 2003, and Impath was acquired by Genzyme Genetics for $215 million (physician service business unit) in mid-2005. These private for-profit pathology enterprises have established competitive advantages through branding, centralization of processing and diagnostics, and contracting payor (insurance) relationships.

A recent article suggested that smaller pathology practices could successfully combat the increasing competition from bigger labs through niche market strategies, such as establishing joint ventures with hospitals in their development of lucrative anatomic pathology outreach business. Surgical centers and doctor’s offices were pointed to as two standout factors pushing the growth of outreach services, with dermatopathology, gastrointestinal pathology, uropathology, and gynecologic pathology as being the
subspecialties with the greatest volumes. These smaller community-based practices are going head to head with the larger national practices, such as Labcorp and Dianon, in their direct physician marketing efforts and are focusing their efforts on establishing long-lasting relationships.

As services offered by these groups converge, anatomic pathology practices face increasing levels of competition. Several factors have been highlighted as key to the ability of such practices to compete with national laboratory chains. Three standout features that could provide a competitive advantage are (1) developing a strong information technology infrastructure, (2) building relationships with clinicians and hospitals, and (3) staying current with new tests and services.

Data suggests that dermatopathology, a subspecialty of anatomic pathology, is a growing and lucrative market. As a result of an increased focus on specialized testing, increasing cancer incidence, an aging population, and information technology advances, many private for-profit diagnostic enterprises are making use of this growing opportunity by expanding the scale and scope of their services. Not-for-profit academic medical centers, medical enterprises that focus on teaching, research, and clinical duties, face increased competition on all fronts. Biotechnology and pharmaceutical companies compete with academic medical centers in the discovery of predictive markers as well as targeted therapeutics, and private for-profit practices compete on the clinical aspects of their practice in diagnostics and testing. The incentives that drive academic physicians—physicians who teach, practice medicine, and conduct research—vary from those that drive practitioners in the competing entities. Hence, process improvements in the academic medical center setting must be carefully considered in the context of levers for improvements.
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CHAPTER 3: FROM PATIENT TO DIAGNOSIS: THE STORY OF A FUNNY-LOOKING MOLE AND ITS DIAGNOSIS AT MASSACHUSETTS GENERAL HOSPITAL: JULY 2005

In October, 2005, the Massachusetts General Hospital (MGH) planned to move its clinical dermatology unit to Staniford St., off the main campus and further away from its dermatopathology unit, which would remain on the main campus. An overall anatomic pathology process review had been performed recently, and a more specific dermatopathology process review had been performed more than ten years ago. However, the process involved in getting a dermatopathology diagnosis to a patient in the MGH hospital system still needs to be explored in the context of this changing environment.

Since the last process review in 1994, performed by the then new director of dermatopathology, Dr. Tom Flotte, many changes to the internal practice of the hospital, as well as in the market for the diagnosis of skin lesions, have taken place. Powerpath, a new hospital accessioning system whereby samples are tracked and a diagnosis is produced for the doctor and patient, was implemented in the summer of 2004. The implementation of Powerpath led to many changes in the handling of patient data, specimens, and diagnoses, both logistically and virtually. The Health Insurance Portability and Accountability Act (HIPAA), a new legal standard regulating patient privacy, was passed by the government in 1996. In addition to these planned and implemented internal changes, many other private, for-profit, diagnostic laboratories and practices were now operating in the Boston area, thus increasing competition for patients. Despite the fact that MGH is recognized for clinical and research excellence, the mission for the hospital is based on potentially conflicting and competing goals: excellence in research and patient care, the need to remain a profitable entity, and the legal obligation to care for patients without prejudice as to ability to pay for treatment. In an industry mired in
regulatory difficulties and facing the spiraling costs of health care, remaining afloat while providing unbiased care and making competitive progress in the medical arena is difficult for even the most efficient of private nonprofit hospitals. Many factors affect the goal of the MGH dermatopathology unit to continue as a margin-bearing subspecialty, namely, the increasingly scarce and expensive property in Boston and its surrounding suburbs, both external changes in the market and internal operational changes, and the regulatory landscape. How do these factors affect this goal?

3.1 The Diagnostics Industry in 2005

Presently, there are a number of both nonprofit hospitals that do in-house diagnostics and private for-profit diagnostic pathology labs in the Boston area. World-class hospitals such as MGH, the Brigham and Women’s Hospital (BWH), the Dana Farber Cancer Institute (DFCI), and the Beth Israel Deaconess Medical Center (BIDMC), as well as successful private diagnostic labs such as AmeriPath and Cohen Dermatopathology, all perform routine processing and clinical diagnostic procedures for patients in the metropolitan Boston area, as well as for out-of-state patients.

Founded in 1811, MGH is the third oldest hospital in the nation. With representation from virtually every medical specialty and subspecialty, MGH is a renowned center of medical excellence in diagnostic and therapeutic care, imaging research, and cancer genetics. In 1994, MGH joined with BWH to form Partners Health Care System, Inc.21

All founded in the late 1800 to early 1900s, BIDMC, DFCI, BWH, Harvard Medical School (HMS), and the Harvard School of Public Health (HSPH) are located on Longwood Avenue in the heart of Boston. Together with MGH, they have formed a collaborative body of institutions known as the Dana Farber/Harvard Cancer Center (DF/HCC).
AmeriPath is an anatomic pathology and molecular diagnostics operation that offers a range of testing and information services used by physicians in the detection, diagnosis, evaluation, and treatment of cancer and other diseases and medical conditions. They have over 400 highly trained, board-certified pathologists who provide medical diagnostics services in outpatient laboratories, as well as in hospitals and ambulatory surgical centers.

Cohen Dermatopathology, established in the late 1990s, is a dermatopathology laboratory service in Massachusetts. The organization provides a full range of dermatopathology services, including slide preparation and special stains and studies.

3.2 Dermatopathology Subspecialty Practice at MGH

The pathology unit at MGH is chaired by Dr. Robert Colvin, a renal pathology specialist. The unit is organized into three major subspecialties: anatomic pathology, laboratory medicine, and molecular pathology and research. The anatomic pathology division is led by Dr. Robert Young and is siloed into seven subspecialties, of which dermatopathology is one. Laboratory medicine is headed by Dr. Michael Laposta and is divided into four main labs. The molecular pathology and research division is headed by Dr. David Louis and aims to facilitate the development of basic and translational research.
3.3 Melanoma

Melanoma was first named by Sir Robert Caswell (1793–1857) in 1838 as a tumor with cancerlike properties. However, there was much disagreement in the medical world as to the disease process that it was named for.\textsuperscript{22}

Melanoma is the most deadly skin cancer. Its incidence continues to rise with increasing rapidity and will be diagnosed in over 50,000 Americans this year. In contrast to the 1 in 250 Americans diagnosed in 1980, the corresponding rate of diagnosis for 2000 was 1 in 75.\textsuperscript{23}

The most common skin cancer types are basal cell and squamous cell carcinomas (BCC and SCC, respectively), which, like all cancers, originate from the cells for which they are named (i.e., BCC and SCC are tumors of keratinocytes, the protective layer of cells on the outermost surface of the skin). Melanoma, on the other hand, is the result of dysregulation of melanocytes, the cells in the skin that produce the melanin pigment responsible for skin color.

While both BCC and SCC, if left unchecked, may metastasize (spread to lymph nodes and other organs), melanoma does so much more rapidly and aggressively (with quicker time to metastasize and stronger ability to invade). If caught “early,” as defined by staging criteria\textsuperscript{24} by the American Joint Commission for Cancer (AJCC), most stage I disease is almost always cured by local excision (minor surgery). For patients diagnosed with stage II, III, or IV disease, a rough prognostic indicator is their estimated fifteen-year survival rates, which are 52\%, 27\%, and 9\%, respectively.\textsuperscript{25} Effective prognostication, the ability to predict how a patient’s disease will progress, coupled with the discovery of effective treatment therapies, is the holy grail for academic dermatopathologists (pathologists who specialize in diseases originating within the skin).
3.4 Prognostic Variables and Relevance in Diagnosis

Disease progression of melanoma is still not entirely understood, but many factors are known to play significant roles. Many studies implicate Ultra Violet B radiation (280–315 nm). Progression from normal melanocyte to metastatic melanoma has many diagnostic and clinical hallmarks to indicate disease progression (figure 3.1). The robustness of a patient’s prognosis is defined by the ability to predict recurrence of disease, as well as the number and length of disease-free intervals. In diagnosing melanoma, the dermatopathologist takes into account diagnostic factors in the tissue as well as prognostic factors, although each practice has different criteria for data collection. For example, a tumor registry in an academic setting may use a multifactorial model, which may include many nonstandard data elements, whereas a diagnostic laboratory may look at and record only the minimum factors needed to render a diagnosis accurately. Some standard prognostic factors, such as Breslow thickness, age, sex, site, and Clark level, are used in clinical diagnosis.

The correlation between primary tumor thickness and survival was established by Alexander Breslow in 1970. Breslow thickness, which is tumor thickness measured perpendicularly from the top layer of the epidermis to the deepest melanoma cell, is still the gold standard as a basis for disease staging, as well as for surgery and immunotherapy. The Clark level of the tumor, described by Wallace Clark Jr., MD, is a description of the anatomic level of invasion and is similar to tumor thickness as it describes the degree of vertical invasion by the tumor. Each Clark level describes a range of thickness and includes the parameter of anatomical site.

When examining a stained slide under a microscope, the pathologist takes into consideration many of these factors; however, Breslow thickness remains the gold standard for melanoma diagnosis. While
melanoma can be very accurately diagnosed, there is still very little in the way of chemotherapy, biochemotherapy, or immunotherapy that can be done for patients diagnosed beyond Clark level I, or stage 0. Several clinical trials are being performed in the Boston area, as well as across the country; however, successful therapeutic choices for patients have yet to be realized.

Several pioneer clinicians who have changed the standards for melanoma diagnosis, Breslow, Clark, Charles Mihm and Thomas Fitzpatrick, have all held appointments at Harvard Medical School and headed the unit or practiced at MGH. They have been responsible for teaching the art of dermatopathology to generations of Harvard-taught doctors, some of whom have gone on to lead successful private laboratory practices, and others of whom have continued to practice at MGH or at other top academic medical centers around the world. For this reason, when a private pathology laboratory receives a difficult-to-diagnose case, the case is sent to MGH for a consult. Such a case may be a suspect melanoma with odd features, which may turn out to be diagnosed as a spitz nevus, a mole with features barely distinguishable from melanoma but for which the disease progression is markedly different (outcomes are far better).

3.5 Excision of the “Funny Looking Mole” and Diagnosis

A patient with a suspect mole (in a clinical diagnosis, that is, diagnosis of the mole by a dermatologist or surgeon) will make an appointment to see an MGH-affiliated Doctor, either on the main MGH campus or at an MGH-affiliated site close to MGH in Cambridge or the Boston suburbs. Once at the doctor’s office, the patient signs in with the receptionist, fills out some forms, perhaps sees a nurse practitioner, and then sees the doctor. The suspect mole will be removed and prepared for transport.
When a sample arrives at MGH, it is routed to the gross anatomy lab in the Blake Building, Level 3, where it is first accessioned, by a secretary, into the hospital’s clinical database and given a unique identifier. The sample is then “grossed,” that is, examined by a resident or pathologist assistant, carefully cut, and placed in a plastic cartridge in preparation for processing, and the gross anatomical features are dictated. After grossing, the sample (now known as a tissue block) then travels across the hall to the histology lab (known as the back bench) to be processed overnight, while its corresponding transcription tape is sent to Level 2 of the Warren Building. Any backlogged samples occurring that day wait until the next morning to be processed, a wait that could be averted, says Dr. Flotte, “If they could only schedule techs on until about 8 p.m., but currently, their shift ends at 5.”

While MGH serves the greater Boston area primarily, a patient’s sample may have to travel by road from off-campus sites or from the main-campus Pigmented Lesion Clinic. Traveling by road as governed by the Department of Transportation (DoT) puts a kink in a sample’s expeditious delivery to the gross anatomy lab (where it is entered into the hospital’s database and the process of pathological diagnosis begins). “The sample has to be packaged as if it’s going to California,” says Dr. Flotte, pointing out that any clinical sample that has to travel by road (which are by definition under the jurisdiction of the Department of Transportation) has to be packaged similarly, even if it is traveling half a mile.

This protocol of packaging not only means that extra time and money are spent preparing the samples for delivery to the gross anatomy lab, but sometimes results in bulk delivery of all samples to the gross lab at the end of the day, when technicians are completing their shifts, leaving the samples unprocessed overnight to be done first thing the next morning.
From the gross lab, the process of diagnosis splits; the transcription tape goes to the Warren Building, and the tissue block goes across the hall to the back bench in the Blake Building. The tape is transcribed, and an initial report is generated, after which it is either transported to Level 8 of the Warren Building, where the dermatopathologists have offices and a sign-out room, or it is given to a resident on the second floor of the same building. The paperwork is then matched with the corresponding glass slides by the resident on Warren 2 or by staff or a fellow on Warren 8.

In the meantime, the plastic containers and the tissue are processed in the tissue processor overnight in a process that preserves the morphology (the configuration) and microelements (DNA, some RNA, and proteins) of the tissue. The following morning, the tissue undergoes a process that embeds it in paraffin wax, preserving it for up to twenty years. The paraffin blocks are then cut (sectioned) by a histotechnician to create three diagnostic slides that are stained with Haemoloxin and Eosin (H&E) in a process that allows morphological features of the tissue to be recognized and distinguished under the microscope. The remaining tissue blocks are stored for a week in the back bench, then sent to the basement for long-term storage. After staining, the diagnostic slides are delivered to Warren 2 or Warren 8.

The diagnostic H&E slides and their corresponding paperwork are reviewed under the microscope by either a pathology fellow or a pathologist. The diagnosis is written on the paperwork. Transcription on Warren 8 types the report and checks billing and coding for accuracy. The staff enters the file into Powerpath, then proofreads and finalizes the report, which is then printed and mailed or faxed to the referring dermatologist.
FIGURE 3.1  Progression from normal melanocyte to metastatic disease

Normal melanocyte

Sun-damaged melanocyte/nevus

Primary melanoma in situ

Primary melanoma invasive (thin or deep)

Metastatic melanoma
FIGURE 3.2  Representative section of the skin

Epidermis
Papillary dermis
Reticular dermis
Subcutaneous fat
FIGURE 3.3 Process diagram of melanoma diagnosis: a broad overview
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CHAPTER 4: PROCESS FLOW DIAGRAM AND DETAILED DESCRIPTION OF PROCESS

ACCESSION TO HISTOLOGY

Regular Specimen
- Gross In: Lilac Cassettes
  - @ small side bench
- Wait
- Formalin Bucket
- Grouped & Bagged

<0.2cm or delicate
- Gross In: Blue Mesh
  - @ small side bench
- Wait

Transport to Histology

Requisition sort by type
- Path Assistant Or Resident
- Large Specimen
- Large Side basket
- Sort
- Gross In: Lilac Cassettes
  - @ Derm bench
- Wait
- Formalin Bucket
- Bagged

Small Specimen
- Gross In: Blue Mesh
  - @ Derm bench
- Wait
- Formalin Bucket
HISTOLOGY TO PATHOLOGIST

Tissue Processing
Sort by type
Overnight (12-16hrs) for large cassettes
Same Day (2hrs) for small cassettes

Regulars
Tiny
Automatic
Special Stains

Slides Cut
Slides Cut
Slides Cut in Special Stains
Slides Dried Stained & Coverslipped
Slides Dried Stained & Coverslipped

Labels made

Slides Arranged

Blocks Filed

Boxes on WRN 1

Taken to WRN 2

Resident-Free service: Histologist
Resident-Staff Service: Resident

Matched w/ Blocks

Slide Trays

35
DIAGNOSIS

Delivery to WRN8

Resident-Free Service: Histologist
Resident-Staffed Service: Resident

Order Paperwork and Slides

SECRETARY (1 FT)

Microscope

DERMATOPATHOLOGIST
(2 per service)

Transcription of diagnosis

SECRETARY (1 FT)

Diagnosis Received

REFERRING DR

Fax

COMPUTER GENERATED

Signout

DERMATOPATHOLOGIST
4.1 Description of the Process

The following description is a direct interpretation of the process flow diagram presented above. Skin biopsies find their way to the desk of a pathologist for diagnosis through several access points. The specimens arrive at the pathologist’s desk as stained tissue sections on glass slides. The sections are either cut and stained at MGH (in-house cases) or have been cut and stained at another institution (consults). The following discussion focuses on those cases that are received in formalin and are cut and stained at MGH.

Off-site tissue specimens arrive by hospital transport, a private mail carrier, or courier service. Specimens coming from surgeries on the hospital grounds are hand delivered. All tissue specimens are delivered to the gross anatomy laboratory on Blake 3, where a secretary signs them into the database, which generates a unique identifying number. The outpatient specimens from the clinics are sorted onto the small side bench in the gross anatomy lab, while the inpatient specimens from the main campus are sorted onto the large side bench. After initial sorting into small and large samples, the specimens are inspected. Surgical pathology technicians inspect the large samples on the dermatopathology bench, sorting them again according to whether they are small or regular, while pathology assistants or residents inspect the small or delicate specimens on the small side bench, sorting them by size and features into regular and < 0.2 cm/delicate groups. The regular specimens for both types of specimens are placed in lilac plastic cartridges, and the small or delicate samples for both groups are placed in blue mesh cartridges. The specimens are cut and placed in their plastic cartridges while the patient information and specimen features are described and dictated onto tape. The tapes and patient paperwork are sent to Warren 2 for transcription. After dictation and cutting, the samples are held in their groups in formalin buckets. The large regulars and small regulars are each “grouped
and bagged” at the end of the day and taken across the hall for processing in the histology lab on Blake 3. All but the small delicates in blue mesh are processed overnight on a sixteen-hour program in the tissue processor. The small delicates are processed in the same machine but on an accelerated two-hour processing program.

After processing, the samples, now called tissue blocks, are sorted into groups as (1) tiny, (2) regular, and (3) automatic special stains. Each group is handled by a histotechnician who carefully prepares glass slides for microscopic inspection by slicing the tissue with a microtome, a tissue-cutting machine not dissimilar from a deli slicer. After slicing, the 4-μm-thin sections of tissue are adhered to glass slides and stained to enable certain features to be distinguished. A protective 1-μm-thin glass cover is glued over the stained tissue. These slides are then labeled and matched to the originating tissue block.

The remaining tissue blocks, if all are not used in producing slides, are stored in the lab for a week, and then sent to the basement for long-term storage. Histology lab personnel sort the slides and match them (to the paperwork transcribed on warren 2). Slides and paperwork are then delivered to the pathologists’ desk, either the residents on Warren 2 or the staff dermatopathologist on Warren 8.
CHAPTER 5: DISCUSSION OF LEVERS

Since 2005, several changes have been made to the process of making a diagnosis, the details and effects of which are discussed below. As detailed in chapter 2, outreach services are increasingly attractive to academic medical centers and hospitals across the United States. In contrast, MGH no longer pursues outreach cases unless requested by physicians. Along with this cut in outreach services, MGH has focused on demand smoothing by addressing transportation scheduling, the rebalancing of staffing, and changes in sample setup. Other changes include amendments to the employee group structure and the private consultations policy, which may have long-term effects on the productivity and quality of diagnoses made. Below, I outline these changes to the process and discuss the interaction of process structure with the firm’s mission. In addition, I discuss how quality measures are thought of in the context of the nature of diagnostic pathology as both a service and a manufacturing operation.

5.1 Demand Smoothing

The arrival of specimens at the gross anatomy lab can be likened to the demand for processing services. The arrival rate of samples affects the rate of work done both at the gross anatomy lab and at points downstream. The decision to cut outreach services has left two remaining clinics within the MGH dermatopathology process that provide outpatient services, the Watertown and Staniford Street dermatology practices. The specimens from these two clinics represent 70% of sample volume, while

*viii* Interview with Dr. Lyn Duncan, MGH dermatopathologist.
the remaining 30% of specimen volume comes from surgeries performed on the MGH campus (inpatient specimens).

Specimens were formerly transported once per day to the gross anatomy lab between 5 and 6 p.m. This single large delivery created a backlog of specimens as they waited to be grossed in, accessioned, and loaded into the tissue processor by 9 p.m. The remaining specimens not processed by 9 p.m. would wait until the next morning. The Pathology Department has smoothed the arrival of outpatient specimens through the institution of a mid-morning transportation run. Now, specimens that make it onto the mid-morning transport run can be grossed, loaded into the tissue processor, sectioned onto slides, and readied for diagnosis by the next morning. The remaining 30% of specimens processed are hand-delivered at the gross lab in intermittent batches by surgical physician’s assistants, who bring the specimen straight from surgeries performed on campus. The arrival of inpatient specimens has not been changed and is discussed in the section titled “Further Improvements to the Process.”

5.2 Staffing Changes

In coordination with the transportation changes described above, staffing levels have been adjusted to match demand. One full-time pathologist and one full-time histologist have been placed in the gross and histology labs, respectively, during the day in order to process the specimens that arrive with the mid-morning transport. Stress on the staff in dealing with the evening backlog has also been alleviated somewhat by this personnel scheduling change. One challenge is educating the referring doctors and residents who send the specimens from the outreach offices that, if they were to get their morning patients’ specimens on the mid-morning transport, they could have a diagnosis in twenty-four hours.
As a result of transportation and staffing changes, the productivity of the laboratory has increased, as detailed below.

5.3 Changes to Specimen Preparation

Setup waste in the ordering of specimens adds to the waiting time for processing. For example, specimens were put in order when they are grossed in, held in formalin in a bucket until the end of the shift, deordered when placed in the tissue processor, and then reordered when removed. Specimens are now processed and kept in the order in which they are grossed. Not only has this change reduced wait time, but it has also reduced the probability of matching and identification errors since staff do not have to continuously revisit the process of matching specimen IDs with their paperwork and transcription tape.

5.4 Further Improvements to the Process

These changes outlined above have resulted in a six-fold reduction in the range in wait times for accessioning to histology from 0.75 to 51.3 hours to 0.3 to 11.25 hours.\textsuperscript{ix} However, this wait time is only calculated from the time that the specimen arrives at the gross lab as tissue until it leaves the histology lab in the form of blocks and slides. The wait time for the entire process from patient biopsy to diagnosis is much greater than the maximum wait time at the gross anatomy and histology labs. In order to further decrease the wait time of the entire process, levers such as demand smoothing, staffing, and process changes should be further investigated at other points in the process. For

\textsuperscript{ix} Interview with William Hynes, MGH Pathology
example, further improvements to productivity could be made by linking the surgery schedule to the staffing capacity through the internal computer system, thereby enabling demand forecasting for surgical, on-campus specimens.

It remains to be seen how such process improvements affect MGH’s ability to deliver on its other two mission components of teaching and research. I detail one such potential interaction below.

After the specimens have been sectioned in histology there are two different routes, in the form of service schedules, which the specimens can take: these are the “resident-free” and the “resident-staffed” services. On the resident-staffed service, sectioned specimens are delivered to the resident on service, who then reviews the cases, makes notes, and takes the cases and notes up to Warren 8 for discussion with the dermatopathologists on service. On the resident-free service, the histotechnician who sections the processed tissue delivers the tissue slides directly to the dermatopathologists on Warren 8. The dermatopathologist who makes a diagnosis without simultaneously having to teach a resident is able to increase turnaround time per specimen. The resident-staffed service, on the other hand, may add up to a day to the turnaround time of a diagnosis, but it fulfills both the teaching and clinical aspects of the mission of the firm. In contrast, the resident-free service fulfills the clinical mission only. Pressure to compete with private for-profit firms that focus on clinical work only may have detrimental long-term effects on the teaching mission.

5.5 Service and Manufacturing Operations

As seen in the literature, quality on both a hospital and anatomic pathology level is assessed through both service quality (e.g., perceived quality through patient surveys) and product quality (e.g., through
proxies for quality such as turnaround time, frequency of discrepancy). Although laboratory operations fit into the realm of professional services, they have a strong manufacturing component as seen from the fact that a specimen of tissue is transformed into a diagnostic able sample in the process of the service interaction. It is important to be able perform in both the service and manufacturing dimensions. With performance improvement in mind, several studies have tried to both qualify and quantify the changes that laboratories can make; one such study presented in chapter 2 discussed the use of the Six Sigma measure as a way to do so. However, the strict transferability of Six Sigma or other such manufacturing operations measures should be further scrutinized in the context of medical services such as diagnostic pathology.

Six Sigma is a measure of the difference between the range of customers’ desired product qualities and the actual products’ specifications. In other words, Six Sigma measures conformance of desired product attributes with actual product attributes. Quality in the medical field is confounded by a vast information asymmetry between doctor and patient, general practitioner and specialist, and resident and teacher. In addition, the ability to ascribe certain product attributes to product quality — in this case, it would be turnaround time or some other quality proxy for a tissue specimen used for diagnosis — calls for sampled and robust studies using longitudinal data that follows a risk-adjusted set of patients. Such studies in diagnostic pathology have not yet been performed.

In conclusion, consulting services in the health-services sector exist but may aid short- to mid-run improvements in the clinical aspects of clients’ operations. More attention needs to be given to the interaction of the components of firm’s strategy, as well as to how those components of strategy are implemented through firm functions. Caution should be exercised when attempting to apply popular performance measures used for manufacturing paradigms to diagnostic pathology operations.