

Nature and Rate of Change in Clinical Laboratories

Final Report

Dina Battisto David Allison

Architecture + Health Clemson University

Sponsored by **The Coalition for Health Environments Research (CHER)**

November 2002

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PREFACE

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Sponsor: Coalition for Health Environments Research (CHER)

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Published by: The Coalition for Health Environments Research (CHER)

2200 Pacific Avenue, 6B San Francisco, California 94115 Tel. / Fax. (415) 359 1818 http://www.CHEResearch.org

Publication September 2003 ISBN Number 0-9743763-0-2 Printed in the United States of America

Information on ordering a copy can be found on our web site.

Special Thanks:

Special appreciation is given to Herman Miller, Inc. and the AIA Academy of Architecture for Health for their support of this project and CHER's work. We also appreciate the cooperation of the Clinical Laboratory Management Association (CLMA). Without their efforts this study would not have been possible. Finally, our special thanks to Dina Battisto for her tireless work in bringing this research effort to fruition.

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Acknowledgements

We would like to thank the Coalition for Health Environments Research (CHER) and Herman Miller, Inc. for the opportunity to pursue this area of research. In particular, Tib Tusler, the Executive Director of CHER, and the research committee including: Uriel Cohen, Mardelle Shepley, and Debra Harris have been very supportive throughout the entire process.

Collaborating with the Clinical Laboratory Management Association (CLMA) proved to be an extraordinary experience. In many instances, the organization served as a conduit to bring people together and discuss issues related to the clinical laboratory. In particular, we would like to thank Robert Neri, Executive Vice President of CLMA, the advisory committee, Megan Wilmot, and Frank Shafer.

There are also numerous other individuals who contributed in some manner whether it was answering questions, sharing knowledge and experiences, or reviewing the questionnaires. We are in debt to Barbara Brumagim, Roger Call, Judy Lien, Frederick Marks, Nolan Watson, Leslie Becker, Jane Rhode, Nordie Cantilla, Doug Farber, Joyce Durham, and Lynn Caldwell. Also, thanks to Melanie Easter and Scott Meade who helped with the data collection, analysis and production of this report.

A special thanks to the people in the laboratories who opened their doors to us for our research, particularly Ginger Smith and staff from Greenville Memorial Hospital in Greenville, South Carolina; Linda Cawley and staff from St. Claire's Hospital in Schenectady, New York; and Wendy Rosher and staff from Ellis Hospital in Schenectady, New York. As well, thanks to Dr. Rodney Markin and Jarrell Tillman from LAB-InterLink. Finally, we would like to express our gratitude to all the people who responded to the survey.

Abstract

In response to the accelerating changes in the healthcare field, there has been a great deal of attention devoted to creating flexible designs and furnishings in hospital-based clinical laboratories. Even so, the hypothesis that hospital laboratories require a high degree of flexibility has been essentially untested. This study aims at confirming or negating this need for flexible designs and furnishings as well as providing guidance for addressing flexibility in future hospital laboratory constructions and renovations.

On a theoretical level, an environment-based approach to studying how buildings are used over time inspired this study. Building on Frank Duffy's "Time-layered perspective" and Stuart Brand's "Shearing layers of change," the framework for this study was developed around the specificity of the hospital-based clinical core laboratory. The premise of the framework is that it is important to look at the multiple physical layers in the laboratory in relation to the internal forces (the activities that are housed in them) and the external forces (the technological processes, market forces, and healthcare practices) that define or influence the activities.

To explore the nature and rate of change in clinical laboratories, a multimethodological approach employing both survey research and case study research was used to triangulate conclusions. Self-reported data was collected from a total of 240 hospital laboratory staff from the Clinical Laboratory Management Association's (CLMA's) membership list using an interactive web-based questionnaire. The sample represents a national cross section of clinical laboratories in communitybased hospitals. Case study research was also used to explore three common laboratory typologies—a compartmentalized laboratory, an open/flexible laboratory, and an automated laboratory—with the intent of documenting specific examples of types of changes considered or completed by clinical laboratories.

Findings are organized in three areas: specific activities, technological processes and the physical environment. The physical environment is further divided into three physical layers: infrastructure systems, space plan, and contents in the laboratory. This research supports the premise of planning and designing clinical laboratory environments that are flexible, and versatile to support multiple laboratory applications. The goal of this study is to contribute to a body of knowledge that will help reduce the recurring problem of obsolescence in healthcare buildings by understanding the relationship between activities, the technological processes and the physical environment.

Introduction

"From tasting urine to microscopy to molecular testing, the sophistication of diagnostic techniques has come a long way and continues to develop at breakneck speed. The history of the laboratory is the story of medicine's evolution from empirical to experimental techniques and proves that the clinical lab is the true source of medical authority."

> Darlene Berger, 1999 "Ancient Times Through the 19th Century"

The practice of laboratory medicine evolves as different methods of determining diagnosis are discovered. Over the last 800 years, there have been numerous scientific breakthroughs in both diagnostic methods and tools, such as the creation of blood tests, cause of coagulation, and the invention of the vacuum flask. The current state of knowledge in laboratory science allows for a more objective method of determining a patient's physiological condition. This objective method of determining diagnosis is remarkable, yet the consequence is that there is an increased dependency on technology, the machines that produce the data, as well as medical practices that help direct these technologies (Berger 1999).

Today, the clinical laboratory is physically enormous; it represents the third largest hospital department following surgery and radiology. It houses sophisticated instruments and equipment, which are used to analyze body fluids and tissues. Test results are used in the prevention, diagnosis, and treatment of patients. Although the laboratory is often viewed as an ancillary service, the information produced in the laboratory is indispensable to the practice of medicine. In fact, estimates have shown that clinical laboratories provide about two-thirds of all the objective information regarding the status of health (cited in Coffman 1998). Consequently, this may be why some predict that with more improved intellectual process control and data management, the laboratory may become the most frequently used, and most important, source of diagnostic information in medicine (Felder *et al.* 1999). Others predict that as clinical laboratory results are refined and incorporated in outcomes optimization schemes, laboratory results will become "the focus of managed care, health maintenance, and disease management companies within the next 5 years" (Markin and Whalen 2000).

The accelerating rate of change in technology in general, medical science, the delivery of medical care, and market forces are all forcing healthcare providers to reassess the role and nature of hospital-based clinical laboratory services and facilities. As a result, providers are either contemplating, or making, significant changes in both the nature of clinical laboratory services and the facilities where these services are provided. To respond to the accelerating changes in the healthcare field, there has been a great deal of attention devoted to creating flexible designs and furnishings in hospital laboratories.

Even so, the hypothesis that hospital laboratories require a high degree of flexibility has been essentially untested. Therefore, this study aims at confirming or negating this need for flexible designs and furnishings as well as providing guidance for addressing flexibility in future hospital laboratory construction and renovation projects. This study targets clinical core laboratories located in community hospitals. The core laboratory is the primary laboratory performing comprehensive testing versus a satellite laboratory which is a smaller laboratory performing a select test menu.

A review of the literature shows that significant changes in clinical laboratories may be attributed to technological/equipment advances (Wilson 2000), pressure to contain costs and operate efficiently (Wright and Ferguson 2001), regulatory requirements (Mortland 2000), and healthcare trends (Felder *et al.* 1999). These four forces were studied with respect to both the physical environment and the delivery of laboratory services. Despite the articles that note the motivators of change, no recent research study was found that documents the comprehensive nature and rate of physical facility changes in hospital clinical laboratories. This study targets this gap in the research.

The fundamental question to answer is, "What is the nature and rate of change in the clinical laboratory?" To answer this general question, three areas are identified. First, it is necessary to explore the range of testing activities and human activities that are specific to clinical laboratories located in hospitals. Second, it is necessary to explore how the laboratory operates, or the technological processes that support diagnostic testing in the laboratory. Finally, it is necessary to explore the multiple layers that define the physical environment in relation to the first two areas to understand how, where and when the physical environment needs to change.

These three areas: specific activities, technological processes, and the physical environment provide a structure to ask more specific questions.

1. Specific Activities

What specific activities change in the clinical laboratory? Where do they change? How do specific activities change? How often do they change in the laboratory?

2. Technological Processes

What technological processes change in the clinical laboratory? Where do they change? How do technological processes change? How often do they change?

3. Physical Environment

What aspects of the physical environment [infrastructure, space plan, and contents] change in the clinical laboratory? Where does the physical environment change? How does the physical environment change? How often does the physical environment change in the laboratory?

This report is organized into three sections: Methods, Findings, and Conclusions. First, the Methods section discusses the theoretical frameworks influencing this study, a proposed framework that applies to the clinical laboratory, and the research methods used: survey research and case study research. Second, the Findings section is organized around three areas: specific activities, technological processes, and the physical environment. Within each section, a series of claims have been formulated from the research. Following each claim, findings from the survey and case study research as well as the existing literature are integrated and presented as evidence. Finally, in the Conclusions section, the future of the clinical laboratory is outlined in relation to the idea of change. Responses from openended questions noting the clinical laboratory areas that anticipate the most changes in the next five years as well as strategies to prepare for these changes are discussed. In addition, four design principles are presented as strategies to plan for change.

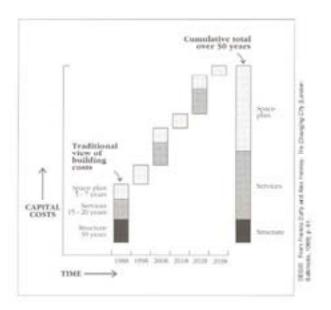


Figure 1: Map of Money in the Life of a Building Source: cited in Stuart Brand, original source Duffy, 1990

"Over 50 years, the changes within a building cost three times more than the original building. Add up what happens when capital is invested over a fifty-year period: the Structure expenditure is overwhelmed by the cumulative financial consequences of three generations of Services and ten generations of Space Plan changes. That is the map of money in the life of a building. It proves that architecture is actually of little significance – it's nugatory."

Methods

Theoretical Frameworks Influencing the Study

On a theoretical level, an environment-based approach of studying how buildings are used over time provides a framework to help answer the research questions. The theoretical framework originally developed by Frank Duffy (1990), the "Time-Layered Perspective," and the subsequent theoretical framework proposed by Stuart Brand (1994), "Shearing Layers of Change," were instrumental in shaping this study. In Brand's pioneering book entitled, *How Buildings Learn*, he states that it is necessary to view "the building as a temporal whole, rather than just a spatial whole." His premise was influenced in part by Duffy's conclusions from investigating office buildings. Duffy concluded that when viewing the building as an assemblage of different components and studying each component in relation to the others, it is evident that "different components have different rates of change, often acting against each other" (Duffy, 1998). These two theoretical frameworks are summarized below.

Time-layered perspective, Frank Duffy, 1990

Frank Duffy (1990) formulated a "time-layered perspective" to understand how buildings behave over time. His position is that it is important to look at the behavior of buildings, the use of the building over time, to understand the life cycle of buildings and to determine a "theory of value." Duffy concludes from his investigation on office facilities that operating costs are enormous compared to initial capital costs, and that change is expensive—three times the cost of the original building over a 50-year period (refer to Figure 1). This differential is inherently much greater in hospitals in general and clinical laboratories in particular because they are in operation 24-hours a day all year long. Therefore, the unit of analysis is not the building, but rather the use of the building through time. Duffy proposed a four-layered framework to investigate the different rates of change.

Nature and rate of change of each layer:

Shell:	Structure lasts the lifetime of the building (50 years in Britain, around 35 in North America).
Services:	Cabling, plumbing, air conditioning, elevators, etc., are replaced every 15 years or so.
Scenery:	Layout of the partitions, dropped ceilings, etc., change every 5 to 7 years.
Set:	Furniture is shifted by occupants often times monthly or weekly.

"There isn't such thing as a building... A building properly conceived is several layers of longevity of building components."

Frank Duffy (1990)



Figure 2: Shearing Layers of Change Source: Stuart Brand

"... different components have different rates of change, often acting against each other."

Cited in Duffy (1998)

Shearing Layers of Change, Stuart Brand, 1994

Building on Duffy's work, Stuart Brand (1994) purposed "shearing layers of change" for a general application to all building types (refer to Figure 2). Brand's premise is that different components in a building have different rates of change, some are more permanent while others are more transient. When slow moving things impede change in faster moving things, it becomes problematic and as a result buildings are transformed or abandoned. Brand identifies six shearing layers:

Nature and rate of change of each layer:

Site:			
nature:	Geographical setting, the urban location, and the legally defined lot, whose boundaries and context outlast generations of ephemeral buildings.		
rate:	Eternal.		
Structure:			
nature:	The foundation and load-bearing elements are expensive to change, so people don't. These are the building.		
rate:	30 to 300 years (few buildings make it past 60, for other reasons).		
Skin:			
nature: rate:	The exterior surfaces of a building. 20 years or so, to keep up with fashion or technology, or repair.		
Services:			
nature:			
rate:	They wear out or obsolesce every 7 to 15 years.		
Space Plan:			
nature: The interior layout –walls, ceilings, floors, and doors.			
rate: Turbulent commercial space can change every three years or so exceptionally quiet homes might wait 30 years.			
Stuff:			
nature:	Chairs, desks, phones, pictures, kitchen appliances, lamps, hairbrushes, etc.		
rate:	Daily or monthly.		

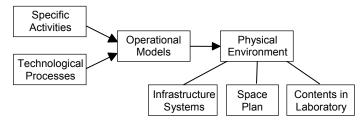


Figure 3: Proposed Framework to Explore the Nature and Rate of Change in Clinical Laboratories

Proposed Framework – Laboratory Components of Change

Building on Duffy and Brand's work, the framework for this study is developed around the specificity of the clinical core laboratory located in community-based hospitals. The premise of this framework is that the specific activities and the technological processes come together and guide an operational model, which is then supported by the physical environment. The physical environment is related to the type of activities that go on inside and what internal and external forces shape or reshape the physical environment. Therefore, the framework is organized around three components: (1) Specific activities, (2) Technological processes, and (3) Physical environment (refer to Figure 3). For each component, the nature or type of change, the rate or frequency of change in a five-year period and the magnitude of change are explored. Below each laboratory component is briefly defined:

Specific Activities–Refers to the activities in the laboratory Types and quantity of tests and human activities.

Technological Processes–Refers to how the laboratory operates Laboratory services and technologies, laboratory information systems (LIS), automation and automations.

Physical Environment–Refers to the place that supports the specific activities in the laboratory and how diagnostic testing occurs. It consists of the stuff that takes up space.

The physical environment is divided into three layers:

- Infrastructure: Heating/Air/Exhaust (fume hoods), electrical or lighting, cabling for LIS, plumbing, sinks or floor drains.
- Space plan: The interior layout of the laboratory.
- Lab contents: Equipment, instruments, workstations and/or cabinetry.



Note: 214 responses are shown

Figure 4: Geographic Distribution of Survey Respondents

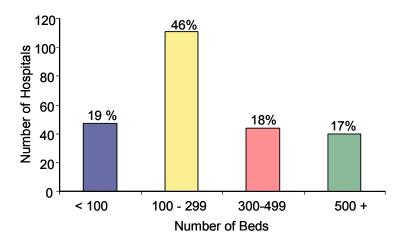


Figure 5: Survey Respondent Breakdown by Hospital Bed Size

Research Design

A multi-methodological approach was used to understand change in the clinical laboratory. First, a survey of a national sample provided an overall representation of the types of changes that are occurring in laboratories as well as the frequency of these changes. Second, a case study research strategy provided a more indepth understanding of the context of the clinical laboratory in hospitals. Finally, findings from these two research inquiries are compared and contrasted with findings from the literature.

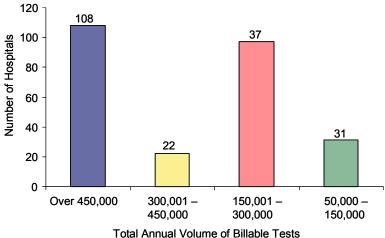
Survey Research: Research Design, Survey Instrument, and Sample

A survey research strategy was used to collect specific information from a relatively large number of hospital-based clinical laboratories with the intent of describing the nature and rate of change and the motivators of change. The sample is a cross-section of clinical laboratories in hospitals. It includes various types and sizes of hospitals from all over the country. The hospitals were built at different time periods and have a range of physical typologies. Figures 4 and 5 show the geographic distribution of survey respondents and the breakdown of hospitals by bed size.

Self-reported data was collected from hospital laboratory staff from the Clinical Laboratory Management Association's¹ (CLMA's) membership list, using an interactive web-based questionnaire that was linked to CLMA's website. A total of 2,600 members were identified as laboratory staff who work in community-based hospital laboratories. CLMA sent an email to the selected sample asking them to participate in the study by going to their website and completing the survey. A total of 335 questionnaires were received among which 240 were fully completed (9% response rate).

The survey instrument was developed via a three-step method. In step 1, a preliminary survey was developed using information inspired from the research

¹ The Clinical Laboratory Management Association (CLMA) is an international organization with approximately 7,000 members who are responsible for laboratories and clinical services in hospitals and health-care networks, group practices, commercial facilities, and independent settings. Of the 7,000 members, approximately 65% are from hospital based clinical laboratories. CLMA's mission is to enhance managerial and leadership skills; to promote efficient, productive, and high-quality operations; to generate and perpetuate data and research relevant to laboratory practices and processes; and to advocate on behalf of quality patient care and the membership.



Breakdown of Volume: 47% inpatient. 35% hospital outpatient, 18% outreach

Figure 6. Clinical Lab Testing Volume

Table 1. Breakdown by Testing Methodology and Location

Testing Methodolgy and Location	# of cases	Average %	Standard Deviation
Automated tests in the core lab	247	74	14.1
Manual tests in the core lab	241	16	11.2
All tests in satellite hospital labs	128	10	18.9
All tests referred out / off-site	227	9	7.8

Note: % for each category represents averages. therefore, all categories do not total 100%

literature and discussions with approximately 15 people, including laboratory consultants, architects, laboratory managers, researchers and representatives from CLMA. Specific constructs to be measured and potential questions were generated for the survey and were assembled into a legible format. In step 2, a preliminary version of the survey pilot was developed and transferred to the web. The survey was then administered to ten hospital-based clinical laboratories members who are also on the board of CLMA. In a secondary review, laboratory managers from four different hospital laboratories completed the survey, and provided feedback on the readability and content of survey. The survey was then evaluated for internal validity. Finally, in step 3, the survey was revised based on a review of the pretest results from step 2. The web-based interactive survey was revised and then deployed. The incentive for completing the survey was a discount rate on a single audio conference of choice (\$99 as compared to \$149) and eligibility to win a free registration to the CLMA/ASCP 2002 Conference and Exhibition in New Orleans, Louisiana. The winner was drawn in May 2002 (the email letter is in the Appendix).

The survey instrument was organized around five thematic sections: (1) Workload and type of hospital laboratory; (2) Physical characteristics of the hospital laboratory; (3) Nature and rate of change in hospital laboratories; (4) Forces and trends impacting changes in hospital laboratories; and (5) Future forces impacting hospital laboratory and strategies to prepare for change. The data collected from the survey was analyzed using frequency distributions, cross-tabulations, and bivariate correlation analysis. Content analysis (Krippendorff 1980) provided a technique to reduce the large volume of data collected from the open-ended questions into manageable content categories.

(1) Workload and Type of Hospital Laboratory: A series of questions were asked on the survey to collect information on the workload and type of hospital laboratory. Findings show that approximately 96% of all the laboratories were operated by the hospital, and 4% were operated by or in partnership with a commercial laboratory. The hospital laboratories reported servicing a variety of entities including the hospital, physician practices (hospital-based, hospitalaffiliated or independent), other hospitals within the system, and other independent hospitals. The laboratories also had a variety of organizational layouts, yet the majority of the laboratories represented the three following types: the core laboratories servicing hospital and other sites (44%), a core laboratory in the hospital (27%) and a core laboratory servicing the hospital and other sites with

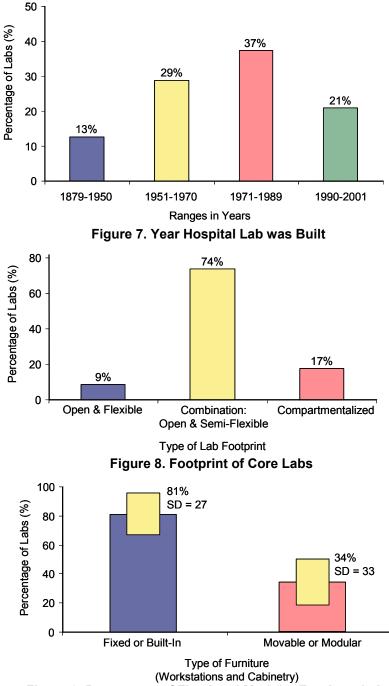


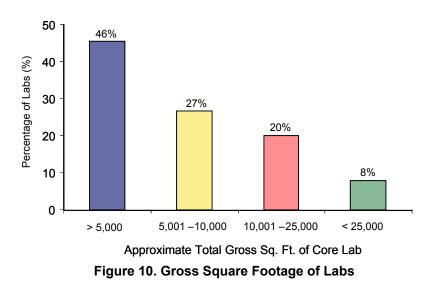
Figure 9. Percentage of Fixed and Modular Furniture in Lab

satellite laboratories in the hospital (18%).² The emergency department, critical care units, and ambulatory care were the three most sited locations for satellite laboratories. The sample ranged in number of tests performed in the laboratory each year from 1,200 tests per year to 6,300,000. Approximately 55% of the sample had annual test volumes over 450,000 and 15.5% had annual tests volumes less than 150,000 – representing the two largest groups (refer to the Figure 6). The testing methodology ranged as well. On average, laboratories reported that between 70 and 80% of the total testing volume were automated tests performed in the core laboratory, between 10 and 20% were manual tests performed in the core laboratory, between 5 and 15% were performed in satellite laboratories, and between 5 and 15% were referred off-site (refer to Table 1). On average, 78% of the laboratories reported that volumes have increased in the last two years and about 70% of the laboratories anticipate volumes to increase in the next two years.

(2) Physical Characteristics of the Hospital Laboratory: The physical facilities of the hospital laboratories varied as well. The hospitals' construction year was on average 1956 and ranged from 1879 to 2001. The average year the hospital was last remodeled was 1991 (+/- 4.5 years) (refer to Figure 7). Approximately 44% reported that the hospital laboratory was part of a multi-hospital system. Of this 44%, 87% stated they had a core laboratory as opposed to a satellite laboratory within a hospital system. The footprint of the hospital's core laboratory represented three different typologies. The average reported from all the laboratories shows that 9% reported having an open and flexible laboratory, 74% a combination of open/flexible and compartmentalized laboratory, and 17% have all compartmentalized sections in the laboratory (with fixed walls) (refer to Figure 8). The degree of flexibility in the laboratory also is dependent upon the furniture in the laboratory (workstations and cabinetry). The average of all the responses show that approximately 81% (+/- 13.5%) have fixed or built-in furniture and 34% (+/-16.5%) have movable or modular furniture (refer to Figure 9). The size of the laboratories represented in the sample ranged from approximately 500 gross square feet to 135,000 gross square feet (refer to Figure 10).

(3) Nature and Rate of Change in Hospital Laboratories: Within this section, the types of changes were organized into two areas: service/technological

² For more details, refer to question number three in the survey instrument to see the diagram with all the organizational layouts.



components and physical components. The physical components were then subdivided into three layers: infrastructure systems, space plan and contents in the laboratory. For both the service and physical environment areas, questions were asked on the types of changes that occurred in the last five years and the extent of these changes (individual units, multiple units, all units or new construction). The four areas are outlined below. Findings are presented in the Findings section.

Services and Technology - Modalities supporting delivery of product

- Expanded test menu
- Implemented brand new laboratory technologies & services
- Added new or updated existing laboratory information systems (LIS)
- Added new or updated island automation (departmentalized)
- Added new or updated front-end automation (processing)
- Added or updated total automation (entire laboratory)
- Added or repaired robots

Infrastructure Systems - Working guts of the building

- Heating/Air/Exhaust (Fume hoods)
- Electrical or lighting
- Cabling for laboratory information systems (LIS)
- Plumbing, sinks or floor drain fume hoods

Space Plan - The interior layout of the laboratory

- Renovated existing laboratory space
- Expanded laboratory
- Relocated functions/departments within the laboratory
- Moved laboratory to another location
- New construction of laboratory or laboratory areas

Contents of Laboratory - equipment, workstations and cabinetry

- Relocated equipment
- Purchased new equipment
- Modified existing workstations or cabinetry
- Added workstations or cabinetry
- Consolidated workstations or cabinetry
- Replaced work tops

(4) Forces and Trends Impacting Changes in Hospital Laboratories: Four forces

that impact change found in the literature were used to structure this section:

(1) Need to reduce costs or increase revenue; (2) Need to improve operational efficiency; (3) Regulatory requirements; (4) Changes in healthcare practices.

These areas were explored in the form of the following question, "To what degree have the following forces motivated change in your laboratory in the last five years?" The response categories were none, small, moderate, and large.

To understand which forces motivate service/technology and physical changes in the laboratory, bi-variate correlation analysis was performed using Chi square tests. Each of the variables that measured service/technology and physical changes (see previous section for how these areas are defined) were recoded into a yes (1) or no (0) variable³. The analysis explored which forces were more or less consistently associated with the service/technology and physical changes. The findings are described in the Findings section. The four forces were measured using the following variables:

To Reduce Costs or Increase Revenue

- A need to change core services
- A need to change STAT services
- A need to increase outreach
- A need to refer more tests off-site
- A need to decrease staffing (downsizing)

To Improve Operational Efficiency

- A need to decrease turnaround times
- A need to fill staff vacancies
- Availability of qualified staff
- Reduce errors in testing and reporting
- A need for laboratory benchmark systems
- A need to reengineer workflow

Regulatory Requirements, a need to respond to:

- Life safety codes (e.g. OSHA)
- Building codes (e.g. NFPA, BOCA)
- Accreditation agencies (e.g. JCAHO, CAP)
- State or local codes/regulations
- Federal regulations (e.g. CLIA 1988)

Changes in Healthcare Practices:

- Merge or consolidation of laboratory
- Changes in the percentage of HMO business
- Added or subtracted medical practices

 $^{^{3}}$ 1 = changes occurred in last five years and 0 = no changes occurred in the last five years.

- Shift in patient demographics
- Shift of services to outpatient setting
- Added or closed hospital beds
- Increase in point-of-care testing
- Joint venturing with outside laboratory
- Need for support services (i.e. call center)
- Increase of physician-owned laboratories

(5) Future Forces Impacting Hospital Laboratories and Strategies to Prepare for <u>Change</u>: To conclude the survey, two open-ended questions were asked regarding future changes in the laboratory along with a follow up question to understand what strategies would help prepare for these changes. The two questions were:

- Can you pinpoint which clinical disciplines are likely to undergo the greatest rate of change in the next five years?
- What strategies will help you prepare for these changes?

Case Study Research

To gain insight on what specific aspects of the physical environment are changing and how they are changing in relation to the delivery of laboratory services, case study research was used. Three common laboratory typologies were targeted:

(1) A compartmentalized laboratory, (2) A combination open/flexible and compartmentalized laboratory, and (3) An automated laboratory (refer to Figure 11). For the first two typologies case research was conducted to observe, document, and understand how the physical environment is linked to the sequence of events in the clinical laboratory as well as interactions between different laboratory areas. People in the laboratory were informally asked about their experiences and thoughts about the laboratory in general as well as the area where they worked. As for the third typology, the automation laboratory, the intent was to understand the concept and the impact it has on the future of the clinical laboratory. The concept was explored through frequent conversations with a representative from the company, LAB-InterLink. Below is background information of each case study:

(1) Compartmentalized laboratory: Greenville Memorial Hospital, South Carolina

A 640-bed hospital (about 1,000 beds for the system) that serves as both a community hospital and a regional referral center. It offers the area's most advanced health services and medical technology including a Level 1 emergency trauma center, cardiac services, surgery services, a cancer



Figure 11. Clinical Lab Typologies (1) Compartmentalized Lab, (2) Combination Open and Compartmentalized Lab, and (3) Automation Lab

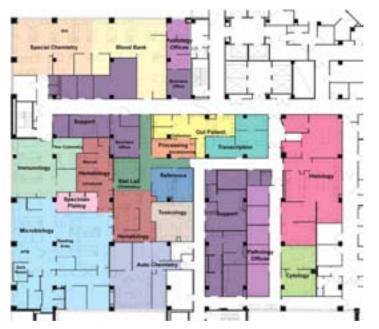


Figure 12. Zoning Diagram, Greenville Memorial Hospital



Figure 13. Zoning Diagram, St. Clare's Hospital

center, women's services, and a children's hospital. The hospital-owned laboratory services numerous constituencies including the hospital, hospital-based physician practices, hospital-affiliated physician practices, independent physician practices, other independent hospitals and other system hospitals. The laboratory performed a total of approximately 1.5 million billable tests of which about 89% were performed in the core laboratory, 6% in satellite laboratories, and 5% were referred out/off-site. The laboratory was originally built in 1975 and expanded in 1982. The total surface area of the laboratory is approximately 21,700 gross square feet and is divided into departmental areas, defined by fixed walls (refer to figure 12). The fixed walls in the lab limit flexibility and the ability to integrate areas and allow staff to cover multiple areas efficiently. Therefore, three future strategies are being considered: renovate the existing laboratory space and expand; renovate and add automation systems; and/or relocate to a new facility.

(2) Combination: Open and Semi-Flexible Laboratory: St. Clare's Hospital, Schenectady, New York

A 200-bed Catholic community hospital that services the hospital, hospital affiliated physicians, and independent physician practices. The laboratory performed a total of 461,000 billable tests in 2001 of which 97% of the tests were performed in the core laboratory. The laboratory was originally built in 1946 and then completely remodeled and expanded in 2000 around an open plan configuration with modular casework to support Hematology, Chemistry, Special Chemistry and Processing. Three somewhat compartmentalized sections (blood bank, histology and microbiology) were preserved with direct access to the open laboratory. The laboratory also expanded by adding support space into some existing shell space. Currently, the total surface area of the laboratory is approximately 8,900 gross square feet and the cost for the renovation was \$1.2 million dollars, which translates to about \$135.00 per square foot for reconfiguring, refinishing and expanding the clinical laboratory. Some of the concerns included trying to renovate the space within the existing irregular structural grid. Physical environmental components that were highly flexible were selected. During the interview, the laboratory manager said, "Laboratories need modular furniture because when the equipment changes, you need to change the furniture" (refer to Figure 13 to see the zoning of the laboratory after renovation).

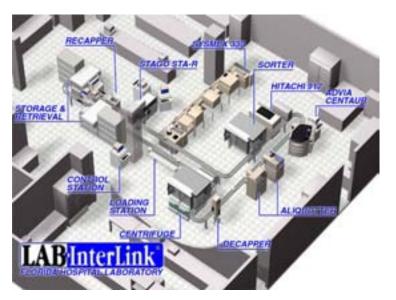


Figure 14. Zoning Diagram, LAB-InterLink

(3) Automated Laboratory: LAB-InterLink, Inc.

The company LAB-InterLink, founded almost ten years ago by Dr. Rodney Markin, markets a full automation system that provides multiple processing options including pre-analytical specimen processing, specimen analysis, post-analytical processing as well as a transport system. The unique open system, which is guided by process control software, easily accommodates a range of instruments from different vendors. The plugand-play system has standard modules that are customized around each clinical laboratory to create the automation system. This automation system is a vehicle to create a production method that is functionally efficient, cost effective, reliable, and easy to update (refer to Figure 14 for an example illustration). Conversations with Dr. Markin, and a representative from the company provided insight on how the physical environment needs to be more flexible as a result of the rapid technological advances in automation systems and information systems. Although, an actual site visit was not possible, information was gathered on various applications of automation systems. Numerous laboratory sites are in the process of planning or designing automation systems.

Findings

This section highlights the findings from both the survey research and the case study research. The nature and rate of changes in the clinical laboratory are described as well as some of the motivators of change in the clinical laboratory. This section is organized around three themes including: 1. Specific activities, 2. Technological processes, and 3. Physical environment. Within each section, a series of claims, or position statements, have been generated from the research. Following each claim, findings from the survey and case study research as well as

the existing literature are integrated and presented as evidence. How change can be addressed is presented in the Conclusions section. Below is a series of questions that will be addressed in this section:

1. Specific Activities

What specific activities change in the clinical laboratory? Where do they change? How do specific activities change? How often do they change in the laboratory?

2. Technological Processes

What technological processes change in the clinical laboratory? Where do they change? How do technological processes change? How often do technological processes change?

3. Physical Environment [Infrastructure, Space Plan and Contents]

What aspects of the physical environment change in the clinical laboratory? Where does the physical environment change? How does the physical environment change? How often does the physical environment change in the laboratory?

Table 2. Percentage of Respondents Who Considered
the Following Internal and External Forces as Having
Some Impact Ranked In Decreasing Order

Forces impacting change	Cumulative impact (% of labs)
Need to reengineer work flow	95
Need to decrease turnaround times	94
Reduce errors in testing or reporting	91
Availability of qualified staff	89
Need to increase outreach	88
Need to change core services	87
Need to fill staff vacancies	87
Shift of services to outpatient setting	84
Need to change STAT services	83
Increase in point-of-care testing	83
Accreditation agencies	82
Need for laboratory benchmarking systems	78
Life safety codes	78
Added or subtracted medical practices	73
Shift in patient demographics	70
State or local codes/regulations	67
Building codes	65
Federal codes	64
Need to decrease staffing (downsizing)	63
Added or closed hospital beds	61
Need to refer more tests off site	51
Changes in the percentage of HMO business	49
Need for support services (i.e call center)	44
Merger or consolidation of laboratory	40
Increase of physician-owned labs	36
Joint venturing with outside lab	29

1. Specific Activities

Specific activities are measured by the range of activities that occur in the core clinical laboratory, particularly testing and human activities. The internal and external forces motivating change in the laboratory activities will be discussed. To understand the activities in the laboratory, the type and volume of each testing service line and how it integrates with other testing lines are explored. In addition, human resources in the laboratory are considered since they are integral to understanding laboratory activities.

Nature of Change – Specific Activities

1. The number of specimens tested, the scope of testing, and the method of testing specimens, are guided by the hospital/system's services. Numerous internal and external forces influence the growth of hospital/system services. Therefore, the space plan, infrastructure and contents in the laboratory should be flexible to accommodate the expansion of services.

A review of the literature shows that numerous internal and external forces directly and indirectly impact laboratory services. Internal forces (such as an organization's structure, services, and activities) are fueled by external forces. External forces include healthcare practices and technological processes. Table 2 is a summary of all the forces having some impact on change in laboratories ranked in decreasing order. According to Saad, *et al.* (1998), organizations are internally "restructuring core business processes horizontally around customer-oriented processes" and externally, "organizations are moving toward integrated systems of care as the appropriate choice for population health management."

Correlation analysis showed that of all the forces explored (see Methods section), the following seven forces were most consistently associated with changes in **services and technology**: (1) A need to decrease turnaround times (TAT); (2) A need to reengineer work flow; (3) A need to change core services; (4) A need to increase outreach; (5) The shifting of services to the outpatient setting, (6) Added or closed beds; and (7) State and local codes. Refer to the appendix to see summary tables generated from the correlation analysis.

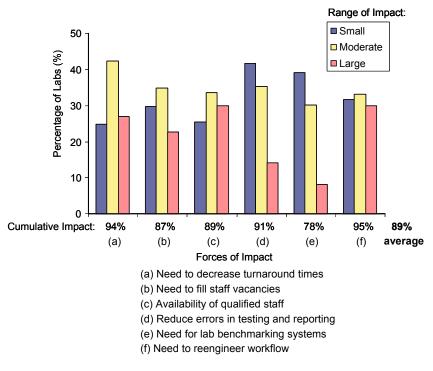


Figure 15. Forces Impacting Change To Improve Operational Efficiency

Table 3. Growth in Services in the Last Five Years atGreenville Memorial Hospital

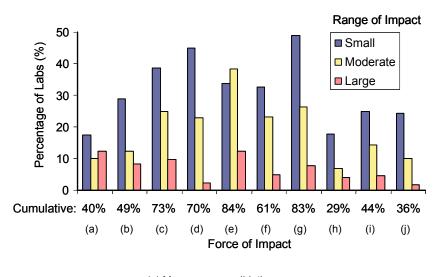
1997	2002
37,000	45,000
705,000	1.2 million
125,000	151,000
20,000	23,000
	37,000 705,000 125,000

Source: Greenville News, July 2002

Similarly, of all the forces explored, the following eight forces were most consistently associated with changes in the **physical environment:** (1) Shifting of services to the outpatient settings; (2) Reengineer workflow; (3) Change in STAT services; (4) Added or closed beds; (5) A need to support services; (6) Accreditation agencies; (7) Federal codes (CLIA); and (8) Change in core services. These findings are consistent with frequencies from survey data (refer to Figures 15, 16 and 17).

Internal forces: One of the biggest concerns of healthcare organizations is the increasing pressure to do more with less. There has been a steady growth in clinical laboratory activities due to the fact that several hospital departments are experiencing a growth in services. One survey respondent noted, "We are not sure why our volume continues to increase at 10% per year." Another respondent said. "We have added staff and completed process improvement projects. Our growth rate has been averaging 15+% per year for the last 4 years, mostly due to outreach and increased ER volumes." Emergency departments, for example, have grown exponentially in the last few years and will continue to grow as the uninsured population increases. Today, more than 44 million persons in the United States are without health insurance and access healthcare primarily through the emergency department. Similarly, there has been a growth in inpatient cardiac services as more men and women suffer from heart disease. In 1997, the leading cause of death in the United States was heart disease (31.4%). This trend will continue as baby boomers age (Healthy People 2010). Emergency services and cardiac services are primary customers of laboratory services. One case study, Greenville Memorial Hospital, clearly illustrates the growth in their services in the last five years (refer to Table 3). The growth in their services will continue since the population is expected to increase in the next five years by 5.4%, which is above the national average of 4.7%.

A growth in outpatient services and inpatient acuity is further evidenced in the volume increases reported from survey respondents. A total of 78% of laboratories reported volume increases in the last two years, and 70% of laboratories anticipate volume increases in the next two years. When respondents were asked why onsite testing volume increased, the following six patterns emerged from the openended responses: (1) Shifting of services to outpatient setting; (2) Increase in hospital growth; (3) Shift in patient demographics, an aging population; (4) Joint venturing with outside laboratory; (5) Increase in outreach activities; and (6) Core services changed.



(a) Merger or consolidation
(b) Change in % of HMO business
(c) Added and subtracted medical practices
(d) Shift in patient demographics
(e) Shift of services to outpatient setting
(f) Added or closed hospital beds
(g) Joint venturing with outside lab
(h) Increase in point-of-care testing
(i) Need support services

(j) Increase in physician-owned labs

Figure 16. Healthcare Practices Impacting Changes

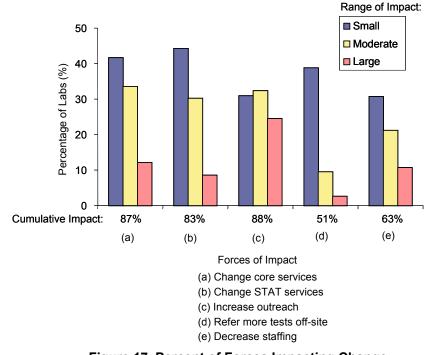
The following quotes from open-ended responses illustrate why laboratory activities are changing:

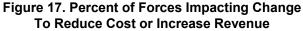
- "Census has been strong and continues to grow"
- "Adding new services cardiac program"
- "Increase in beds, clinics, physician practices"
- "Continued demand for sophisticated testing as well as volume growth"
- "Rapid growth in city, very little competition, addition of new testing"
- "Expansion of services and increased volumes in outpatient and inpatient work"

This growth in services is putting a strain on the operational efficiency of the laboratory and is evidenced in some of the responses noted earlier. More specifically, the need to reengineer workflow, the need to decrease turnaround times, and the need to reduce errors in testing are outcomes from the rapid grow of core and STAT tests from multiple locations. Consequently, laboratories are searching for operational strategies, technologies, staffing models, physical and/or configurations that can aid in the efficient and accurate delivery of test results.

External Forces: Healthcare practices are constantly evolving, which consequently impacts the nature of activities in the clinical laboratory. According to Markus (1985), "mergers and acquisitions,⁴ joint/cooperative ventures, an increase in freestanding laboratories, and prospective payment have changed the status of onsite hospital laboratories from profit centers to cost centers (potentially profit "eaters")." As a cost center, laboratory services are to be "minimized as much as possible rather than a value added service contributing to better and less-expensive healthcare" (Coffman 1998). This may change in the future since consumers are demanding more services, and evidence continues to show that laboratory services are a valuable component in the healthcare continuum (Coffman 1998). According to Saad, *et al.* (1998), "They [consumers] want an emphasis on prevention and wellness, which means that diagnostic testing must address early identification and monitoring of high-risk groups." A respondent noted this trend by stating, *"We have seen an increase in usage by physicians and demand by patients."*

⁴ 735 of the nation's hospitals were involved in mergers and acquisitions during the 1995 calendar year (cited in Holland 1998).





Which healthcare practices impact change in the clinical laboratory? Findings from the survey suggest that the following five forces (out of ten) have the largest cumulative impact on change in the clinical laboratory: (1) Shifting of services to the outpatient setting (83%); (2) Joint venturing with outside labs; (3) The addition or subtraction of medical practices (73%); (4) A shift in patient demographics (70%); and (5) Adding or closing hospital beds (61%) (refer to Figure 16). These findings were reinforced in the open-ended responses. For example, a survey respondent said, *"Change in medical staff are dictating more testing performed on-site."*

2. To remain cost effective, the overall percentage of inpatient, outpatient and outreach tests performed in the hospital's core laboratory fluctuates over time. Therefore, the space plan, infrastructure, and the workstations must be able to accommodate the specific space and functional needs of each type of test as volumes change.

Ten years ago the laboratory test mix was 25% outpatient and 75% inpatient and today these numbers are almost reversed (cited in Wright and Ferguson 2001). The average test mix reported from the 240 respondents from this study showed a similar trend toward a decrease in inpatient volumes and a growth in outpatient and outreach volumes. The breakdown is as follows: 47% inpatient, 35% hospital outpatient, and 18% non-hospital patient (outreach).

Fluctuations in test-mix are common and most often linked to a strategy to reduce costs or increase revenue. According to correlation analysis, the two strategies to reduce costs or increase revenue most consistently associated with changes in **service and technological processes** were: (1) A need to change core services, and (2) A need to increase outreach. In addition, the three strategies to reduce cost and increase revenue that were most consistently associated with **physical** changes in the clinical laboratory are: (1) A need to change core service, (2) A need to change STAT services, and (3) A need to increase outreach. Referring more tests off site was least consistently associated with any physical changes in the laboratory. These findings were consistent with frequency distributions from survey data. The cumulative impact shows that three out of the five forces impacted change in over 75% of clinical laboratories: (1) Increase outreach (88%), (2) Change in core services (87%), and 3. Change in STAT services (83%) (refer to Figure 17).

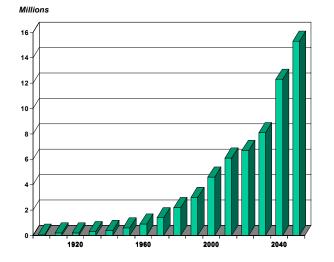


Figure 18. Growth of Population 85 Years and Older Source: U.S. Department of Commerce

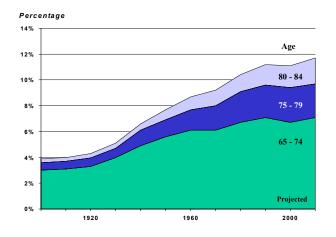


Figure 19. Growth of the Elderly within the U.S. Population Source: Census Bureau

Patterns that emerged from open-ended responses echo these trends. More specifically, laboratories are modifying core and STAT services, adding more aggressive outreach-testing programs or partnering with other laboratories to find a balance between volumes, services, financial resources and available staff. A respondent said, *"Losses due to physician lab competition will be offset by bringing reference tests in-house."* On the flip side, tests are often referred out if there is an insufficient number of tests to make a laboratory service cost effective, if there is insufficient space to add the laboratory service, or if staffing is an issue. According to Eagan and Lien (March /April 2001), if more than 250 of a particular test procedure are referred annually, it may be more efficient to bring that test procedure in-house. The reverse is also true, it is best to outsource fewer than 250 of a particular test type. This decision may be complicated by the availability and efficient use of qualified laboratory staff.

There are spatial and functional implications when the test-mix fluctuates. The number of locations that specimens come from increases as outpatient and outreach activities increase. As outpatient and outreach testing increase, laboratory space needs to be organized to manage the intense upfront receiving, and processing of specimens from outside the hospital. One respondent stated, *"We plan a major overhaul of our main laboratory to facilitate centralized processing."*

3. As patient acuity in the hospital increases, so will the demand for laboratory services. Similarly, as diseases are discovered or evolve, the demand for esoteric testing will increase. Therefore, the space plan, infrastructure, and contents in the laboratory must be capable of supporting the space and functional needs that correspond to variations in the scope and number of routine and special testing.

Over the last 10 years, there has been a gradual decrease in the average length of stay of patients in the hospital and a growth in outpatient activity. As a result of advances in medical science and technology (and fueled by reimbursement reductions and market forces), more procedures are now available within a variety of outpatient settings. The consequence of this shift in services to the outpatient setting is that the patients who are now in the hospital are sicker. A respondent acknowledged this trend by stating, "Our referral testing is increasing – there is a higher acuity in the patient population that we serve, with more esoteric testing being requested."

Technological inventions and advances in medical science coupled with the baby boomers generation reaching 65 years of age will increase the demand for laboratory services (refer to Figures 18 and 19). According to statistics, the 65 and over age group is the group that consumes the largest overall percentage of healthcare services. One respondent said, *"The severity of illness and the aging population are impacting and will continue to impact laboratory services."* The impact of the aging population on clinical laboratory services is also documented in the literature (Etnyre-Zacher and Isabel 1997).

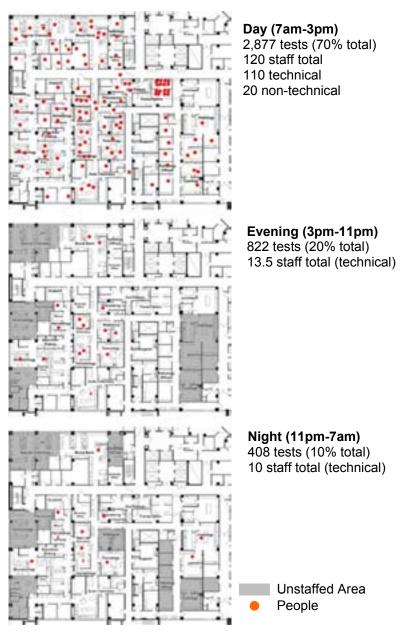
4. The availability of qualified laboratory staff coupled with the push to do more with less financial and human resources are transforming the way in which laboratory services are delivered.

The availability of qualified staff is decreasing due to the attrition of laboratory staff, the aging of laboratory staff and the decrease in the number of schools training medical laboratory technicians. According to the survey, 89% of laboratories reported that the availability of qualified staff was a motivator of change in the laboratory. Several open-ended responses addressed the staffing shortage and some responses are noted below:

- "MLT's [Medical Lab Technicians] are a thing of the past in this area. Train and nurture MLT's to do the work once done by MT's [Medical Technician]. We already train our own HT's [Histology Technicians] and our own phlebotomists because we have no training programs and we don't have enough trained ones around. Our MLT program closed this past year so it's only going to get worse."
- "We will continue to utilize cross trained techs even to the extent of training MT's as HT's.
- "We have increased staffing to meet increased workload; although finding the staffing has not always been easy!"
- "Qualified licensed staff will continue to diminish in numbers."

To respond to this trend, laboratories are cross training staff (Luczyk 1997). The importance of cross training programs for staff will increase as the shortage of staff magnifies. Another strategy employed by laboratories is to implement automation systems so qualified staff can be reallocated to other areas in the laboratory to help offset the shortage. According to Dr. Markin at LAB-Interlink, automation systems will not replace staff since the medical technologists are the individuals who "produce" the results by integrating a series of clinical data, instrument data,

and other operational and observable characteristics to produce a valid result. In traditional laboratories, department-specific staffing was reinforced by the compartmentalized layout of the laboratory. Now staff needs to easily flow between different clinical areas.





Rate of Change – Specific Activities

1. The quantity and scope of tests vary by the day, evening, and night shift. The layout of the clinical laboratory should accommodate changes in the workflow as the number of staff change throughout the day. For optimal efficiency, the laboratory should be designed to accommodate peak periods during the day and also the night shift when limited staff cover multiple areas simultaneously.

Staffing requirements correspond to the scope of services the laboratory performs, the operational model, the staffing model, and the facilities that shape the laboratory. Staffing numbers vary by laboratory department and fluctuate considerably by shift. Overlaying the number of staff in each department on the clinical laboratory floor plan at Greenville Memorial Hospital (refer to figure 20) reveals that the night staff have to travel excessive distances to and from workstations. The laboratory manager stated that the first shift (day shift) performs approximately 60 - 70% of the total daily volume, the second shift (evening)

10 - 20%, and the third shift (night) 5 - 15% of the total volume. Due to the limited number of staff who cover multiple areas in the laboratory during the night shift, the clinical laboratory should be organized and designed around the night shift. A survey respondent noted this efficiency problem by saying, *"We reconfigured the lab for PM and Night shift efficiency."* As testing volume increases, more testing may be performed during the evening and night shift when there is not so much congestion in the laboratory due to peak periods in testing. Furthermore, distributing testing throughout the 24-hour day takes advantage of the expensive instruments and equipment.

2. The movement of each specimen and the activity associated with each specimen changes constantly and depends upon the combination of many variables. Some of these variables include the location where the specimen was collected, how the specimen arrives into the department (via in person, tube, or automation), the patient affiliation with the hospital, the types of tests required, as well as the method used for testing. As new instruments are introduced into the laboratory each year, the sequential movement of the specimen needs to be reevaluated, optimized and most importantly supported by the physical environment to avoid the obsolescence of laboratory facilities.

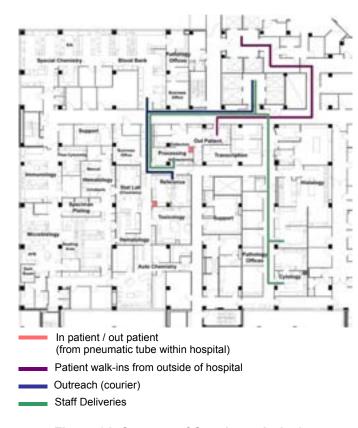


Figure 21. Sources of Specimen Arrivals, Greenville Memorial Hospital

Table 4: Percentage of Labs Reporting Rate of Changein Service and Technology in Last Five Years

	Percentage of Labs Reporting Change in the Last Five Years				
Services & Technology	Never	At least once	Once	2 to 4 times	5 + times
Expanded test menu	1%	99%	4%	37%	58%
Implemented new lab technologies & services	3%	97%	9%	52%	36%
Added new or updated existing (LIS)	9%	91%	42%	41%	8%
Added new or updated island automation	43%	57%	21%	31%	5%
Added new or updated front-end automation	84%	16%	13%	3%	0%
Added or updated total automation	81%	19%	8%	9%	3%
Added or repaired robots	96%	4%	3%	1%	0%

There is constant flow of activity in the clinical laboratory and it is dependent upon the types of specimens filtering into the laboratory. In a sense, it is unpredictable as to what tests may be required at any given moment. Several people move in and out of the laboratory to deliver equipment, to deliver specimens from outpatient and outreach testing sites, to deliver blood, and to deliver supplies. People also come to the laboratory to pick up specimens for referrals. Additional people are in the laboratory to service equipment, update software for LIS, or for cleaning, and removing trash and hazardous waste materials. Figure 21 illustrates the different pathways in which specimens and blood arrive to the laboratory. Upon arrival, the sequential movement of each specimen may differ.

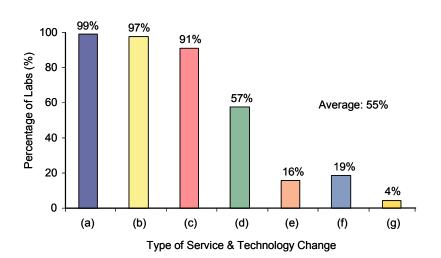
Activity is anticipated to increase as hospital outpatient and non-hospital/system patient (outreach) services continue to grow. Open-ended responses suggest that some laboratories are improving public access to the laboratory or incorporating customer service departments to deal with the increase in public interactions in the hospital's core laboratory. A respondent said, *"We added a customer service department and space for courier pickup and drop-off."* Another type of change noted was improving outpatient accessibility to the hospital's core laboratory. Similarly, another change noted was moving laboratory areas that receive the most deliveries or pick-ups (specimen intake area – receiving, processing areas, reference/send out area, blood bank) to a location adjacent to public access areas.

2. Technological Processes

The clinical laboratory is driven by technology. The machines (instruments and equipment) are a product of this technology and are used for processing and testing specimens. Expanding existing laboratory services, and implementing new services/technologies, information systems, and automation systems all influence how the laboratory operates and therefore are used to measure the technological processes in this study. Within this section, it will become clear how integral technological processes are in the function and sustainability of the clinical laboratory.

Nature of Change – Technological Processes

1. Test menus are being expanded and new technologies are constantly being plugged into the laboratory. Therefore, highly automated areas need to



(a) Expanded test menu

(b) Implemented new lab technologies & services
(c) Added new or updated existing LIS
(d) Added new or updated island automation
(e) Added new or updated front-end automation
(f) Added or updated total automation
(q) Added or repaired robots

Figure 22. Percentage of Labs in which at Least *ONE* Service & Technology Change Occurred in the Last 5 Years

Table 5: Testing Methodology and Location

Testing Methodolgy and Location	# of cases	Average %	Standard Deviation
Automated tests in the core lab	247	74	14.1
Manual tests in the core lab	241	16	11.2
All tests in satellite hospital labs	128	10	18.9
All tests referred out / off-site	227	9	7.8

Note: % for each category represents averages, therefore, all categories do not total 100%

be organized around an open plan to support technology as opposed to traditional department-specific areas.

Clinical laboratory areas that involve high volume testing and demand rapid turnaround-times have become increasingly automated (e.g. Chemistry and Hematology). These areas are a product of technology and consequently services are updated frequently. According to survey findings, a typical type of change in the laboratory is to expand test menu (99% reported) and implement new technologies and services (97% reported) (refer to Table 4 and Figure 22). Since technological processes are changing rapidly, laboratory staff are constantly eliminating physical barriers in an effort to find an efficient workflow to and from workstations. An outcome of examining the workflow in the clinical laboratory is to organize the laboratory by technologies (automated versus manual processing) as opposed to traditional laboratory departments (Dadoun 2000). Open-ended responses from the survey support this claim. Two quotes are noted below:

- "The strategies to survive in the future will include automating any tests that we can automate and moving all automated procedures to an automated area."
- "We are in the process of renovating our lab to have a large open "automated" area and smaller "manual" area."

Automated testing accounts for a significant portion of the overall testing volume. The survey shows the following overall breakdown: 74% are automated tests performed in the core laboratory, 16% are manual tests performed in the core laboratory, 10% are performed in satellite laboratories, and 9% are referred out/off-site⁵ (see Table 5). This concurs with other references. According to the 1996 Online Certification Survey conducted by the US Health Care Finance Administration⁶, of the estimated 7.25 billion tests performed in the US in 1996, automated hematology and chemistry analyzers were the most frequently used methods for testing (cited in Steindel, *et al.* 2000).

Some laboratory departments are still compartmentalized or have section walls due to functional requirements (e.g., Microbiology, virology, and toxicology), however, this may change in the future as technologies change. A panel of experts organized by the Food and Drug Administration's (FDA's) Center for Devices and

⁵ The percentages are averages of the total responses, so the total of all categories combined does not equal 100%.

⁶ Now called the Center for Medicare and Medicaid Services (CMS).

Radiographic Health in 1997 predict that molecular medicine will be developing future technologies for the next century. In agreement with this panel, the Medical Automation Research Center (MARC) at the University of Virginia, Charlottesville, VA identified molecular automation as a growth area that will have a technological impact on the future of laboratories. Survey findings are consistent with this increasing dependency on technology. One respondent said, *"We added more automated equipment to allow for increased workload with the same staff and we made LIS changes so technicians would not have to remember so much."*

2. The interior layout, workstations and cabinetry of the clinical laboratory should allow contents in the laboratory to be relocated, reconfigured, or removed to accommodate new automated analyzers, the introduction of automation systems as well as emerging technologies in an effort to create an efficient work flow.

Reimbursement reductions and constant pressures to perform more efficiently have driven hospital administrators to reduce the length of the typical stay in hospitals. The laboratory is expected to assist in this effort. Vendors have responded by introducing new specimen handling and processing devices, transportation systems and automated instruments. As new technologies are added to the lab, it is often necessary to reengineer the flow of work to and from these automated test stations (Lehmann 1999).⁷

Automation systems and information systems are becoming mainstream in clinical laboratories. Preliminary studies are showing that automation systems are answering problems related to quality issues, improving and stabilizing turn-around-times, staffing shortages, cost reductions, and the increased risk of biohazard exposure (HIV, HCV, HVV, etc.) (Markin and Whalen 2000). As a result, laboratories are adding or updating automation systems. In the last five years, island automation was the most common type of change in the laboratory (57% of laboratories added new or updated a modular automation system) followed by total/full automation (19% of laboratories), and front-end automation (16% of laboratories). This trend is further reinforced by the growth of organizations in the last few years focusing on how technological processes can assist with improving

⁷ According to a discussion with a representative from a leading manufacturer of lab instruments, Beckman Coulter, major lab instruments are released every two to three years on average.

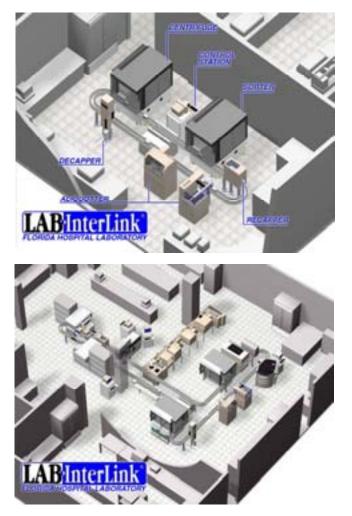


Figure 23. Examples of Automated Systems by LAB-InterLink

and managing laboratory services. For example, The Association for Laboratory Automation (ALA) was created to research and advance the worldwide utilization of automation, and artificial intelligence in order to improve quality, efficiency, and relevance of laboratory analysis.

As for industry, the company LAB-InterLink⁸, is a business outgrowth of 13 prior years of research and development to understand and improve automated clinical laboratory operations. (refer to Figure 23 for an example of a LAB-Interlink automation system). In a recent co-authored article (by the founder of LAB-InterLink, Dr. Rodney Markin), Markin and Whalen (2000) state that the "trend in automation has moved from a hardware-driven system to process control, from a one-of-a-kind novelty toward a standardized product, and from an in-vitro diagnostics novelty to a marketing tool." They further state that the design of laboratory automation system (LAS) should be "centered on the patient, with a software design that allows patient-related information and laboratory process to be under control (direction) of the software. The hardware then serves the function of the appendages or end-actuators similar to the application of technology in a parallel environment: computer-integrated manufacturing."

According to Dr. Markin at LAB-InterLink, as smaller and smaller volumes of specimen containers are financially feasible, automated systems will increase and become a viable option for small community and rural hospitals in a cost effective range⁹. To prepare for automation systems, laboratories should be highly flexible environments to accommodate the changing and variable instruments and their corresponding footprints, space requirements, and operational requirements (stable/filtered power, drains, water, air, communication etc.).

Open-ended responses suggest that laboratories are in the process of considering, planning, or completing automation systems. The following three quotes from respondents highlight this trend:

⁸ For background information on LAB-InterLink see the case study research section, p. 14 or refer to their website at <u>http://www.labinterlink.com/</u>. In particular, their book entitled <u>Automation for the Clinical Laboratory – A LAB-InterLink Design & Planning Resource</u> <u>Manual</u> is available to download on their website. This manual is an excellent overview of automation theories, applications and technologies they have developed over their 13 years in research and development and nine years in the business of automating clinical laboratory operations.

⁹ Currently, LAB-InterLink claims that depending upon the test mix, approximately 200 specimen containers per hour is the minimum number of specimens needed before purchasing an automation system to support service delivery.

- "We are currently evaluating front-end automation and automation cells"
- "The core chemistry/hematology lab is Total Lab Automation and as such has a non moveable track. The lab was designed for the track."
- "Instrumentation is updated on an as-needed-basis, this year it will be hematology systems, last year coagulation, etc."

3. The advancement of information systems is transforming the way in which laboratory services are delivered. The space plan and workstations must be flexible to support the fluid transfer of information through technical means as well as through direct physical contact.

The growth of laboratory information systems (LIS) is transforming laboratory services and the responsibilities of laboratory staff. According to the survey findings, 91% of laboratories added new or updated existing (LIS) within a five-year period. The emergence of information systems is changing the role and responsibilities of the laboratory technicians from a medical technician to an information specialist as software becomes central to laboratory operations (Miller 2000). Markin and Whalen (2000) claim that "automation design philosophy has evolved from a hardware-based approach to a software-based approach to support repeat testing, reflex testing, and transportation management, and overall computer-integrated manufacturing approaches to laboratory automation..." Similarly, Willis (2000) predicts that, "as soon as security and access issues are resolved, data will be sent across the internet for evaluation by distant experts." He states that at the University of Virginia, the central laboratory uses either a network connection or the Internet to validate test results of instrumentation in remote locations.

Wireless technology will also impact how clinical laboratories communicate with clients and other providers. Two applications have emerged and are currently being implemented into laboratories: (1) Radio frequency identification (REID) has begun to replace handwritten requisitions, thereby reducing the time to process large volumes of specimen data; and (2) Radio frequency (RF) chips and networks are being used for storing and transmitting data, providing easy access from a hospital information system (HTS) (Wilson 2000). The following quotes from two respondents highlight the increased utilization of information systems in the clinical laboratory.

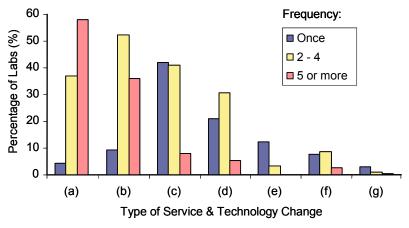
 "Automation and Web-based information will be among the driving forces in the lab." "Have attempted to increase efficiencies through automation, improved technologies and improved utilization of LIS."

4. The space plan should accommodate the shifting and reallocation of space throughout the laboratory as technological advances permit the cost effective and efficient use of point-of-care testing.

Technological advances are rapidly making point-of-care testing a viable option for some laboratories. Another reason point-of-care testing is gaining widespread use is that it expedites turn-around-times. Point-of-care programs are often developed in hospital departments that are high users of laboratory services, such as the emergency department, surgery, and critical care units (Lehmann and Leiken 1996). According to the survey, 41% of laboratories have satellite laboratories in the hospital, primarily in the following areas: emergency departments, critical care – adult and pediatrics, surgery and ambulatory care. Responses from open-ended questions suggest that laboratories are in the process of planning and implementing new satellite laboratory locations and point-of-care managers are being hired to assist in this effort. Below is a sample of some comments from survey respondents:

- "Point-of-care testing will likely replace many lab tests. With the shortage of Medical Technologists and Technicians, I see more tests being sent out of the hospital and running mostly point of care tests in house."
- "The point-of-care testing area continues to grow and from a laboratory perspective we need to be supportive. If not it will be developed around us without our input."
- "I expect to see emerging technologies become standard routine tests. I also expect more bed-side tests will become as routine as glucose testing is now, particularly coagulation studies."

This trend is echoed in the literature. According to the Medical Automation Research Center (MARC), point-of-care testing will be a growth area that will have a technological impact on the future of laboratories (cited in Collier *et al.* 1998). The reduction in size and affordability of hand-held analyzers, the increase in home care, and the availability of direct access testing will also transform the location and delivery of laboratory services (Felder *et al.* 1999).



(a) Expanded test menu

(b) Implemented new lab technologies & services

(c) Added new or updated existing LIS

(d) Added new or updated island automation

(e) Added new or updated front-end automation

(f) Added or updated total automation

(q) Added or repaired robots

Figure 24. Percentage of Labs in which Changes to Lab Services & Technology Occurred in the Last 5 Years

Rate of Change – Technological Processes

1. The technological processes change more frequently than the space plan and infrastructure systems. Expanding the test menu and/or implementing new technologies typically occur, on average, in the laboratory at least once every year.

The survey shows that 99% of laboratories expanded their test menu, and 97% implemented new laboratory technologies and services at least once in the last five years. In the last five years, 58% of the laboratories expanded their test menu five or more times which translates to at least once every year, and 37% expanded their test menu between two to four times which translates to at least once every other year. In the last five years, 36% implemented new laboratory technologies and services five or more times, and 52% implemented new laboratory technologies and services between two to four times. (refer to Figure 24).

Figure 24 shows that the most common type of automation change was island automation (21% of laboratories reported making changes once and 36% at least two times in the last five years). Adding new or updating front-end and total/full automation were the least common changes occurring in the past five-years. (16% and 19% respectively made at least one change). Only 4% of respondents made changes to robots in the clinical laboratory in the last five years. The inclusion of front-end and total automation and robots into the clinical laboratory may increase in the future. Currently, laboratories are reluctant to add automation systems because of the huge upfront investment as well as the complete transformation of the laboratory. Wing (2000) states that, "Automation systems introduce new complexities into this matrix [the laboratory environment], requiring highly coordinated materials flow, increased planning flexibility and merging and reorganization of traditionally separated laboratory disciplines." Furthermore, Dr. Markin, the founder of LAB-InterLink, said in a conversation that "the clinical laboratory automation technology currently on the market changes the way the clinical laboratory operates from a batch mode which is very conducive to manual (human) labor to random access processing which is not conducive to manual (human) labor, however, results in a significant decrease in turn-around-time and increase in quality." He further stated that "equipment [laboratory instrument] changes in automation systems will be less significant in the future as compared to historical times." As evidence, the NCCLS has developed and published a set of

five interrelated prospective standards for clinical laboratory automation (Auto 1 through Auto 5). The Area Committee on Clinical Laboratory Automation through the NCCLS has continued to work on future automation standards to augment the five base automation standards currently produced.

2. Software will change more frequently than hardware in the front-end and full automation laboratories where laboratory information systems are integrated with automated equipment and interface with hospital information systems.

Of the 91% of laboratories that added new or updated existing LIS, almost 50% made changes to cabling at least once every other year. This percentage may grow considerably as automation becomes more widespread and affordable in clinical laboratories, particularly front-end and full-automation. As an information-intensive industry, healthcare organizations rely on technology. Saad *et al.* (1998) claim that technology innovations will provide the vehicle to "move samples (as opposed to patients), integrate disparate information systems, and reduce duplication of testing, the integration of inpatient, outpatient, and nonpatient laboratory databases..." They further state that, "Laboratories that embrace change through information technology and drive the use of that technology will be the ones positioned to compete effectively in the future." Open-ended responses echo this trend. One respondent said, *"We installed new LIS in 1998 for Y2K, then again in 2000 for new owners."*

According to a representative from LAB-InterLink, as new instruments (analyzers and supporting equipment) are added to the laboratory, or test menus change, the information systems need to be updated to allow for the constant flow of information. Therefore, in highly automated areas in the laboratories (such as Chemistry and Hematology), changes made to the software (information systems) will be more common than changes made to the hardware (instruments and equipment). Access to information systems (data ports) and electrical sources from various locations within these highly automated areas is mandatory.

	Percentage of Labs Reporting Change in the Last Five Years						
Infrastructure Types	Never	At least once	Once	2 to 4 times	5 + times		
Heating/Air/Exhaust (Fume hoods)	31%	69%	48%	19%	2%		
Electrical or Lighting	43%	57%	33%	19%	4%		
Cabling for Information Systems	8%	92%	41%	36%	15%		
Plumbing, sinks or floor drains	36%	64%	38%	22%	3%		

Table 6: Percentage of Labs Reporting Nature and Rate of Infrastructure Changes in the Last Five Years

	Percentage of Labs Reporting Magnitude of							
		Ch	lange					
Type of Infrastructure units	Individual	Multiple	Entire	New				
Type of initiastructure units	units	units	System	Construction				
Heating/Air/Exhaust (Fume hoods)	46%	26%	14%	14%				
Electrical or Lighting	39%	31%	12%	17%				
Cabling for Information Systems	20%	39%	26%	15%				
Plumbing, sinks or floor drains	59%	19%	4%	17%				

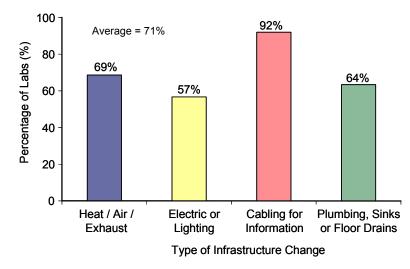


Figure 25. Percentage of Labs in which at Least ONE Change Occurred in the Last 5 Years

The physical environment is divided into three layers: the infrastructure, the space plan, and the contents in the laboratory. The infrastructure includes heating, air and exhaust (fume hoods), electrical or lighting sources, cabling and data ports for Laboratory Information Systems (LIS), plumbing, sinks, and floor drains. The space plan is defined by the interior layout of the laboratory, which includes the walls, functional areas as well as circulation space. The contents in the laboratory include all the major physical contents such as equipment, instruments, and furniture (both fixed and movable workstations and cabinetry).

Nature of Change in the Laboratory Infrastructure

1. Flexible utilities (power supply and data ports) are needed to accommodate the location and relocation of instruments and equipments, and their specific utility requirements.

Technological advances, which are manifested in the machines/instruments, dictate the type, quantity and speed of testing specimens as well as the space and functional requirements needed to support the machines. According to survey findings, equipment/instrumentation is relocated or added to the laboratory at least once every other year. Utilities requirements have to support both the initial location of equipment as well as the relocation of equipment.

Since the laboratory contains flammables, combustibles, high voltage, biohazards and high technology, the regulations that govern the laboratory are more stringent than most structures (Mortland and Mortland 2000). Evolving regulatory requirements can mandate the relocation of equipment or the redesign of physical space for the safety of laboratory staff. Therefore, laboratory facilities need to be flexible to support building codes (such as NFPA, BOCA), operational life safety codes (such as OSHA), state or local codes, federal regulations (such as CLIA) and to respond to mandates from accreditation agencies (such as JCAHO, CAP) (Mortland 1997). Open-ended responses addressed the impact of regulations on change. One respondent noted, *"We added space and moved Micro due to JCAHO deficiencies, and added a biological safety cabinet to Microbiology."* According to correlation analysis of survey data, physical changes made to the HVAC systems were consistently associated with all the regulatory organizations (building, operational & safety) in the clinical laboratory.

3. Physical Environment

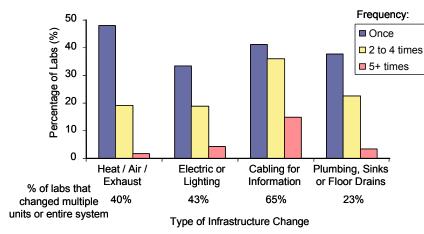


Figure 26. Percentage of Labs in which Changes Occurred in the Last 5 Years

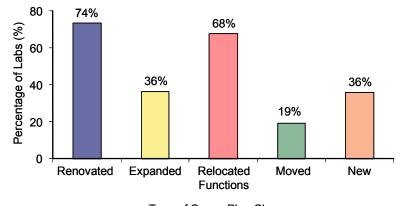
2. Changes made to ventilation systems are most common in areas that involve infectious diseases (e.g., Microbiology, Immunohematology) as well as in areas that house a density of high-volume, fast throughput instruments. Therefore, HVAC systems should be planned in separate zones and have additional capacity so air quality can be improved as testing procedures and testing methodologies evolve.

Laboratory areas that require extensive air handling capabilities due to flammables, combustibles, and biohazards (such as immunohematology, toxicology, microbiology – TB, flow cytometry) tend to be more enclosed and separate due to the functional requirements. These areas are often times more difficult to relocate because of the specific infrastructure systems required (such as ventilation, fume hoods, and multiple plumbing lines). Preliminary results from case studies and open-ended responses suggest that within these areas, infrastructure systems change more frequently than the space plan since these areas are costly and disruptive to move. In addition, preliminary findings suggest that areas that house high-volume automated equipment are more susceptible to improvements in heating and ventilation changes. One reason may be that the equipment emits heat, yet requires controlled ambient temperatures.

Rate of Change in the Laboratory Infrastructure

1. One of four infrastructure systems is replaced, upgraded, relocated or expanded at least once over a five-year period. Cumulative changes occur more frequently to cabling for LIS, followed by Heating/Air/Exhaust (Fume hoods), plumbing, sinks or floor drains, and finally electrical and lighting.

The survey indicates that 71% of laboratories made some form of changes to infrastructure systems in the last five years. Cabling for IS systems was the most common change (92% of laboratories reported at least one change in last five years). 69% of laboratories reported that Heating/Air/Exhaust (fume hoods) were changed at least once and 64% of laboratories reported that plumbing, sinks or floor drains were changed at least once. Electrical or lighting was the least likely to be changed, (57% of laboratories made at least one change in the last five years) (refer to Figures 25 and 26).



Type of Space Plan Change Figure 27. Percentage of Labs in which Change Occurred at Least ONCE in the Last 5 Years

Table 7. Summary of the Type and Magnitude of Space
Plan Changes in the Lab in the Last Five Years

			Total SF	% of	Total SF	% of
	#	Total SF	Changed	Total	Changed	Total
Type of Change	Reported	Reported	Low	Low	High	High
Renovations:						
Refinish	41	350,649	19,610	6%	63,079	18%
Reconfigure + Refinish	64	800,518	98,333	12%	234,156	29%
Total Renovation	24	427,831	130,309	30%	268,877	63%
Expanded Lab	62	903,810	95,013	11%	239,581	27%
Relocated Functions	55	857,610	90,750	11%	235,732	27%
Moved Lab	35	537,712	113,387	21%	247,700	46%
New Construction	41	614,542	237,171	39%	277,692	45%
Total Average	54	641,810	112,082	18%	223,831	36%

Note: The actual total number reported was a greater number, although cases were only included if the square footage of the lab was reported.

The magnitude of changes made to cabling, electrical and lighting, and HVAC, is greater than changes made to plumbing, sinks and floor drains (65%, 43% and 40% respectively reported making changes to multiple units or the entire system). Only 23% of laboratories reported making changes to multiple or all plumbing, sinks and floor drains.

Nature of Change in the Laboratory Space Plan

Of all the different space plan change types investigated (renovated, expanded, relocated functions, moved the laboratory, and/or new construction) between 18% and 36% of the total gross square footage reported was involved in some type of space plan change. The average breakdown for each space plan type is summarized in Table 7.

1. Clinical laboratories are eliminating physical barriers that separate various sections of the laboratory to help facilitate better workflow between workstations and improve efficiency. As a result, the open plan allows for renovating and relocating functions within the clinical laboratory in order to remain functionally viable.

Renovating, relocating functions within the laboratory and new construction are the most common types of space plan changes. According to the survey findings, 74% of laboratories renovated existing space in a five-year period, 68% relocated functions/departments within the laboratory, and 36% of laboratories involved new construction. Moving to another location occurred the least (refer to Figure 27). Not only did the space plan change in many laboratories, a significant percentage of the total laboratory space was involved in changes. The breakdown for renovations is defined in three categories: (1) between 6% and 18% of the total laboratory space was involved in either refinishing or replacing fixtures, furniture or finishes; (2) between 12% and 29% of the total laboratories space involved reconfiguring walls plus refinishing or replacing fixtures, furniture or finishes; and (3) between 30% and 63% was involved in total renovations. The percentage of space involved in changes illustrates the magnitude of the change. The percentages of other space plan types is as follows: between 11% and 27% expanded; between 11% and 27% relocated functions; between 21% and 46% moved the laboratory and between 39% and 45% for new construction.

The following quotes from respondents illustrate some of the changes made to the layout of the laboratory:







Figure 29. Renovate Existing Lab and Add Automation in Next Five Years, Greenville Memorial Hospital

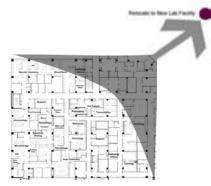


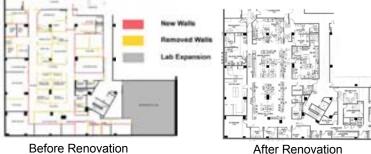
Figure 30. Relocate Entire Lab to New Facility in the Next Five Years, Greenville Memorial Hospital

- "*"Moved laboratory to a temporary location for 9 months and then moved back.*"
- "Built temporary laboratory outside hospital and moved in while new permanent laboratory was being remodeled inside hospital."
- "Consolidated Hematology (Automated) with Chemistry (Automated); duplicated equipment for backup and handling volume"
- "The laboratory was moved from a compartmentalized, fragmented basement location to a new addition of the hospital in 1999, this happened concurrently with the installation of the first LIS for the laboratory."
- "We are looking at a major remodel of our hospital including our laboratory and I see the laboratory being closer to ED and surgical departments."
- "Ongoing renovations requiring multiple small moves within laboratory are confining, primarily for new HVAC & asbestos abatement."

The case study of Greenville Memorial Hospital's clinical laboratory provides an example of the types of changes a compartmentalized laboratory have completed recently as well as changes they are considering in the next five years. The compartmentalized laboratory case study is a common typology of older laboratories in hospitals and was planned when all the clinical laboratory disciplines were departmentalized. This typology, however, does not support contemporary clinical laboratories due to the increasing overlapping clinical departmental boundaries and availability of staff. Three options are being considered for the next five years: (1) The existing laboratory space will be renovated plus a possible expansion, (2) The existing space will be renovated and a automation system will be added, or (3) The existing laboratory will be relocated to a new facility in which an open, flexible plan will be developed with long term plans for a total automation system (refer to Figures 28, 29, and 30 to see the three types of changes being considered).

Responses from open-ended questions suggest that laboratories are taking down walls and opening up the space to facilitate the integration of laboratory areas. Below are some examples:

- "We recently completed putting Chem/Hemo/Urines/Coag together in one space, opening up walls to allow laboratory to see each other, and installing some modular furniture."
- "A major problem we face is to remodel entire laboratory to streamline workflow and open up the laboratory."



Before Renovation



Figure 31. Renovation from Compartmentalized Lab to Semi-Open and Flexible Lab, St. Clare's Hospital

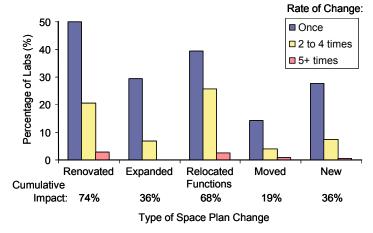


Figure 32. Percentage of Labs in which Changes to Lab Space Plan Occurred in the Last 5 Years

The case study at St Clare's Hospital showed a similar trend - a compartmentalized laboratory was converted into a primarily open, flexible laboratory (refer to Figure 31).

Rate of Change in the Laboratory Space Plan

1. Renovating existing space and relocating functions within the clinical laboratory occur more frequently than expanding the laboratory, moving the laboratory to another location or building a new laboratory. Renovating laboratory areas and relocating laboratory areas occur at least once in a fiveyear period. Thus, the layout of the laboratory needs to accommodate reconfiguring walls, relocating functions and ease of refinishing or replacing fixtures furniture or furnishes.

Based on research findings, the layout of the laboratory changes at least once every five years. Renovating and relocating functions are the primarily types of space plan changes that occurred. The survey shows that 29% of laboratories relocated functions/departments in the laboratory at least two times, and 24% of laboratories renovated existing laboratory space at least two times in a five-year period (refer to Figure 32). Two respondents said:

- "We have begun master planning for laboratory space needs with an architect."
- "We are planning for renovation and total laboratory automation over the next two fiscal years starting July 2002 and the approximate cost is 1.3 million dollars."

Nature of Changes in the Laboratory Contents

The clinical laboratory houses an array of instruments, laboratory equipment, workstations, cabinetry and supplies. These physical components take up space, yet are often times the most temporal aspects of the physical environment. For the purposes of this study, the contents in the laboratory were measured by the equipment and furniture (workstations and cabinetry). This section describes how often and where equipment is typically added and relocated to the clinical laboratory. In addition, the types of changes made to the workstations and cabinetry are discussed.

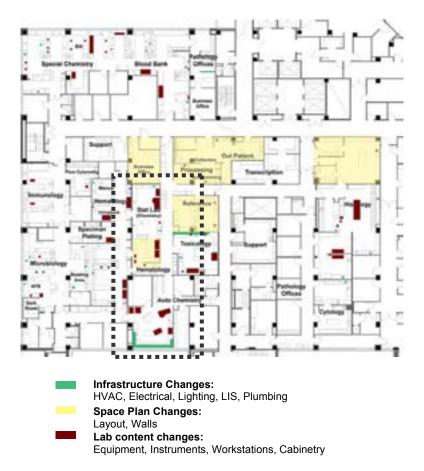


Figure 33. Cumulative Physical Changes in the Lab in the Last Five Years at Greenville Memorial Hospital

1. The physical environment needs to accommodate technological advancements and the constant addition and subtraction of multiple testing instruments as well as supporting equipment.

According to the survey findings, 90% of laboratories relocated equipment at least once in a five-year period and 97% purchased or leased new equipment at least once in a five-year period. Preliminary findings from case study research and responses from open-ended questions suggest that the highly automated areas (STAT area) update or replace equipment more often than areas that primarily involve manual testing. Figure 33 shows the cumulative changes from Greenville Memorial Hospital, suggesting that the STAT laboratory (Hematology and Chemistry) and Auto Chemistry are the areas that involve the most equipment changes.

Responses from open-ended questions suggest that leasing is the primary source of acquiring new equipment because it allows for easy upgrades as new technology is released. Two respondents said:

- "We never purchase instruments; we usually do reagent rental agreements."
- "Leasing allows for easier transition to newer instrumentation and technology. We are developing a 5 year plan for upgrades in services and technology."

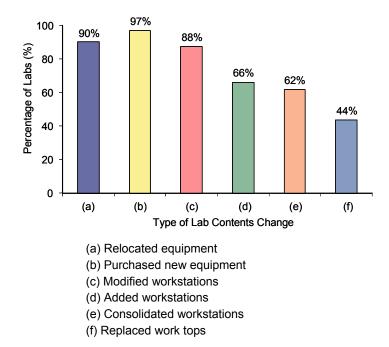


Figure 34. Percentage of Labs in which at Least ONE Change to Lab Contents Occurred in the Last Five Years

2. Clinical laboratory furniture (workstations and cabinetry) are being modified, added to, and consolidated in order to create a working environment that supports the constant addition and subtraction of instruments and equipment as well as new configurations of machines.

According to the survey, modifying furniture (workstations and cabinetry) was the most common type of changes made to the furniture, followed by adding furniture and then consolidating furniture. 88% of laboratories modified existing workstations or cabinetry, 66% of laboratories added furniture, 62% consolidated furniture, and 44% replaced worktops (refer to Figure 34). Three survey respondents noted the nature of change being made in their laboratories:

- "We are in a constant state of change always trying new things to see if in our cramped space we can do things better. With semi modular design we can rearrange the furniture without major cost."
- "We have "flexible furniture" so moving, changing countertops is easy."
- "Moving, changing and tweaking workspaces are ongoing projects here."

Changes in the furniture are motivated by changes in the equipment. Over the last 10 years, the equipment has changed to respond to various forces including: expectations to increase volume capability, the demands for faster throughputs as well as demands for expanded test menus. The footprint of each instrument is proportional to the volume it can handle and the type of test performed. Configurations of the instruments also vary over time. They can be counter mounted or floor mounted. The instruments may vary from a "U" configuration, to an "L", or to a straight line. To complicate matters, the types of supporting equipment in addition to the configuration may change. As more automation systems are implemented into laboratories, equipment manufacturers may produce more straight-line configurations for versatility. As for now, there is great inconsistency in configurations.

According to the survey respondents, on average 81% of the laboratory furniture (workstations and cabinetry) in the core laboratory is fixed or built-in and 34% is movable or modular. Responses from open-ended questions suggested a trend toward movable or modular furniture as noted below:

- "We are adding instrumentation, so we need to gut the laboratory and get modular so we can easily shift work spaces around."
- "We are adding flexible furniture; modular counters and cabinetry."

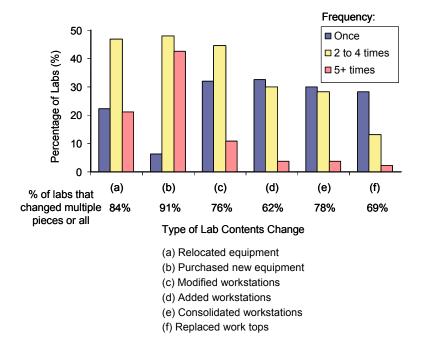


Figure 35. Percentage of Labs in which Changes to Lab Contents Occurred in the Last 5 Years

Table 8. Type of Content Change and Magnitude of Changes inLab Last Five Years

	Percentage of Labs Reporting Magnitude of changes					
Types of Contents in Lab	Single	Multiple	Entire/ All	Cumulative Total		
Relocated equipment	16%	74%	10%	23%		
Purchased new equipment	9%	90%	1%	25%		
Modified workstations or cabinetry	24%	68%	8%	22%		
Added workstations of cabinetry	38%	56%	5%	15%		
Consolidated workstations or cabinetry	22%	72%	6%	14%		
Replaced work tops	31%	57%	13%	10%		

Modular furniture/casework systems (workstations and cabinetry) also permit the layout of laboratories to be reconfigured to comply with specifications mandated by evolving regulatory requirements for building, safety, and operation purposes. The inclusion of multiple code requirements and jurisdictional guidelines is mandatory for accreditation (Mortland and Mortland 2000). Exploring the association between regulatory requirements and changes made to the physical environment, laboratory services and technology show that accreditation agencies & Federal codes (CLIA) are the two forces most consistently associated with **physical** changes in the laboratory. In addition, State and local codes are most consistently associated with **service and technology** changes (test menu and add or update front-end automation) in the laboratory. The data shows that life safety, accreditation, and federal codes are not consistently associated with services and technology in the laboratory (refer to the correlation summary tables in the Appendix for more detail).

Rate of Change in the Laboratory Contents

1. Multiple pieces of equipment/instruments are relocated, added or removed within the laboratory at least once each year, therefore the layout of the laboratory and furniture need to be flexible to support evolving technological processes.

The cumulative total shows that 90% of laboratories relocated equipment at least once in the last five years. When looking at the frequency of change, 47% relocated equipment between two and four times in the last five years, and 21% relocated equipment at least five times. Of all the laboratories that relocated equipment, 84% relocated multiple pieces or all equipment (refer to Figure 35).

A similar trend emerged with adding new equipment to the laboratory. The cumulative total showed that 97% of laboratories purchased or leased new equipment at least once in the last five years. When looking at the frequency of change, 48% purchased or leased new equipment between two and four times in the last five years, and 43% purchased or leased new equipment at least once a year. Of all the laboratories that purchased new equipment, 91% purchased multiple pieces or all equipment (refer to Table 8).

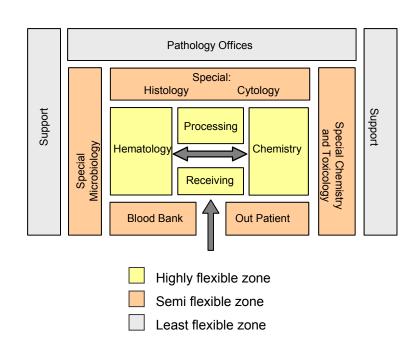


Figure 36. Conceptual Diagram of the Clinical Laboratory

Conclusion

This research supports the premise of planning and designing clinical laboratory environments that are flexible, and versatile to support changing and variable laboratory applications. This study aims at contributing to a body of knowledge that will help reduce the chronic problem of obsolescence in healthcare buildings by understanding the relationship between activities, the technological processes and the physical environment.

Neglecting the interdependency between specific activities, technological processes and the physical environment results in outdated, dysfunctional, and in often cases abandoned buildings. Based on a combination of anecdotal evidence, open-ended responses, and the literature, four principle strategies are presented in an effort to provide guidance for addressing flexibility in future hospital laboratory construction and renovation projects (refer to Figure 33 when reviewing the strategies).

- The clinical laboratory should be organized in zones. Clinical areas that primarily use automated systems (e.g. Chemistry and Hematology) in conjunction with central receiving and processing areas should constitute the highly flexible zone. As such, these areas need to be located within close proximity to all other clinical areas and be accessible from a public pathway. The most frequently used automated systems within each area should be physically located closest to the centralized processing and receiving areas. Special testing areas (esoteric testing) including both semi-automated processing plus manual processing should be located within the semi-flexible zone. Offices and support areas should be located at the periphery of the laboratory in a least flexible zone as not to disrupt workflow.
- The highly automated areas need to be most flexible and physical barriers (fixed walls and fixed furniture) should be avoided to permit a fluid workflow between workstations.
- Plug-and-play utility systems (such as overhead power supply and data ports) should be included particularly in the highly automated areas to accommodate the location and relocation of instruments and supporting equipment.
- Modular furniture (workstations and cabinetry), adjustable height tables, as well as portable furniture are recommended so workstations can be removed or reconfigured as technological processes change.

Below is a quote from a survey respondent that depicts the state of mind of laboratory managers:

"We have attempted to work within new regulations and compliance guidelines. We have researched how laboratory automation can help us do more with less. We have modified how we operate, consistently changing the way which we operate from an internal perspective. We have invested in information systems to assist us in our endeavors. We constantly assess our test menu to determine if we should be testing in-house or send our work to our reference laboratory. We are members of a hospital laboratory consortium created to compete with commercial laboratories for managed care laboratory contracts. We are planning on redesigning our laboratory to create a more efficient workflow."

According to the research, it appears that change is a part of life in the clinical laboratory and there is no end in sight. Respondents predict that several of the laboratories areas will undergo great changes in the next five years. From the open-ended responses, the following were the most commonly cited areas that will potentially change the most in the next five years: Molecular studies/diagnostics, Microbiology, Chemistry, Hematology, and Blood Bank. Automation and point-of-care testing were two other commonly cited responses.

- "Chemistry and Microbiology are likely to see the greatest rate of change due to advances in molecular technology, point of care requirements in critical care settings, development of chip technology, and new diagnostic and predictive assays."
- "Our blood bank department is moving to Gel Technology. Also we are starting to perform DNA probes for various tests in our Microbiology Department."

There are limitations to this study as a result of the research design and methodology. This study targeted community-based hospitals so findings are not specifically applicable to clinical laboratories in academic medical centers, commercial or research laboratories. Also, due to the under-representation of automated laboratories it was not possible to ascertain the impact of inserting automation systems into an existing laboratory environment or how the physical environment supports automation technologies. Furthermore, it is not possible to

ascertain from the data if fixed or movable/modular workstations were added, if laboratories with modular furniture (workstations and cabinetry) were making more changes than laboratories that have fixed furniture, or what specific areas were involved with more changes. The survey did show that on average 81% of laboratories reported have fixed or built-in furniture and on average 34% had movable or modular furniture¹⁰. The open-ended questions also suggest that clinical laboratories are considering replacing fixed furniture with modular furniture.

As evidenced above, questions emerged from the research informing a future research agenda, particularly in three areas. First, empirical-based research that tests the effectiveness of physical strategies and applications in supporting change is needed. For example, in what areas of the laboratory is modular furniture more useful than fixed furniture? Is the upfront investment less than the cumulative costs of replacing or reconfiguring fixed furniture? Second, will automation systems mitigate or perhaps eliminate several of the issues laboratories are facing today? Third, the methodology developed in this study could be tested in other hospital departments that face rapid changes, particularly surgery, radiology, and the emergency department. These departments are also influenced by the rapid change in technology, medical science, the delivery of medical care and market forces. Understanding the temporary and permanent layers within each department will help guide an overall system-wide planning and design approach that can support all departments throughout the life of the hospital.

When asked what strategies would help you prepare for the future, the following eight patterns emerged from all the open-ended responses: (1) Keep informed with new/current technologies; (2) Consolidate instrumentation; (3) Lease instruments; (4) Consider front-end and full automation; (5) Retain and recruit qualified staff technicians; (6) Increase point-of-care testing; (7) Include modular workstations; and (8) Encourage involvement in professional organizations such as CLMA, ASCP, AACC. Examples of quotes are noted below:

 "Prepare for increased automation, lines between disciplines will become blurred, e.g. many immunology and microbiology procedures will be done on chemistry instrumentation. Prepare to train staff on new techniques."

¹⁰ These numbers are averages of the two categories and therefore do not total 100%.

"Besides needing additional square footage, the current space needs to be re-designed to accommodate the flexibility required to meet increasing volumes as our system expands while maintaining/improving our current service levels and expanding the test menu to be more competitive with our outreach program."

To conclude, it is not possible to accurately predict what will happen in the clinical laboratory in the future. All areas of the research support the hypothesis that hospital laboratories require a high degree of flexibility. Interestingly, a review of the open-ended questions reveal that several laboratories are in the process of planning or completing construction of new clinical laboratories. This finding suggests that their existing physical facilities are either worn out or unable to accommodate the rapid changes that clinical laboratories are facing. As Brand (1994) says, "The quick processes provide originality and challenge, the slow provide continuity and constraint"..."the slow constrains the quick, slow controls the quick." The premature demise of buildings and more specifically laboratory facilities occurs when the physical layers of change no longer support the changes of activity within them. Thus, the clinical laboratory that embraces the concept of change and creates a physical environment that supports change will be better positioned to sustain the life in the laboratory.

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Survey

CONTACT INFORMATION

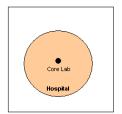
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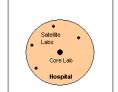
WORKLOAD AND TYPE OF HOSPITAL LAB

- 1. Who is responsible for the operation of your hospital-based core lab?
 - Hospital
 - Commercial lab
 - Partnership with hospital and commercial lab
 - Other, please specify
- 2. What entities does your core lab service? (Check all that apply)
 - Hospital only
 - Hospital-based physician practices
 - Hospital-affiliated physician practices
 - Independent physician practices
 - Other independent hospitals
 - Other hospitals within your system
 - Other, please specify

3. Which organizational diagram most accurately resembles your hospital lab?

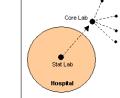
(Definitions: Core lab is a primary lab performing comprehensive testing and a satellite lab is a smaller lab performing a select test menu).



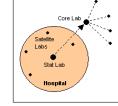


A. Core lab in hospital

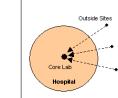
B. Core lab with one or more satellite labs in hospital



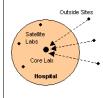
C. Core lab off-site with stat lab in hospital



D. Core lab off-site with stat lab and satellite labs in hospital



E. Core lab servicing hospital and other sites



F. Core lab servicing hospital and other sites with satellite labs in the hospital

If you have satellite labs, then where are your satellite labs located? (check all that apply)

- Emergency department
- Ambulatory care
- Other

- □ Surgery
- □ Critical care



- 4. What was the total annual volume of billable tests performed by your hospital's core lab in 2001 or for last completed fiscal year? (include on-site volume and off-site volume that came through your lab)
- 5. What was the estimated percentage breakdown of your total testing volume in 2001?

% automated tests performed in core lab % manual tests performed in core lab % automated or manual tests performed in satellite lab(s) in the hospital % referred out/off-site (Note: To equal 100% total) 6. Please indicate the overall percentage breakdown of your hospital's core laboratory volume in 2001 for: % Inpatient % Hospital outpatient % Non-hospital patient (outreach) (Note: To equal 100% total) 7. In the last 2 years, has the ON-SITE test volume in the core laboratory: Decreased □ Staved the same Increased 8. In the next 2 years, do you expect the ON_SITE test volume in the core laboratory to: □ Increase Decrease □ Stay the same Why do you expect it to change? PHYSICAL CHARACTERISTICS OF THE HOSPITAL LAB

- 9. Approximately what year was your hospital lab built?_____
- 10. Are you part of a multi-hospital system?
 - □ Yes □ No
- **11. If you are part of a multi-hospital system, then are you the core lab or a satellite lab?** □ Core lab □ Satellite lab
- 12. What is the footprint of your hospital's core lab: (Check all that apply)
 - A. Open lab with modular/movable workstations and/or cabinetry
 - B. Open lab with fixed cabinetry
 - C. Open lab with a few compartmentalized sections
 - D. All compartmentalized sections (with fixed walls)

14. Please indicate what percent % Fixed or but	uilt-in	urniture (wor	kstations and cabin	netry) in your core lab is	S:
% Movable o	or modular				
(Note: To equal 100% total)					
15. What is the approximate tota (Gross square footage includes				e lab?	
16. How many full-time employed Technical (MT, MLT, HT, etc,)_ Non Technical (Support, Phleb		-	our lab:		
17. What is the maximum numbe	er of people i	n the core lab	, including the pro	cessing area, at any one	e time?
NATURE AND RATE OF CHANGES I	<u>N HOSPITAL</u>	LABORATOR	RIES		
What year was the hospital's	s core lab last	remodeled?			
		_			
19. What types of changes have	your organiz	ation complet	ted within the LAS ⁻	FIVE YEARS, how ofte	en has each change occurred and was the
extent of some of the change		•			5
(Note: For the extent of the cha		dual units, mult	iple units, all units, r	new construction- check a	all that apply)
Type of change		How of	ten occurred in the	last five years?	
SERVICES AND TECHNOLOGY					
Expanded test menu	Never	Once	2 to 4 times	5 or more times	
mplemented brand new laboratory	Never	Once	2 to 4 times	5 or more times	
echnologies					
& services					
Added new or updated existing lab	Never	Once	2 to 4 times	5 or more times	
nformation systems (LIS)					
Added new or updated island automation	Never	Once	2 to 4 times	5 or more times	
departmentalized)					
Added new or updated front-end	Never	Once	2 to 4 times	5 or more times	
automation (processing)					

2 to 4 times

2 to 4 times

5 or more times

5 or more times

13. If you have an open lab with a few compartmentalized sections, which sections are compartmentalized?

Added or updated total automation (entire

laboratory)

Additional Comments:

Added or repaired robots

Never

Never

Once

Once

INFRASTRUCTURE

Altered/Added/Replaced = Changed:

Heating/Air/Exhaust (Fume hoods)	Never	Once	2 to 4 times	5 or more times	
If applicable, changed:	Individual elements	Multiple elements	Entire system	New construction	
Electrical or Lighting	Never	Once	2 to 4 times	5 or more times	
If applicable, changed:	Individual units	Multiple units	Entire system	New construction	
Cabling for lab information systems (LIS)	Never	Once	2 to 4 times	5 or more times	
If applicable, changed:	Individual areas	Multiple areas	Entire system	New construction	
Plumbing, sinks or floor drain	Never	Once	2 to 4 times	5 or more times	
If applicable, changed:	Individual elements	Multiple elements	Entire system	New construction	

Additional Comments:_____

Type of change	How often occurred in last five years?						
SPACE PLAN							
Renovated existing lab space	Never	Once	2 to 4 times	5 or more times			
If applicable, the changes were primarily involved with:	Refinishing or replacing fixtures, furniture or	Reconfiguring walls plus fixtures, furniture and	Total renovation of lab				
If applicable, what percentage of the lab was renovated?	finishes Less than	finishes 10% to 24%	25% to 49%	50% or more			
	10%						
Expanded lab	Never	Once	2 to 4 times	5 or more times			
If applicable, the lab was increased by approximately what percentage?	Less than 10%	10% to 24%	25% to 49%	50% or more			
Relocated functions/departments within the lab	Never	Once	2 to 4 times	5 or more times			
If applicable, the total lab floor area relocated accounts for what percentage of the total lab?	Less than 10%	10% to 24%	25% to 49%	50% or more			
Moved lab to another location	Never	Once	More than once				
If applicable, what percentage of the lab was moved?	Less than 10%	10% to 24%	25% to 49%	50% or more			
New construction of laboratory or lab areas	Never	Once	More than once				

If applicable, the new construction accounts for what percentage of the lab floor area?	Less than 10%	10% to 24%	25% to 49%	50% or more
What was the cumulative total square footage involved for all the space plan projects mention above?				
What was the cumulative total construction costs for the space plan projects mentioned above? (excludes equipment costs)				
Additional				
Comments:				
	r			
Type of change		How often	occurred in last fi	ve years?
CONTENTS OF LAB				
Relocated equipment	Never	Once	2 to 4 times	5 or more times
If applicable, relocated:	Single piece of equipment	Multiple pieces of equipment	All lab equipment	
Purchased new equipment	Never	Once	2 to 4 times	5 or more times
If applicable, purchased:	Single piece of equipment	Multiple pieces of equipment	All lab equipment	
Modified existing workstations or cabinetry	Never	Once	2 to 4 times	5 or more times
If applicable, modified:	Single work station and/or cabinet	Multiple work stations and/or cabinetry	All lab work stations and or cabinetry	
Added workstations or cabinetry	Never	Once	2 to 4 times	5 or more times
If applicable, added:	Single work station and/or cabinet	Multiple work stations and/or cabinetry	All lab work stations and or cabinetry	
Consolidated workstations or cabinetry	Never	Once	2 to 4 times	5 or more times
If applicable, consolidated:	Single work station and/or cabinet	Multiple work stations and/or cabinetry	All lab work stations and or cabinetry	
Replaced work tops	Never	Once	2 to 4 times	5 or more times
If applicable, replaced:	Single work counter top	Multiple work counter tops	All lab work counter tops	
Additional Comments:				

20. How many major instruments are floor mounted?_____

21. Approximately how many major instruments are counter mounted?_____

22. Have there been other changes made in the core laboratory within the last five years not mentioned above?

FORCES MOTIVATING CHANGE IN YOUR HOSPITAL LAB

23. To what degree have the following forces motivated change in your lab in the last five years?

Forces	Magnitude of Impact			
To Reduce Costs or Increase Revenue				
A need to change core services	None	Small	Moderate	Large
A need to change STAT services	None	Small	Moderate	Large
A need to increase outreach	None	Small	Moderate	Large
A need to refer more tests off site	None	Small	Moderate	Large
A need to decrease staffing (downsizing)	None	Small	Moderate	Large
To Improve Operational Efficiency				
A need to decrease turnaround times	None	Small	Moderate	Large
A need to fill staff vacancies	None	Small	Moderate	Large
Availability of qualified staff	None	Small	Moderate	Large
Reduce errors in testing or reporting	None	Small	Moderate	Large
A need for laboratory benchmarking systems	None	Small	Moderate	Large
A need to reengineer work flow	None	Small	Moderate	Large
Regulatory Requirements, a need to respond to:				
Life safety codes (e.g. OSHA)	None	Small	Moderate	Large
Building codes (e.g. NFPA, BOCA)	None	Small	Moderate	Large
Accreditation agencies (e.g. JCAHO, CAP)	None	Small	Moderate	Large
State or local codes/regulations	None	Small	Moderate	Large
Federal (e.g. CLIA 1988)	None	Small	Moderate	Large
Changes in Healthcare Practices				
Merger or consolidation of laboratory	None	Small	Moderate	Large
Changes in the percentage of HMO business	None	Small	Moderate	Large
Added or subtracted medical practices	None	Small	Moderate	Large
Shift in patient demographics	None	Small	Moderate	Large
Shifting of services to outpatient setting	None	Small	Moderate	Large
Added or closed hospital beds	None	Small	Moderate	Large
Increase in point-of-care testing	None	Small	Moderate	Large

Joint venturing with outside lab	None	Small	Moderate	Large
Need for support services (i.e call center)	None	Small	Moderate	Large
Increase of physician-owned labs	None	Small	Moderate	Large
24. What did you do in your lab to respor	nd to these	e forces m	entioned abo	ove?

FUTURE CHANGES

25. Can you pinpoint which clinical disciplines are likely to undergo the greatest rate of change in the next five years?

26. What strategies will help you prepare for these changes?

Email Letter Sent to Respondents

Dear CLMA Member:



We need your help! CLMA is collaborating with the Center for Architecture & Health at Clemson University on a research project to study the nature and rate of change in hospital-based clinical laboratories within the last five years. To date, there is no research documenting the typical and range of non-typical changes clinical labs experience over time and the motivators of these changes. Changes are defined as replacing, upgrading, relocating, and/or expanding lab equipment, technology, services, and/or facilities. Therefore, the project team is sending a questionnaire out to CLMA members in hospital-based labs. Findings from this study will assist: (1) Hospitals in making informed decisions as to where to invest in adaptable support systems such as moveable furniture, cabinetry and fixtures;(2) Design professionals in making planning, programming and design decisions as to what areas in the lab should be permanent and what areas should be more flexible; and (3) Manufacturers in making decisions regarding the development of new product lines of modular and adaptable workstation and cabinetry to support clinical laboratories.

Incentive

In return for your participation in this study, you will be eligible to receive a discounted rate on a single audio conference of your choice (\$99 as compared to \$149). In addition, you will also be eligible to win a FREE REGISTRATION to the CLMA/ASCP 2002 Conference and Exhibition in New Orleans, Louisiana. The winner will be drawn at the end May 2002.

Please complete the online survey at [website link] by May 15, 2002.

Questions, please contact...

Megan Wilmot, Educational Programs and Healthcare Policy Coordinator for CLMA, at 610-995-2640, ext. 245 or <u>mwilmot@clma.org</u> or Dina Battisto, Assistant Professor in the Architecture & Health Program at Clemson University at (864) 656-6794 or <u>dbattis@clemson.edu</u>.

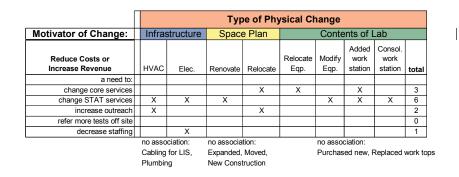
Results

A summary report highlighting research findings will be available through CLMA after August 1, 2002. Findings from this study may also be submitted for publication, however, no names or identifying characteristics will be included. This research is supported by CHER (Coalition for Health Environments Research), a not-for-profit organization dedicated to "promote, fund, and disseminate research into humane, effective and efficient environments through multidisciplinary collaboration dedicated to quality healthcare for all."

Anticipated time to complete questionnaire: 30 minutes

Thank you in advance for your participation

Correlation Analysis Summary Tables



	Type of Change										
Motivator of Change:	Infra	Infrastructure			Space Plan		Contents of Lab				
To Improve Operational Efficency	HVAC	Elec.	Plumb.	Re- novate	Re- locate	Move	Modify Eqp.	Added work station	Consol. work station	Replace work tops	total
a need to:											
decrease TAT	Х										1
fill staff vacancies					Х				Х		2
availabiliy of qual. Staff						Х					1
reduce errors in testing/reporting											0
lab benchmark systems					Х						1
reenginner workflow		Х	Х	Х	Х		Х	Х	Х	Х	8
	no association: no association: n			no asso Relocate		urchase E	Eqp.				

Table 1: Correlation Analysis summary between strategies to reduce costs or increase revenue and service and technological changes Table 3: Correlation Analysis summary between strategies to improve operational efficiency and service and technological changes

Motivator of Change:		Type of Ser	vice and Te	chnology C	hange	
				New or	Added or	
To Improve	Expand Test	New Lab	New or	Updateed Isl.	Repaired	
Operational Efficency	Menu	Tech. & Services	Updated LIS	Auto.	Robots	total
a need to:						
decrease TAT	х	Х	х		Х	4
fill staff vacancies						0
availabiliy of qual. Staff			Х			1
reduce errors in testing/reporting						0
lab benchmark systems			х			1
reenginner workflow			х	Х		2
•	no association					

Add or update front-end auto., Add or update total auto.

Table 2: Correlation Analysis summary between strategies to reduce costs or increase revenue and physical changes

Motivator of Change:	т	ype of Service a	and Technolo	gy Changes	
Reduce Costs or	Expand Test	New Lab	New or	Added or	
Increase Revenue	Menu	Tech. & Services	Updated LIS	Repaired Robots	total
a need to:					
change core services		Х		Х	2
change STAT services		Х			1
increase outreach		Х	Х		2
refer more tests off site	Х				1
decrease staffing					0
	no association:	•	•	•	

Add or update isl. auto., Add or update front-end auto., Add or update total auto.

Table 4: Correlation Analysis summary between strategies to improve operational efficiency and physical changes

Motivator of Change	Type of Services and Technology Change						
Respond to Regulatory Requirements	Expand Test Menu	New or Updated Front-end Auto.	total				
a need to:							
Life Safety Codes			0				
Building Codes	Х		1				
Accreditation Agencies			0				
State and Local Codes/Reg.	Х	X	2				
Federal Regulations			0				

no association:

New Lab Tech, & Services, New or Updated LIS, New or updated isl. auto.,Add or update total auto., Added or repaired Robots

Table 5: Correlation Analysis summary between strategies to respond to regulatory requirements and service and technological changes

Motivator of Change:	Type of Service and Technology Change								
	New Lab		New or	Added or	Added or				
	Tech. &	New or	Updated Isl.	Updated Total	Repaired				
Changes in Healthcare Practices	Services	Updated LIS	Auto.	Auto.	Robots	total			
a need to:									
Merger or Consol. of Lab					Х	1			
Changes in % HMO Business			Х			1			
Change in # of Medical Practices		Х				1			
Shift in patient demographics	Х	Х				2			
Shifting of service to OP		Х	Х			2			
Added or Closed Hospital beds		Х		Х		2			
Increase in POC testing						0			
Joint venturing w/ outside lab					Х	1			
Need for support services				Х		1			
Increase of physician-owned lab				Х		1			

Extended test menu, Add or update front-end auto.

Table 7: Correlation Analysis summary between changes in healthcare practices and service and technological changes

	Type of Physical Change							
Motivator of Change:	Infras	tructure	Spac	e Plan	Contents of Lab			
Respond to Regulatory Requiremnets	HVAC	Elec.	Renovate	New Const.	Replace work tops	total		
a need to:								
Life Safety Codes	Х					1		
Building Codes	Х					1		
Accreditation Agencies	Х	Х	х		Х	4		
State and Local Codes/Reg.	Х					1		
Federal Regulations	Х		х	Х		3		
	no assoc	iation:	no association	i.	no association:			
	Cabling for LIS,		Expand, Reloo	ate, Move	Relocate Eqp., Purchase Eqp., Modify			
	Plumbing	1			Add work stations, Cons	ol. Work sta		

Table 6: Correlation Analysis summary between strategies to respond to regulatory requirements and physical changes

	Type of Change										
Motivator of Change:	Infrastructure		Space Plan			Contents of Lab					
Changes in Healthcare Practices	HVAC	Elec.	Plumb.	Re- novate	Re- locate	Move	Relocate Eqp.	Modify Eqp.	Added work station	Consol. work station	total
a need to:											
Merger or Consol. of Lab		Х				Х					2
Changes in % HMO Business											0
Change in # of Medical Practices											0
Shift in patient demographics				Х						Х	2
Shifting of service to OP	Х	Х	Х	Х	Х		Х	Х	Х	Х	9
Added or Closed Hospital beds	Х	Х		Х					Х		4
Increase in POC testing								Х	Х		2
Joint venturing w/ outside lab									Х		1
Need for support services	Х	х							Х	Х	4
Increase of physician-owned lab	Х			Х							2
	no association: no association: no association: cabling for LIS, Expand, Relocate, Relocate Eqp., Purchase Eqp., Modify word Plumbing Move Add work stations, Consol. Work stations										

Table 8: Correlation Analysis summary between changes in healthcare practices and physical changes