

Methodology for the Preliminary Design of a System of Integrated Clinical Laboratories

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Abstract

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Clinical laboratory testing is used for deriving patient diagnoses, monitoring treatment and predicting the expected outcome of a disease (prognosis). Thus, the performance of clinical laboratories is critical for our healthcare systems and it is determined by the precision and accuracy of the test results, turnaround time and laboratory costs. This thesis presents a methodology for the preliminary design of a system of integrated clinical laboratories (PDL) which, if applied correctly, can improve turnaround time and laboratory costs, among other metrics, providing an efficient physical configuration of the clinical laboratory space and an efficient process to achieve those objectives. The preliminary design phase is where requirements are developed, and several solutions are outlined; where a focus on the clinical laboratory processes allows form to follow function. The PDL methodology has three stages: Stage 1 formulate the concept; Stage 2 develop design alternatives; and Stage 3 evaluate alternatives. The first stage is where the concept of the clinical laboratory is generated and where data and information are collected and transformed into requirements and processed information. The second stage is where the different preliminary designs alternatives are developed. And the third stage is where the designs are evaluated using criteria determined in Stage 1. The final

results are a set of preliminary designs and a design package that organizes all of the information generated during the three phases of the PDL effort. The stages are not strictly sequential, since there are continuous feedback loops between them. Throughout the PDL methodology different concepts derived from different disciplines can be applied (e.g., facilities planning and design, lean management, project management, systems architecture, multiple-criteria decision-making, operations research). The clinical laboratory of Seattle Children's Hospital is the case study of this thesis where the PDL methodology was successfully applied. The PDL methodology served the purpose of initiating the facility design for the clinical laboratory and preparing them to participate in the overall construction project of their new building.

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I saved the more important to the end. Thank you Laura for everything and form our "team". I love you.

DEDICATION

To Labli, you are my everything.

Chapter 1. INTRODUCTION

Approximately 70% of patient diagnoses are derived from results of clinical laboratory testing (Harmening, 2007). Additionally, clinical laboratory testing serves the purpose of deriving medical treatment and predicting the outcome of diseases (prognosis). Thus, the performance of clinical laboratories, in particular, is critical for the improvement of healthcare and it is determined by the precision and accuracy of the test results, turnaround time and laboratory costs (Astion and Chandler, 2018). The physical configuration of clinical laboratories impacts turnaround time and cost, among other metrics. To achieve an efficient physical configuration with an efficient process, this thesis is proposing the development of preliminary designs through a methodology for the **preliminary design** of a system of integrated clinical laboratories (PDL), which is the focus of this work.

Most of the clinical laboratories are in fact a system of integrated laboratories, since they have specialty labs within, derived from the different disciplines of clinical and anatomic pathology. Clinical laboratories process different types of specimens, such as fluids, gases and tissue obtained from patients. Additionally, they need to have a series of support and planning services to function efficiently (Linné and Ringsrud, 1999). Although every subsystem has a specific role, they must work in coordination, not only between them but with external actors (e.g., physicians, nurses, patients). This is even more critical for specimens that degrade in time or test results that are needed urgently.

There are many challenges for designing clinical laboratories, since they are complex organizations (Kinkus, 2012) and their environment is always experiencing change. New tests and new areas of expertise of laboratory medicine are being developed. Currently, there are thousands of distinct laboratory tests but only a small percentage of these tests are routinely ordered (Linné and Ringsrud, 1999). Furthermore, technology plays a key role in their activities as the level of automation tends to increase with time and that can lead to either larger or smaller equipment space requirements. The consequences are drastic changes in how tests are performed (Linné and Ringsrud, 1999) and a growth rate much greater than healthcare organizations in general (Sloane et al., 1999). Thus, the clinical laboratory physical configuration is determined not only by the actual workload but also by the type of equipment (Hayward, 2016) and future demands (Garcia

and Bachner, 2014). This in turn, has always required qualified workers who play a critical role in the correct manipulation of specimens.

Despite some reforms, healthcare costs are increasing (Miller, 2012; Snyder and Wilkinson, 1998), especially in the United States (Flower, 2012). As a fundamental part of the healthcare industry, clinical laboratories are also concerned about increasing costs. This is why they must improve their performance, their quality and their response time without adding more pressure to the healthcare financial system (Harmening, 2007; Rutledge et al., 2010). Studies of several industries have demonstrated, with great consistency, that the physical space has a significant impact on workers and overall system performance (Teicholz, 2001) and can lead to a significant reduction in costs (Tompkins, 2010).

A recommended approach for the construction of a new facility is to first develop a preliminary or conceptual design (Reiling, 2007; Kwok, 2007) to explore different alternatives and prepare the organizations for later stages of the construction project (schematic and detailed design). In the case of a clinical laboratory, how can a good preliminary design be developed? And could it be developed with an efficient process? That is what the PDL methodology proposed in this thesis addresses. The value is not only in the concrete result of the PDL methodology (the preliminary designs) but also in the modeling process itself and the information that will be generated (the design package), where several people will be asked to think hard about their current and future needs and processes, in an orderly way.

The preliminary design process of a major renovation project, or a new facility, is an opportunity for an organization to rethink their systems, processes, and use of technology, searching for better ways to provide their services and determine the right size based on projected demand, staffing, equipment, technology and desired amenities (Hayward, 2016). Today, the process clinical laboratories frequently use to develop new facilities is to depend on experts that provide guidance in specific areas based on their experience, or on external consultants that do not always understand clinical laboratories. Both approaches can have mixed results. It is not rare to find that the majority of the preliminary design work is performed by the architects in later phases of the project, thus reducing the potential for creating a more efficient physical space and possibly adding costs to an already expensive project. Since clinical laboratories are complex and have many challenges, there is a need for domain specific knowledge that ensures a successful preliminary design is created as part of the planning process of a new facility.

The objective of this research is to develop a methodology for the preliminary design of a system of integrated clinical laboratories (PDL). The PDL methodology is not a rigid set of steps; it is a process that can be repeated and has space for adaptability to the different contexts of clinical laboratories. This hierarchical and iterative methodology includes an adaptation of useful knowledge from different domains.

Another objective is to apply the PDL methodology to the clinical laboratory at Seattle Children's Hospital (SCH). SCH will open a new building in 2021 where the clinical laboratories will be located. The new SCH labs is the case study used in the thesis and contributes in two important aspects: to demonstrate the PDL methodology; and to present an application that complements the theoretical background.

Chapter 2. LITERATURE REVIEW

The preliminary design of the facilities for a system of clinical laboratories is a complex project. In the present work, several disciplines are reviewed to gain an understanding of different perspectives that can be included in the PDL methodology for the problem proposed. Some concepts can be applied directly, and others need to be adapted for the specific context of clinical laboratories. This literature review is presented in several categories for practical purposes; many of these categories overlap.

2.1 FACILITIES PLANNING AND DESIGN

Tompkins (2010) defines facilities planning as the process to decide its location and design its components (systems, layout and handling system), having customer satisfaction as the primary objective. Tompkins (2010) presents an interesting comparison between three facilities planning processes. Lee et al. (1997) defines facilities planning as the process of planning and building the facility. They provide examples of different approaches, including descriptions of the important role that the industrial engineer must assume. Additionally, Lee et al. (1997) presents space planning as the central focus of facility design and divides the process into five levels: site location and selection; site planning; building layout; department or cell layout; and workstation design.

Waite (2005) gives a special importance to the role of non-architects in the planning, designing and building capital projects; a long and complex process. Waite (2005) presents six stages of the project delivery process: pre-design planning; schematic design; design development; construction documents; construction administration; and occupancy. The pre-design planning is the most important phase and the period where the non-architects can have great influence. Additionally, Waite (2005) describes the difference between design problems and management or organization problems, and how architects often do not comprehend the difference.

According to Kwok (2007) the architectural design process includes the following phases: pre-design, where the owner's requirements are developed; conceptual design, where an outline of one or more proposed design solution is developed; schematic design, where the project directions outlined in the conceptual design are verified as being technically feasible, within budget, and able to deliver on design intents; and design development, where the details are established.

Space requirements is another important concept. From a facilities management perspective, Rondeau et al. (2006) explains that it refers to the volume and its characteristics. To establish space requirements, there are basic steps: identifying the type and volume of activities to be accommodated; establishing the basis and criteria for space utilization; developing and applying space standards; and calculating space requirements. Also, from a facilities management perspective, Teicholz (2001) gives a special importance to benchmarking described as understanding the best practices of other facilities that have high performance and adapting them to your specific organization. The same author presents four phases for the design and construction process: formulation, design, construction and operations.

A specific set of procedures to follow for the planning of a facility is presented in Muther (1973) and Muther and Wheeler (1962). It is called Systematic Layout Planning (SLP) and it has four phases: location of area to be laid out; general overall layout; details layout plan; and installation. These phases are based on a manufacturing system where the information used is provided by the product, the quantity, the process sequence, the supporting services and the timing. However, it can also be used for other contexts. There are several applications of SLP in the literature (Hosseini et al., 2014).

Francis and White (1974) proposed the following steps for the facility layout problem: formulate the problem; analyze the problem; search for alternative solutions; select the solution; and complete the specification of the solution. Additionally, Francis and White (1974) describes the use of a computer to generate layout designs. The improvement algorithm described is CRAFT and is used when the flow of materials is dominant. The two construction algorithms described are CORELAP and ALDEP and they are used when there are difficulties to collect precise numerical data (e.g., flow of materials). Further discussion can be found in Tompkins (1978).

Stevenson (2005), from an operations management perspective, discusses the importance of having a comprehensive accounting of departments and dimensions, future work flows, distance between locations, special considerations and location of key utilities and access points. Chase and Aquilano (1995), also from an operations management perspective, define the inputs for a layout decision as: specifications of objectives in terms of output and flexibility; estimation of demand; number of operations and amount of flow between departments; and overall space availability.

2.1.1 *Healthcare and the Clinical Laboratory*

Hayward (2016) presents an integrated predesign planning process that can be applied to healthcare facilities. Hayward (2016) gives a special importance to understanding the current facility and the future demand before beginning the detailed operational and space programming. The American Institute of Architects (2006) provide several useful guidelines and requirements for healthcare facilities including the space designated for the clinical laboratory. Klein (1989) explains that an architect needs to know what owners or operators desire or have approved to derive operational requirements. Klein (1989) shows the importance of drawings as an implementation of the ideas of the owner of the facility. In the context of a clinical laboratory, Levary and Schmitt (1986) describes a group decision making process that can increase morale and productivity by considering qualitative and personal factors during the layout finalization phase. Reiling (2007) presents a “Safe by design” approach to hospital design that includes the following phases: predesign, concept design, schematic design, design development, construction documents, bidding and negotiating, and administration.

The Clinical and Laboratory Standards Institute (2016) proposed eight steps for the design and construction of a clinical laboratory, since the complexity of their design requires a structured process to ensure success. Their steps are: project team selection, planning and programming, schematic design, design development, construction documents, bidding and negotiations, construction and moving in. The planning phase is where information is collected, a thorough analysis of existing workflow design for every section of the laboratory is made and a block diagram (general floor plan) is constructed. Baer (1990) presents a complete description of the laboratory design planning process describing the importance of good communications with the architect and the creation of a program and a plan prior to the design. In Baer (1984), Baer (1989), Baer (1995), Battisto (2005), Garikes (2006), (Koenig III, 1983) and, Wodka and Baer (1990) there are several useful guidelines and recommendations. The College of American Pathologists (1985) emphasizes the process of planning and design and all the knowledge that is generated in every step of the process. One of the most significant problems they identify is a lack understanding among the pathologist, architect, and administrator.

2.1.2 *General Laboratory*

Griffin (2000) shows the importance of the design synthesis as a very complex process of putting together all the parts of the laboratory into a whole where more than one design can be tested against the requirements. The author calls this phase the *scheme plan*. DiBerardinis (2013) discusses the use of alternative layouts for the design and construction of new laboratories through a building program that is developed from analysis of data collected of the number and types of personnel, the functions to be housed and the interrelationships among them. This is developed by the architect, the project engineer, the laboratory consultants and, the owners and users. Additionally, DiBerardinis (2013) provides guidelines specific for the clinical laboratory.

2.2 LEAN MANAGEMENT

Lean management, also known as the Toyota Production System and The Toyota Way, is having an increased influence in clinical laboratories and their design, especially when the operational processes are evaluated before the design. It has been described widely in the literature from different perspectives (Liker, 2004; Ōno, 1988; Rother, 2010; Womack, 1996, 2007). Although originally conceived in a manufacturing environment, lean management has been applied to healthcare (D'andreamatteo et al., 2015; Toussaint and Berry, 2013; Wellman, 2017) and the clinical laboratory (Garikes, 2004; Hayes et al. 2014; Joseph, 2006a, 2006b; Appold, 2013; Nicolaou and Borgsdorf, 2007; Rutledge et al., 2010; Sunyog, 2004; Protzman et al., 2015; Yerian et al., 2012) resulting in increased efficiency and quality, and reduced costs. The downside is that typically lean management is applied individually and to existing product lines where all of the original design concepts have already been created (Coletta, 2012).

The philosophy and its principles were not conceived for the specific task of design. Nevertheless, the process improvements that results in major changes, often includes a new design for the workplace. Examples in the clinical laboratory are described in Rutledge et al. (2010), Yerian et al. (2012) and Hayes et al. (2014). Additionally, Toyota developed Production Preparation Process (3P) as a way to combine lean principles with integrated product and manufacturing design (Bresko, 2009). This has also been adapted and applied to the design of healthcare facilities (Hickset al., 2015; Nicholas, 2012; Pelly et al., 2013). Related to 3P, is another important concept derived from Toyota's product development process: set based concurrent

engineering (SBCE), where several sets of possible solutions are considered, gradually eliminating the weaker ones and rapidly converging to the best solution (Sobek et al., 1999). This concept can be used as a guiding principle in the design process.

In the last decade, the concept of lean design emerged (usually incorporating 3P principles). In the context of healthcare facilities, Grunden and Hagood (2012) presents the different steps of lean-led design as master planning, predesign, value stream mapping, schematic design and design development. Guzzo Vickery (2015) presents several examples of lean design applications in healthcare and Mazur et al. (2013) presents an integration between lean design and evidence-based design in a hospital setting. Roerson et. Al (2013) provides a complete description of the construction of a cytology laboratory and Nicolaou and Borgsdorf (2007) describes how several healthcare organizations are taking the fundamental concepts of lean to the next level by incorporating them into the design process.

2.3 PROJECT MANAGEMENT

Project management provides a set of tools that improves the ability to plan, implement, and manage activities to accomplish organizational activities (Gray & Larson, 2008). It provides a useful framework for large projects. In Figure 2.1, a graph of the project life cycle proposed by Gray and Larson (2008) is shown. That project life cycle could be applied to the entire construction project or to each phase, in this case, preliminary design.

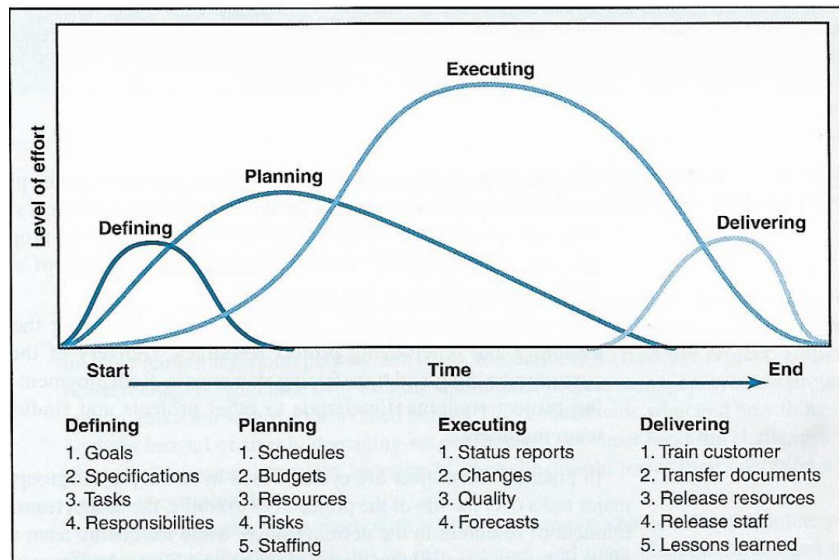


Figure 2.1: Project life cycle (Gray and Larson, 2008)

According to Wysocki and Gillingham (2014), project requirements identifies what is needed and describes what a solution must do but not how to do it. Thus, even if the solution is not known, the requirements of that solution can be established (Wysocki and Gillingham, 2014). In this context, Wysocki and Gillingham (2014) defines the Requirements Breakdown Structure (RBS) as a hierarchical list of what must be developed to meet requirements and also defines the Work Breakdown Structure (WBS) as a hierarchical description of all work that must be done to complete the project as defined in the current RBS. Although RBS and WBS are not used explicitly in the methodology proposed, they are addressed in the last chapter of this thesis. Ramroth (2006) shows the relationship between the six activities of project management with the five phases of a design project (Figure 2.2). The development of a preliminary design is itself a complex project.

SIX ACTIVITIES OF PROJECT MANAGEMENT / FIVE PHASES OF A DESIGN PROJECT

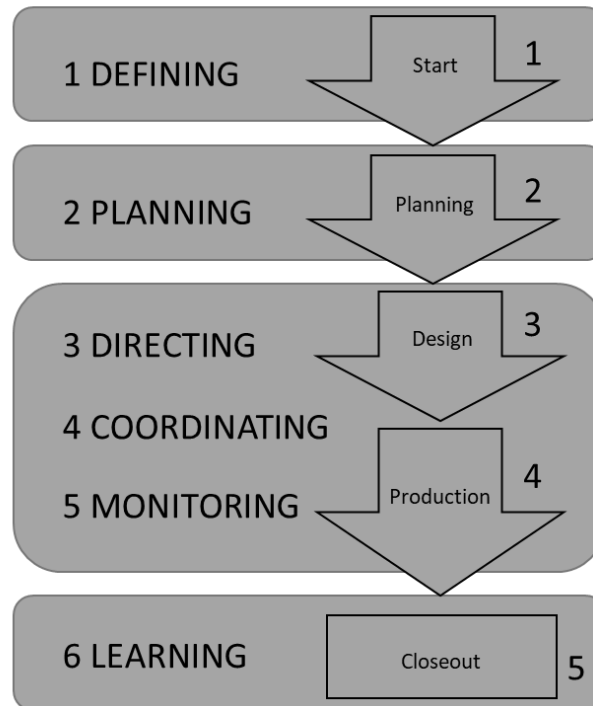


Figure 2.2: Project management and design relationship (Ramroth, 2006)

2.4 SYSTEMS ARCHITECTURE

The essence of systems architecture is structuring, bringing order out of apparent chaos, converting the partially formed ideas of a client into a workable conceptual model (Maier and Rechtin, 2000). The system architect works with the client to deliver a set of abstracted designs of the system and uses models as a primary means of communications with clients, builders and users

(Maier and Rehtin, 2000). Since systems are too different to allow a fixed approach to architecting (Maier and Rehtin, 2000), most of the process or meta-process for system architecting are general guidelines.

Maier and Rehtin (2000) describe the principal activities of systems architecting as scoping, aggregation, partitioning and certification. Sillito (2014) developed a process with six steps: enterprise, operational, system, logical, physical and decision. It is important to acknowledge that the explicit distinction between systems architecture and systems engineering is not completely clear. Blanchard (1998) proposed that the systems engineering design process include the following phases: conceptual design, where the needs are identified, and the system requirements are defined; preliminary design, where the system requirements are translated into design requirements for the subsystem level; and detail design, where the process proceeds to the realization of specific system components.

2.5 MODELING TECHNIQUES

In this subsection specific modeling techniques that can be used as part of the PDL methodology are reviewed. They are primarily two types: solution structuring and quantitative analysis.

2.5.1 *Multiple Criteria Decision Making (MCDM)*

The Analytical Hierarchy Process (AHP), a type of MCDM introduced by Saaty (1980, 1982), is a framework for complex decisions that has been applied widely and discussed in the literature (Ho, 2008; Ho and Ma, 2017). There are many applications to facility layout design (Hadi-Vencheh and Mohamadghasemi, 2012; Hamidreza et al., 2013; Shang, 1993; Singh and Singh, 2011), usually in conjunction with another modeling form.

The Choosing By Advantages (CBA) decision-making systems, introduced by Suhr (1999) is a MCDM method that is based on differentiating the alternatives by summarizing their advantages and at the end of the process weighing the importance of the advantages (Arroyo et al., 2018). It has been applied several times in a lean construction setting (Arroyo et al., 2015; Kpamma et al., 2014). AHP and CBA can be used in the PDL methodology as evaluation methods.

2.5.2 *Queueing Theory*

Queueing theory is the study of waiting. There are many queueing models that represent various types of queueing systems (Hillier and Lieberman, 2015). The main objective is to develop analyses for performance metrics such as the number of entities in a queue or the mean time spent in the system (Ravindran, 2008). C and Iyer (2015) presents an exhaustive literature review of applications of queueing theory in a healthcare environment. Queueing theory can be used as part of the PDL methodology to build analytical models to decide the level of resources needed to meet a performance metric (e.g., turnaround time).

2.5.3 *Discrete Event Simulation*

Discrete event simulation (DES) models are developed for answering specific questions when analytical procedures are not possible (Kelton et al., 2013). Heim et al. (2015), Hu (2014) and Wang et al. (2013) created domain specific models for the clinical laboratory. For the problem of the design of a new facility, Saunders (2010) used a simulation model in the facility planning process to analyze different scenarios and gain insights in the facility's capacity to accommodate demand. Kurkin and Šimon (2011) created a simulation model to optimize the spatial arrangement of a manufacturing system. Another application to a manufacturing environment is described in Dombrowski and Ernst (2013) where a scenario-based approach is used to determine whether different alternatives for the factory layout are adequate for the future. DES models can be used as part of the PDL methodology for the same purpose as the queueing models. Additionally, it can serve the purpose of evaluating different design alternatives.

2.6 PRELIMINARY DESIGN DISCUSSION

There are several terms for the process that involves the construction of facilities and their preliminary design: facilities planning, facilities management, facilities (preliminary or conceptual) design, facilities layout, facilities pre-design, space programming, layout planning and space planning (Hayward, 2016; Lee et al., 1997; Muther, 1973; Rondeau et al., 2006; Teicholz, 2001; Tompkins, 2010; Waite, 2005; Kwok, 2007; Reiling, 2007; Clinical and Laboratory Standards Institute, 2016). In Figure 2.3 there is a simplified Gantt chart to show different stages

of a design project proposed by different authors and presented in previous subsections compared to the preliminary design phase used in the PDL methodology. It is arguable where the PDL methodology stands compared to other authors, especially since every author proposes their own vision of the matter and the stages are not always strictly sequential with different tasks to perform. A simple explanation of preliminary design phase for this thesis, is that it includes the pre-design and conceptual design proposed by Kwok (2007), where the owner's requirements are developed, and different solutions are outlined. The deliberate use of the word preliminary is to separate it from the schematic design performed by architects and to include the pre-design in conjunction with the conceptual design.

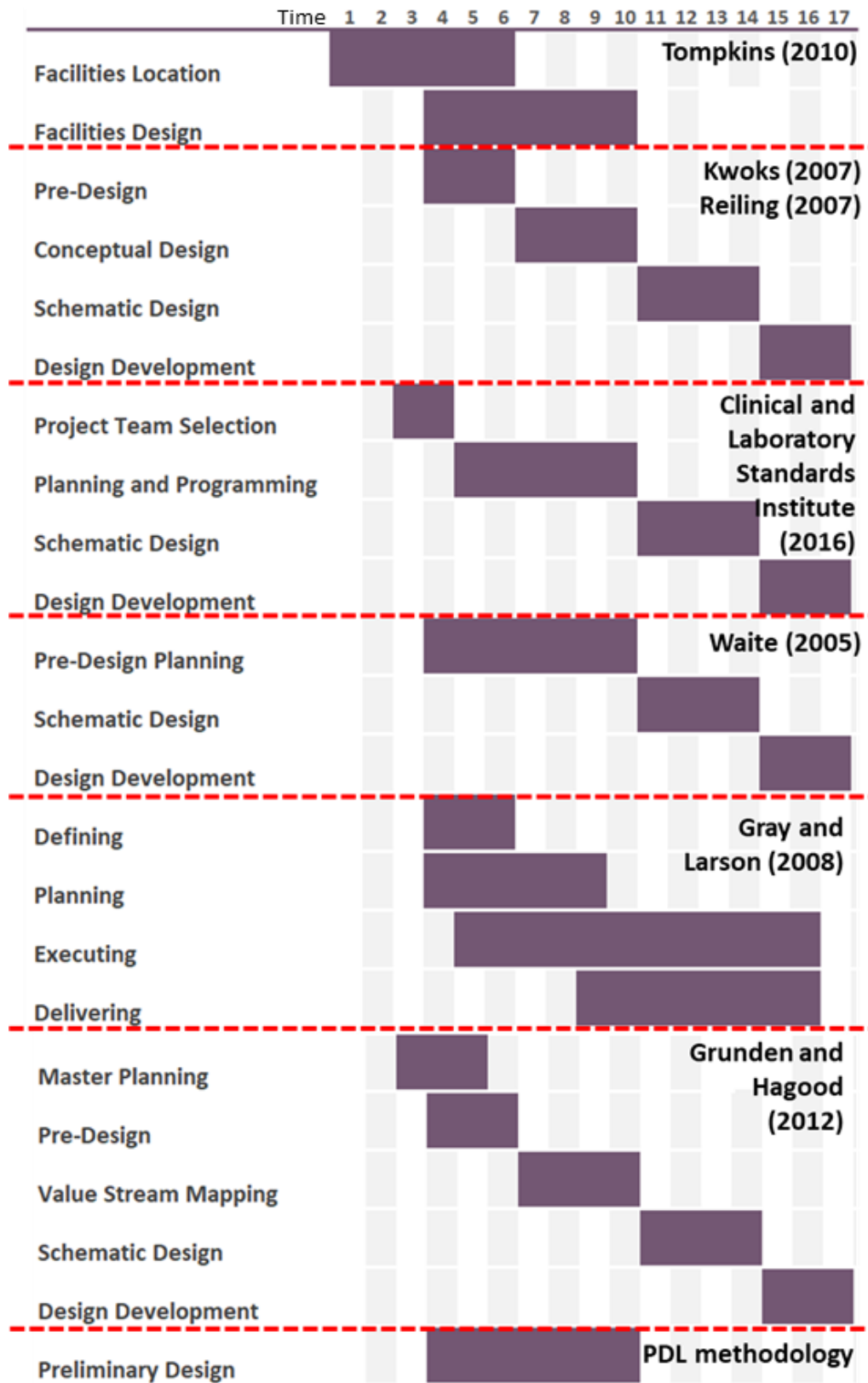


Figure 2.3: Design projects stages comparison

The importance of the preliminary design phase lies not only in the resulting final configuration, but in the fact that these are the times in a project when the ability to influence the overall cost are most significant, as shown in Figure 2.4 taken from Hendrickson (2008). This is because the costs committed tend to increase with time, as seen in Figure 2.5 (Buede, 2000). Additionally, if the preliminary design phase is executed with a defined process similar to the PDL methodology, the cost impact due to changes tend to decrease, as seen in the desired practices of Figure 2.6 (Blanchard and Blyler, 2016).

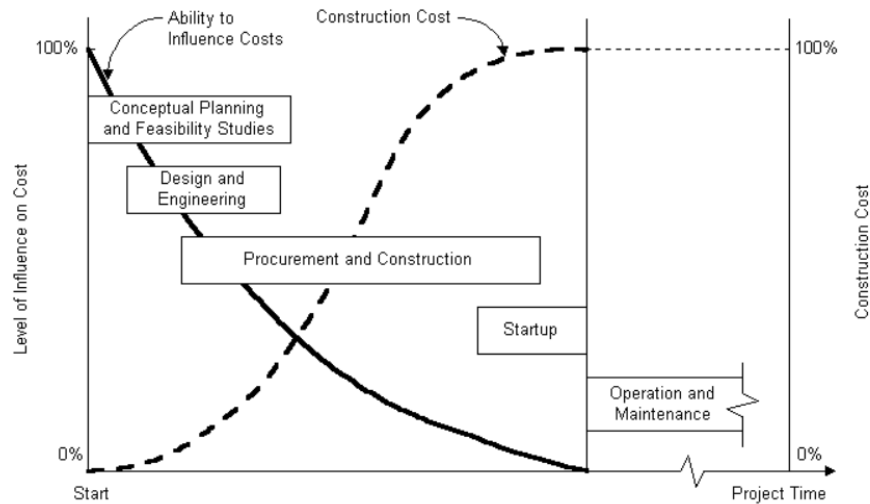


Figure 2.4: Ability to influence construction cost over time (Hendrickson, 2008)

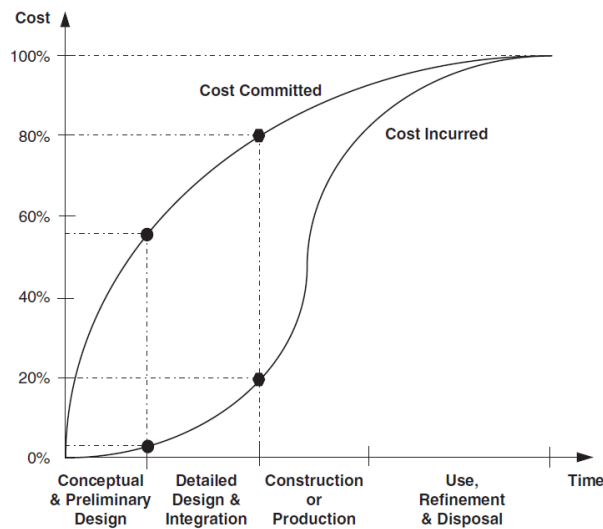


Figure 2.5: Cost commitment and incursion in the system life cycle (Buede, 2000)

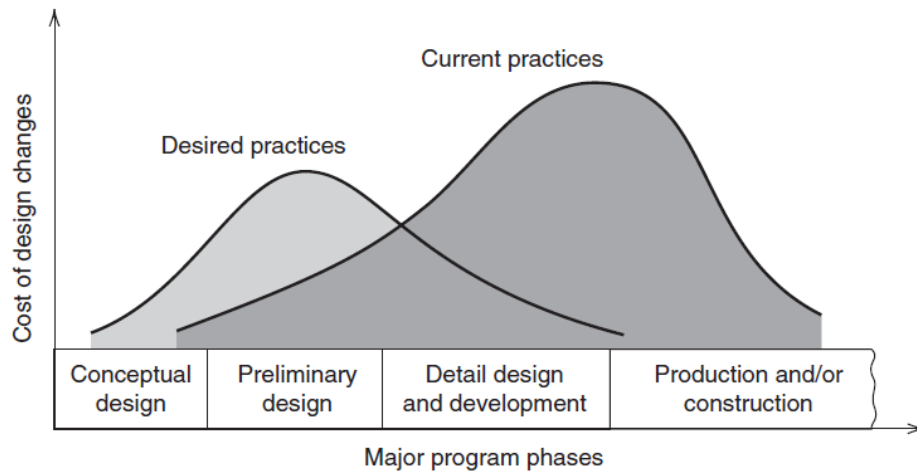


Figure 2.6: The cost impact due to changes (Blanchard and Blyler, 2016)

With a clear definition of preliminary design and why it is important, the PDL methodology is presented in the next chapter. A subsection describing clinical laboratories is provided in case the reader is not familiar with their characteristics and activities.

Chapter 3. PDL METHODOLOGY

At first glance, the design of a system of clinical labs would seem to be a straightforward application of layout practices. However, the clinical laboratory domain is complex, with a number of specific needs and constraints that provide an opportunity to present a specific methodology for this context. Before explaining the PDL methodology, a description of clinical laboratories is presented.

3.1 CLINICAL LABORATORIES

It is important to understand what will be designed, in this case the clinical laboratory. Its primary purpose is to provide the routine clinical testing required for patient care. The workflow consists of three processes: pre-examination, where specimens are collected; examination where tests are performed; and post-examination where reports are generated (Clinical and Laboratory Standards Institute, 2016). The disposal of completed test materials and the long-term storage of residual specimens is also a component of the clinical laboratory (DiBerardinis, 2013).

Clinical laboratories work with many types of specimens such as tissue, blood, urine, stool and other body fluids (Linné and Ringsrud, 1999). Since they are responsible for providing life-critical information, it is crucial that these specimens are properly handled. Except for some collection steps (e.g., phlebotomy), the clinical laboratory staff usually do not interact directly with patients; they generally interact with patient care providers.

Clinical laboratories can be standalone facilities or be embedded in larger organizations (e.g., hospital, clinics). The organization will depend on factors of size, number of tests done and the facilities available (Linné and Ringsrud, 1999). Usually if a laboratory does not perform a specific test they send it to a reference laboratory. As mentioned in the introduction, the clinical laboratory is divided into different sections. Example sections in a clinical laboratory (Clinical and Laboratory Standards Institute, 2016) are:

- Sample processing
- Core laboratory
- Point of care testing
- Microbiology

- Blood bank
- Flow cytometry
- Surgical pathology
- Autopsy
- Customer service

Sloane et al. (1999) provides a complete description of the laboratory personnel where the laboratory is directed by a pathologist (a physician with special training in anatomic pathology or clinical pathology). Laboratory specialists with PhDs provide technical help to the sections. The bulk of the work is carried out by medical technologists with additional help of medical assistants who perform routine procedures under the direct supervision of a medical technologist or physician. Other laboratory staff include phlebotomists, secretaries and clerical personnel. It is important to mention that the availability of qualified staff is decreasing (Battisto, 2004; Yerian et al., 2012)

As noted in the Introduction, the performance of the clinical laboratory is determined by the precision and accuracy of the test results, turnaround time and laboratory costs (Astion and Chandler, 2018). While the four factors are explained partially by the technology used and the quality of the laboratory personnel, turnaround time and laboratory costs are also impacted considerably by the physical configuration of the clinical laboratory. One of the primary performance metrics is the number of defects. The information provided in Table 3.1, different error rates for the clinical laboratory and the process necessary to achieve them --adapted from Laboratory Errors and Patient Safety (2007) and Astion (2018)--, is useful to understand how the clinical laboratory design can impact error rates, especially when advanced design and automation is incorporated. The information provided in the t In addition to traditional factors that contribute to clinical laboratory errors –such as training and technology, there are a number of other neglected factors that contribute to errors. These include suboptimal work culture, overuse of self-assessment, disconnection from patients, misaligned financial incentives, fatigue, shallow analysis of errors and an inadequate physical space (Astion, 2018).

Table 3.1: Clinical laboratory defect rates

Definition	Defect Rate	Characteristics of Process	Example in the Laboratory
10^{-1}	1 or 2 failures per 10	Clear process, reliance on education and vigilance to achieve goal	Failure to wash hands
10^{-2}	<5 failures per 100	Add basic human factors principles	Failure to give test result to patients
10^{-3}	<5 failures per 1000	Add systems for error identification and mitigation	Mislabeled specimen
$10^{-4}, 10^{-5}$	<5 failures per 10000	Add advanced design and automation	Specimen loss

There are two basic structural designs: modular and open (Snyder & Wilkinson, 1998). In the modular laboratory design the emphasis is on departmentalization, with a separate room for each laboratory division. On the other hand, in an open laboratory floor plan the departments interface freely without dividing walls. Although it depends on the context of the clinical laboratory and the functions to be allocated, the open design is usually preferred because it enhances cooperation and coordination. With an understanding of the clinical laboratory, the PDL methodology is presented in the next subsection.

3.2 PDL METHODOLOGY DESCRIPTION

The methodology for the preliminary design of a system of integrated clinical laboratories proposed (PDL) includes the definition of requirements and the outline of different solutions. In this type of project there is space to explore ideas and generate new concepts. The end result will be the preliminary designs and all the information generated (referred to as a design package). When the design project ends, a good preliminary design is defined as the one that satisfies all the questions and requirements from the client. In this case, if the evaluation criteria are chosen appropriately, there should be a direct relation between the needs and the final result.

To understand the details of the methodology recommended, it is crucial to appreciate the different stages and the information required in each. The PDL methodology has three stages:

- Stage 1 Formulate the concept: This is where the project starts and where data and information are collected to generate the concept of the new laboratory. These inputs are

transformed into requirements and processed information that will be used in the next stages.

- Stage 2 Develop design alternatives: With the inputs from Stage 1, different preliminary designs are developed.
- Stage 3 Evaluate alternatives: The different preliminary designs are evaluated according to the method and criteria chosen in Stage 1.

The different stages are not strictly sequential, since there are continuous feedback loops between them. The first feedback loop between Stage 2 and Stage 1 reflects the possibility of requiring more information, while developing the design alternatives, or it can reflect the generation of new information that should be included in the concept formulated. Similarly, the other feedback loop (between Stage 3 and Stage 1) reflects the possibility of not being satisfied with the alternatives generated, or because new information has been generated. Both options require an adjustment to the concept formulated.

The PDL methodology is hierarchical, since it considers the system level (clinical laboratory) and the subsystem level (sections of the clinical laboratory). Figure 3.1 shows a Structured Analysis Design Technique (SADT) diagram (Marca, 1988) of the PDL methodology. It is important to notice that documentation is an important part of this kind of project where at the end, the result is not only the different preliminary designs, but includes all the information generated (the design package) that can serve the evaluation process and the next step in the overall construction project (the schematic design). In each stage there is an opportunity to enhance communication between the different sections of the clinical laboratory. For that reason, it is crucial to choose where an individual section should be considered in isolation and when it is preferred to bring the sections together to achieve a better result.

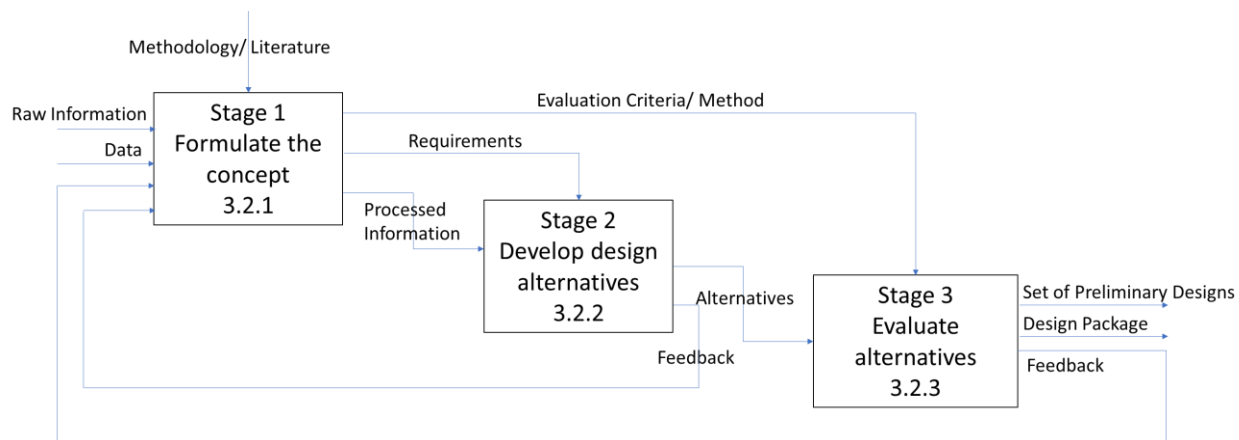


Figure 3.1: SADT diagram of the PDL methodology

There are some specific tasks that should be addressed before applying the PDL methodology: set the project milestones; build the design team¹; define their work schedule; and review the literature available. This last task assures that there are additional resources in hand as support. The following subsections describe each stage of the PDL methodology.

3.2.1 *Stage 1 Formulate the concept*

At this stage, several questions need to be answered. The questions are the same for any clinical laboratory; the difference lies in the process to obtain the answers. That is why the description is focused on the content. However, at the end of this stage description, there is a discussion of examples on how to develop that content. In Figure 3.2 the different questions of Stage 1 are presented. A crucial point to understand is that there is no value in starting a design in this early stage, since the requirements probably have not been carefully defined considering and exploring all of the options available. Baer (1990) goes even further stating that placing a design on paper affects the thinking process negatively. In the next subsections each question is described in detail.

¹ Descriptions about building a team can be found in Clinical and Laboratory Standards Institute (2016) and Hayward (2016).

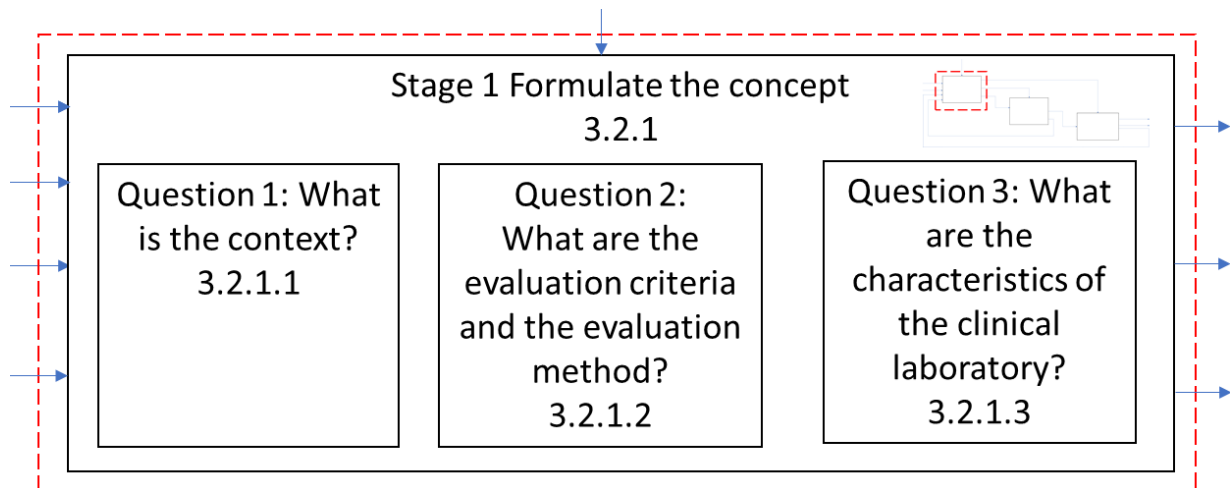


Figure 3.2: Stage 1 questions

3.2.1.1 Question 1: What is the context?

The context is probably the first aspect of the clinical laboratory that needs to be studied in order to gain insight that can influence every decision that will be made in the application of the PDL methodology. A proper understanding of the context makes the difference between a successful project and a failure. The context, as shown in Figure 3.3, can be divided into five categories: the organization, the construction project, the stakeholders, benchmark of other laboratories and design principles.

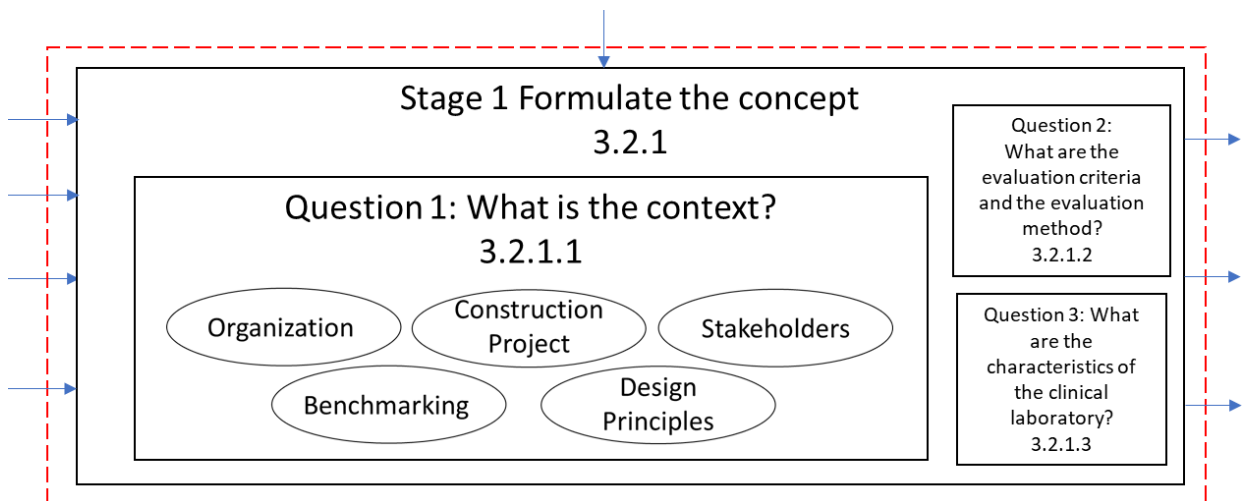


Figure 3.3: Question 1

An understanding of the *organization* is crucial, and an organizational chart can help as a first step. Additionally, the organization's history serves to understand their past and the strategic plan;

including their mission or vision statement serves to understand the present. Baer (1984) states that it is necessary to consider the long-term plans of the organization that the laboratory will serve and the way in which it will grow and change. In terms of designing the laboratory, any information about previous design or construction projects can also help to understand their current situation.

About the actual *construction project*, it is important to document the information available making the distinction on what has been decided and what has not. This includes the budget (financial restraints), the milestones and the sections of the laboratory that will be included in the new design.

Another important part of the context is to understand who the *stakeholders* are in the project. It is recommended to do it with a system perspective separating them in different layers or levels. A context diagram or a stakeholder map can serve the purpose of presenting the information graphically (Bonnema et al., 2016; Sillito, 2014). Although the system of interest, the clinical laboratory, is not part of the external context, it is a good idea to include the different sections in these diagrams.

Since there are many clinical laboratories around the world, a good complementary approach is to *benchmark other laboratories*. Good ideas can come from the different types of laboratories, thus the sample should have enough variability among the clinical laboratories consulted. It is important to define a specific set of questions and it is recommended to include the design of the laboratory as a specific topic to be consulted.

The last aspect of the context is to clearly define *design principles* that will guide the design process of the clinical laboratory. They dictate what is the ultimate goal for the clinical laboratory and should be defined in conjunction with the key stakeholders of the project. Several metrics defined for the clinical laboratory can serve as inspiration (the metrics are included when answering Question 3). Although they are specific to every clinical laboratory context, examples like flexibility and efficiency are likely to be included. After this description of Question 1, the following section presents Question 2: What are the evaluation criteria and the evaluation method?

3.2.1.2 Question 2: What are the evaluation criteria and the evaluation method?

The evaluation criteria and the evaluation method will be used to decide when a preliminary design or a set of preliminary designs are adequate, thus concluding the project. It is important to decide this before developing the alternatives; that way the developing and evaluating are

separated, and the evaluation method and evaluation criteria are not chosen to favor one specific design alternative. Figure 3.4 shows Question 2 as an integral part of Stage 1 Formulate the concept.

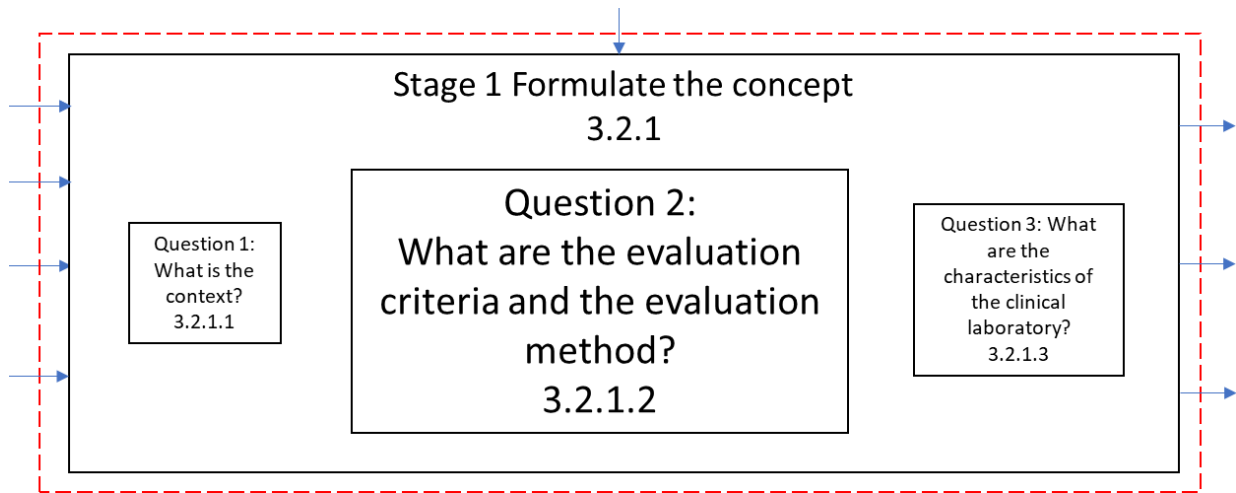


Figure 3.4: Question 2

As for the evaluation criteria, the design principles can be defined as a specific factor or serve as a guide to define concrete factors that serve the purpose of comparing different designs. The same way that the design principles are specific to each clinical laboratory, the evaluation criteria are also specific. However, it can be argued that there are some factors that should be applied to every clinical laboratory (the same situation that is described for design principles). Examples of the criteria chosen for Seattle Children’s Hospital are shown in Chapter 4. In Coletta (2012) examples in a lean 3P context can be found. It is unlikely that only one criterion will serve the purpose to evaluate the design of a complex entity like the clinical laboratory. Many times, they are defined in conjunction with the evaluation method, which can dictate what can be included and what cannot. It is important that each criterion is defined appropriately to avoid misunderstandings and that the criteria can be evaluated independently.

There are several useful evaluation methods. The recommended option for the clinical laboratory is to use a method (or methods) that incorporate quantitative and qualitative criteria. A multi criteria decision making method can serve this purpose (see AHP and CBA in Section 2.5.1). Another method is to use relationship charts, as shown in SLP, to evaluate the critical adjacencies (see Section 2.1). For a MCDM or an adjacency relationship chart, it is useful to perform a sensitivity analysis to see how the results change if the basic scenario changes. An economic

comparison of the scenarios resulting from the different designs (Tompkins, 2010) can help the decision process if specific data are available. More complex methods can be based in quantitative metrics as a result of discrete event simulation. Other examples are based in group decision making methods: list pros and cons and verification of the stakeholders concerns and requirements (Sillitto, 2014).

If necessary, mock/ups can be constructed (Guzzo Vickery, 2015) to realize a physical simulation of different scenarios and make changes (rapid prototyping), although this is generally more productive in the subsequent phases for processes where there is not much variance. The decision of using physical simulation can be postponed to Stage 3 where there is more clarity about wheter is really needed. After this description of Question 2, the following section presents Question 3: What are the characteristics of the clinical laboratory?

3.2.1.3 Question 3: What are the characteristics of the clinical laboratory?

The recommended approach to answer this question is to create descriptions in two levels: the overall clinical laboratory and the sections of the clinical laboratory. It is recommended to think explicitly about the future since probably the new clinical laboratory will be open much later than when it was designed and will operate for many years. The first level describes the information about the clinical laboratory without entering in the details of each section. It is information for the overall design and the relationships between the sections. The next level follows the same logic but is collected for each section of the lab and adds particular information and models, appropriate for this level of decomposition. As a guide, five categories can be developed in each description: general information, requirements, concerns, ideas and physical arrangement. Additionally, it is recommended to create a separate description summarizing the input from the lab users and other stakeholders. The reason for this explicit inclusion, as a separate description, is because this perspective can be very different from the laboratory staff and will give the proper importance and traceability to their input and needs. Figure 3.5 shows the content of Question 3.

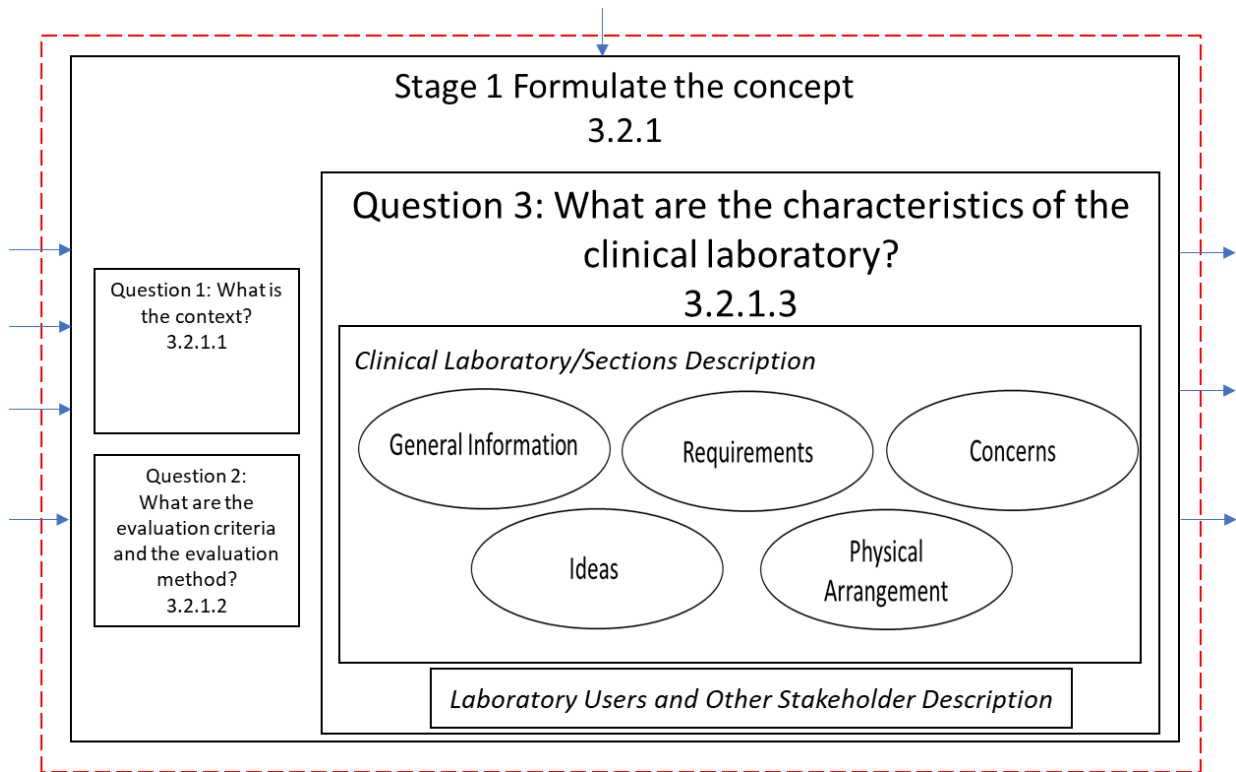


Figure 3.5: Question 3

For all of these descriptions, complementary information can be found in DiBerardinis (2013), Clinical and Laboratory Standards Institute (2016), College of American Pathologists (1977) and Tompkins (2010). The description for the clinical laboratory is explained in the following paragraphs. After that, an explanation is included for the laboratory users and other stakeholders.

Clinical Laboratory/Sections Descriptions

The recommended approach when starting the clinical laboratory description is that there should not be any assumptions about what is performed and who is executing the different tasks. The processes should be defined first and then the physical space (form follows function). For example, there is space to re-analyze where the tests are performed. Also, since this is the preliminary design phase that eventually will serve to inform the schematic design and detailed design developed by architects and engineers, it is useful to identify areas that are not relevant for the preliminary design (e.g., mechanical and electrical detailed design) but that should be captured. For example, each new generation of laboratory equipment requires more power, data connection, deionized water,

vacuum, drains and HVAC (Chandler, 2018) and probably that will be expressed by the laboratory staff. Each piece of information should be captured and classified as part of the design package.

For the clinical laboratory description, the *general information* category should include the list of sections, the work that they perform, their overall strategy, the reference business, the hours of operation and the number of employees. Any other information that is considered useful should be included in this category, since it is conceived to provide the appropriate background needed to understand the other pieces of information. The sections can be coupled together in blocks to reduce the number for practical purposes. Additionally, the space estimates should be included. At first this would be a difficult task, but, as more information is gathered, and more analysis is made, the numbers should start to be defined. Baer (1984) explains that probably any forecast will be inaccurate, thus it is necessary to balance overbuilding with the costs of expansion at a later date.

How much space a clinical laboratory requires depends upon a number of factors including: the number of tests performed; the nature of those tests; the required turnaround time; and the setting (McCutchen, 1985). Thus, the final space estimates will be developed after the section descriptions are complete and maybe even after the first designs are constructed.

For each section of the laboratory, there is a large amount of additional information that should be included. For example: equipment lists, workload numbers, staffing and employees (Clinical and Laboratory Standards Institute, 2016). Additionally, it is important to know the driver for the space needs (generally is test volume or test menu) and the future growth estimation. These can be very different between sections and depend on a number of external factors. The best approach is to provide a space estimate as accurate as possible and then try to fit everything in the space when developing the designs.

If necessary, the general information can be divided to reflect the different characteristics of day, evening and midnight shifts. Metrics and data are always useful to include as part of the general information. It is important that each piece of information that can be retrieved from the information system is destined for a specific purpose. For the first approximation, a special query that can retrieve the test ordered, the different processing time-stamps, equipment used, the section of the lab in charge and the origin of the test (i.e., ambulatory clinic, OR) could serve to provide objective numbers to the current activity of the laboratory and each section. These could be used to make projections. Additionally, their goal for their turnaround time and errors could be other important metrics that can be evaluated before and after the construction of the new facility. Lastly,

value stream maps and flowcharts should be included when necessary, hopefully for each type of process. These diagrams should be analyzed for potential improvements and the potential repercussion in the physical space.

In the *requirements* category, every piece of information of needs than can be translated into an objective requirement should be included (e.g., number of break rooms, nitrogen needs). The regulation codes of the accreditation institutes (e.g., College of American Pathologists) should be revised and their requirements should be incorporated, although they usually impact more in later stages of the design process. It is important to include the monuments² and the physical separation necessary to perform the work. This is extremely important since most monuments are nearly impossible to change in the future and need to be considered strategically. The ideal situation is where specific numbers are included. For example, how many microbiology set-up stations should be included or how much CO₂ tanks does a particular section use in a week? If there is no answer based on objective information, an additional task to estimate that need is appropriate. The end result could be different options or range of numbers to be explored in Stage 2.

In this process of estimation, a mathematical analysis can help determine the requirements for a particular lab. A queueing model can serve the purpose of helping to answer the question of how many benches, stations or monuments a section needs. A simple M/M/s model could provide the necessary information and guidance. The importance is to strategically calculate the average service and arrival rates, since the clinical laboratory workload is not constant (the day can be divided in several timeframes) and the current scenario could change drastically as demand grows or procedures change. If the assumptions of the queueing model do not serve the purpose, a discrete event simulation model could be developed to better reflect the operations and constraints of the clinical laboratory. In terms of the level of abstraction that the requirements should have, the recommended approach is to keep them as abstract as possible. That way the focus is not on a specific solution but on the actual need of the clinical laboratory.

The *concerns* category is to reflect the information that cannot be translated into an objective requirement (at least for the moment). It can serve to show the preoccupations of the people from the laboratory and their existing or possible future problems. This is needed because there are many of situations where there is no specific requirement in plain sight and a concern is the best

² Monuments refers to components that are not easily moved or installed (e.g., fume hoods, biosafety cabinets, rooms with fixed walls).

way to reflect a problem until the translation is found, in the form of a requirement. If that is not possible, they should be considered directly while developing the design alternatives.

In the *idea* category, the different thoughts or models that could serve to develop alternatives should be registered. This is the time for innovation where bold or radical concepts can be explored (e.g., having the processing area at the middle of the lab, implementing a new handling system or decide that a number of satellite laboratories will be constructed). Some of the ideas gathered will require some research that should be included in the descriptions (e.g., feasibility, suppliers). After gathering concerns and ideas, it is recommended to identify which one are strictly operational where they could be addressed immediately as continuous process improvement.

Lastly, the *physical arrangement* category is developing models to serve as a guide for the construction of alternatives. An adjacency relationship chart (Muther, 1973) is a good way to present the information captured. An example is shown in the next chapter (Figure 4.8). It can serve to evaluate the critical adjacencies of the design alternatives. Some sections can be combined if there is certainty that they should stay together. It is important to capture the definition of adjacency and why the adjacencies are important, and if is possible, quantify with numbers. For the sections, the difficulty lies in what to include. Since each section is different, the recommended approach is to personalize the model for each section and to include the most important components. Monuments, important benches or work areas, tube stations and large instruments are always good candidates. The adjacency relationship charts can serve as input to an optimization model that gives the relative position of the sections or components with an optimum adjacency score. This is based on different locations that should be defined beforehand as shown in Figure 3.6 where a hypothetical grid of sixteen locations is defined. In Stage 2, this optimum can be compared to the alternatives developed or used directly as an alternative, if it is possible.

A definition of an optimization model is presented. Let $N = \{1, 2, \dots, n\}$ be the sections of the laboratory and $M = \{1, 2, \dots, m\}$ be the set of available locations in the future lab space. Parameter $w_{i,j}$ represents the adjacency importance between sections i and j and parameter $a_{k,l}$ represents the adjacency of locations k and l . If N is large, a recommended approach is to combine sections.

The decision variables that are used to formulate this problem are:

$$u_{i,k} = \begin{cases} 1 & \text{if section } i \text{ is located at location } k, \\ 0 & \text{otherwise,} \end{cases}$$

where $i \in N, k \in M$. The objective is to design a new laboratory that maximizes total adjacency

score.

$$\max z = \sum_{i,j \in N} \sum_{k,l \in M} w_{i,j} * a_{k,l} * u_{i,k} * u_{j,l} \quad (1)$$

subject to:

$$\sum_{k \in M} u_{i,k} = 1 \quad \forall i \in N \quad (2)$$

$$\sum_{i \in N} u_{i,k} \leq 1 \quad \forall k \in M \quad (3)$$

$$u_{i,k} \in \{0, 1\} \quad \forall i \in N, \forall k \in M \quad (4)$$

Constraint (2) ensures that each section is assigned to a location while constraint (3) ensures that no more than one section is assigned to a specific location.

Location 1	Location 2	Location 3	Location 4
Location 5	Location 6	Location 7	Location 8
Location 9	Location 10	Location 11	Location 12
Location 13	Location 14	Location 15	Location 16

Figure 3.6: Hypothetical grid of sixteen locations

The descriptions mentioned were focused in the clinical laboratory. They can include inputs from people outside the clinical laboratory, but it is usually the case that most of the inputs are from staff from the lab. That is why it is recommended to keep a separate description for external lab users and stakeholders to give them the appropriate importance and to keep the focus on the patient (the ultimate goal for a healthcare system). In the following paragraph, this type of description is explained.

External lab users and stakeholders

The description of the external lab users and stakeholders does not have to be in a specific format, but it is crucial that those stakeholders are engaged and that the laboratory design teams understand what the others expect from the laboratory. The stakeholder map created beforehand can serve as a guide to know who should be contacted. If the laboratory is embedded in a larger organization, the obvious candidates are the physicians and nurses from other areas. Additionally, although the laboratory does not have much contact with patients, they should be the primary concern. This information can serve not only to design the laboratory of the present but to gain insights in the future.

One key aspect is to be sure that the descriptions are shared with every person in the laboratory and that the key stakeholders give their approval. Their logic has to be standard; if a piece of information is relevant for more than one section, it should go to the general clinical laboratory description. Otherwise it should go in the particular description of a section. Once the description templates are ready, all the blanks have to be filled. To answer the three questions presented, the next section contains examples of different activities that can serve the purpose of developing the content required to advance to Stage 2.

3.2.1.4 Methods to answer the questions

There are several ways to formulate the concept, but it is recommended to be involved with the people that perform the work; with the faculty, the leaders, the administration and every stakeholder of the project. There should be several instances to have conceptual discussions and if necessary, educational activities should be scheduled to train the staff in specific topics. It is almost impossible to get everything necessary all at once, thus the formulation of the concept will be likely developed step by step. Additionally, it is always wise to talk to domain experts and people with laboratory design experience. Here is a list of activities that can serve the purpose of formulating the concept:

- Regular meetings and form cross disciplinary teams
- Collect internal documents (e.g.: organizational chart, standard work sheets, current facility blueprints)
- Tour of the facility
- Job shadowing

- Structured interviews
- Ask to fill structured documents
- Explore the laboratory technological development
- Educational workshops (e.g., relationship chart of the critical adjacencies)
- Workshops to generate ideas and new concepts
- Ask for useful data from the information system
- Establish a proper channel for comments and ideas

After these methods (and others) are used to answer the three questions, Stage 2 can be initiated. In Figure 3.6 the SADT diagram of the methodology is presented, highlighting the next stage that will be explained in detail in the following sections.

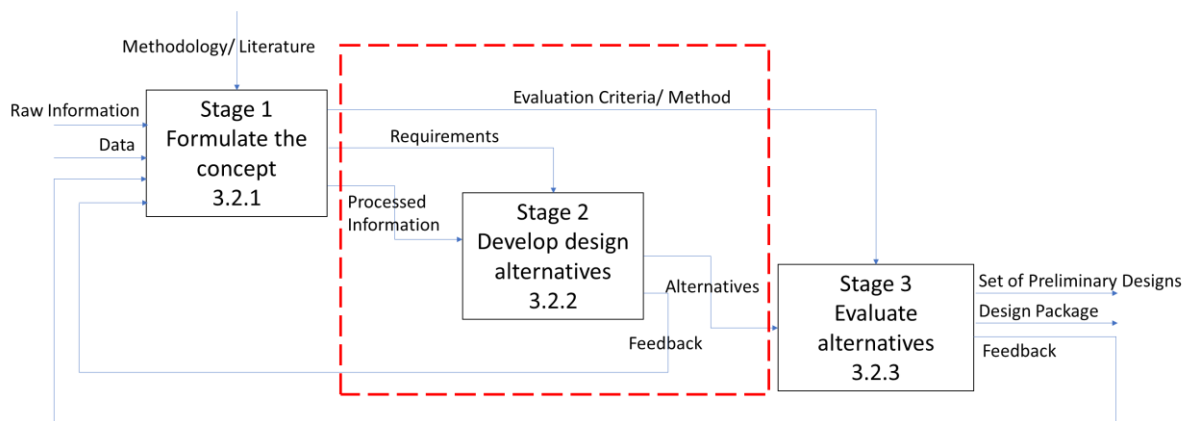


Figure 3.6: SADT diagram of the PDL methodology highlighting Stage 2

3.2.2 *Stage 2 Develop design alternatives*

There are three basic steps to develop the preliminary design alternatives. The first step is to explore the critical adjacencies and different configurations for the clinical laboratory. Then, the second step is to execute a similar but more rigorous process at the section level. Finally, the third step is where the information and diagrams of the two previous steps (clinical laboratory level and sections level) are used to fit the pieces and develop different design alternatives. It is recommended to leave time between steps, so people have the time to further consider their ideas and concepts. The three steps of Stage 2 are shown in Figure 3.7.

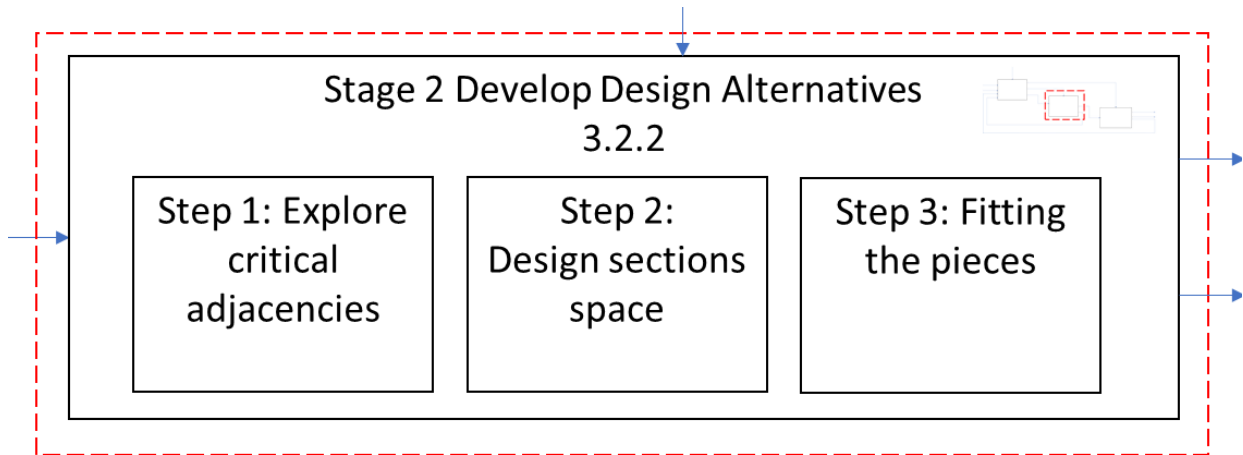


Figure 3.7: Stage 2 steps

In each step, a set-based design approach is taken, since in each step different alternatives are considered concurrently. And in each step it is fundamental to consider the 7 flows of the laboratory, adapted from the Virginia Mason’s 7 flows of medicine (Kenney, 2011). Those are: specimens, laboratory staff, equipment, supplies, information, visitors and waste. For blood bank, plasma and blood products can be added. A practical approach is to include the flows that are more important for each section (usually staff and specimens) and to quantify the relative rate of each flow. Additionally, the entire patient value stream should be analyzed thinking of how to improve the patient experience through operational improvements that can impact the performance of the clinical laboratory.

Since the clinical laboratory is a complex organization and the design process should consider the processes first, the best result is achieved by including the staff who work at the laboratory and know the details of their operation in a participative design setting. That can be done having several workshops for each step of the design process. For example, one workshop might be held for exploration of the critical adjacencies; several workshops or meetings might be necessary to explore each section design; and finally, a workshop to fit the pieces in different configurations that will show the relative layout of each section of the laboratory and the location of critical components (e.g., monuments, rooms). The level of independence of the staff working in these workshops will depend on their availability and their capabilities for thinking in design and processes, and future needs. For each workshop, it is useful to think of the seven ways, adapted from Lean 3P (Coletta, 2012), since it provides a creative setting to explore better ways of delivering the service. It can be difficult to start a design task, but since there are multiple intents,

perfection is not a goal at the beginning, which makes the start easier. A useful activity is to analyze who should participate in each workshop and to include useful information in a friendly format. This is where the work performed in the first stage is used (except the evaluation method that will be used in Stage 3). From this, several scenarios and themes arise (e.g., What if the tube system fails? What if we had centralized post-analytical storage? What if the labs are split across two floors?) that can guide the participants attending the workshop, particularly for topics that have not been decided yet and that, after discussion, it still remains uncertain as to which is the best choice. Lastly, it is recommended to think beforehand what the workshop will accomplish, which questions will be answered and to explore the need for additional workshops. It is in this thinking process where several feedback loops to the first stage may be necessary to re-formulate some concepts or to add additional information (as shown in the thicker feedback flow of Figure 3.8). This serves the purpose of capturing information in a consistent manner (following the structure of Stage 1).

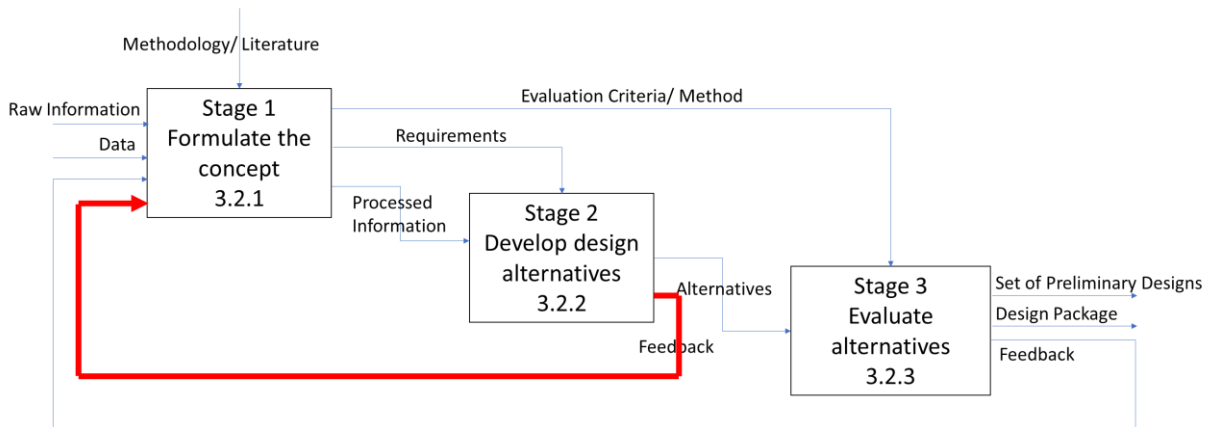


Figure 3.8: Feedback loop from Stage 2 to Stage 1

In Stage 2, the literature research and, contact with domain experts and experienced people can provide valuable information as guidelines for the clinical laboratory preliminary design. The research should not be focused only in the clinical laboratory; other contexts can provide useful advice that can be adapted if necessary. Here is a list of examples of useful guidelines for the clinical laboratory:

Design process

- Once space for the principal activities is allocated, space for support areas and core functions must be allocated (Rondeau et al., 2006).
- Encouragement to generate more alternatives before narrowing down the design options (Rybkowski et al., 2017).
- Discussions of an efficient facility design must include planning for sustainable design and lean operations (Roberson et. Al, 2013)
- There is no standard method or solution to the problems of design. For a particular facility, the number is as varied as the number of laboratories that exists (Koenig III, 1983).

Monuments/Furniture

- A break room area adjacent to the laboratory permits the staff to take necessary breaks while still being available at short notice (Baer, 1990).
- Flexibility can be enhanced by having an open laboratory, rather than small rooms (College of American Pathologists, 1985; Baer, 1984).
- Laboratory benches can be easily removed by using modular-designed laboratory furniture (Baer, 1984).
- Utilize open lab standard flexible benchwork as much possible allowing future changes with only laboratory staff. 60% of total space as standard flexible benchwork is a decent goal (Chandler, 2018).
- Build separate rooms only when specifically required (Chandler, 2018).
- Maximize the percentage of laboratory area that is flexible benchwork to allow for rapid prototyping of new work areas, for constant PDCA (Plan-Do-Check-Act) process improvement and for temporary use (Chandler, 2018).
- For areas in which flexible benchwork is not appropriate, electrical and data connections can come from the ceiling and other type of furniture can be installed in different configurations. For example, it could be useful for the central sample processing area (Chandler, 2018).
- An open lab reduces barriers to communication and, supervises and facilitate flexibility in the assignment of staff and the ability to share equipment/instrumentation (Nicolau and Borgsdorf, 2007).

- Modular casework, adjustable height-tables and movable furniture with casters are recommended so workstations can be removed or reconfigured when technological processes change (Battisto and Frederick, 2005).

Operations

- Extended evening hours can serve to level the workload (Baer, 1995).
- It is frequently more economical to provide a small deionizing water system at the point of use (Baer, 1984).
- The design should restrict access into the laboratory by visitors (College of American Pathologists, 1985).
- If possible, long distances to be covered by the night shift personnel should be avoided. One way to achieve that is to concentrate night shift functions (College of American Pathologists, 1985).
- Smaller satellite laboratories can be useful if transportation to the main lab is not sufficiently rapid and if short turnaround time is a significant patient need. However, satellite labs are associated with significantly higher costs per test than large core laboratories and also have problems associated with bottlenecks since they tend to have a small number of staff who cannot process more than one or two specimens concurrently (Astion, 2018).
- Locate the laboratory in only one place to decrease turnaround time, decrease the chances of error and decrease the chances for lost specimens (Chandler, 2018).
- Minimize sample transit times for time critical high volume area. Examples can be point to point pneumatic tube systems and dumb waiters for anatomic pathology samples from OR (Chandler, 2018).
- Adequate refrigerators at individual workstations eliminates the need for staff to walk back and forth to a bank of centralized refrigerators to obtain necessary supplies (Nicolaou and Borgsdorf, 2007).
- The implementation of the Lean-management approach will greatly impact the laboratory design through the elimination of waste combined with optimizing workflow, relationships, and adjacencies having a profound impact on operational competency (Garikes, 2006).

Although the basic concepts for each step of Stage 2 were already mentioned, these ideas can be expanded. In the following paragraphs each step will be described in more detail. The application should be adapted to each specific context, since the execution can depend on how much is decided about the construction project (these decisions will serve as constraints for each step). If architects are already hired, it is recommended to include them in the process, so they can provide their expert opinion.

Step 1: Explore critical adjacencies

This first step should consider each section of the lab and any additional component that is considered important. Basically, it should be focused on creating bubble diagrams of different ways the laboratory can operate. The relative size of the components should be included if possible. An initial discussion is recommended to describe the goals of this step and to clarify doubts. For a participatory design setting, Post-Its or pre-defined cardboard bubbles are a good way to encourage interaction and create the different alternatives (examples presented in Chapter 4).

For the actual construction of the bubble diagrams, it is recommended to think about the inputs and outputs of each section (7 flows of the laboratory) and, since most of the concepts are conceptual, assumptions could be made. The recommended approach is to capture all relevant pieces of information. Ideas and concerns from Stage 1 can be used as themes or scenarios to develop different diagrams. Although this is only the first step, a preliminary evaluation of the bubble diagrams could be included to generate information about the different alternatives created and to discard those alternatives that do not meet the selection criteria. Pros, cons and a ranking should suffice. Once the high-level alternatives are generated, Step 2 is executed.

Step 2: Design sections space

The second step is to design each section space to reduce the uncertainty of their individual work areas. It can start with bubble diagrams if there is clarity on which areas should be included as bubbles (the relationship chart of Stage 1 could be a starting point). After that, smaller scaled pieces for each individual item (e.g., benches, monuments, fridges) should be taken into account to generate different scaled designs of each section. Information about the scaled pieces is an output of the requirements of Stage 1. For a participatory design setting, the recommended approach is to have scaled cardboard pieces that can be moved and arranged to create the design

alternatives. When placement of the scaled elements is complete an outline can be drawn around each as well as capturing the locations of important doors and walls. With the proper ruler or drawing placed over scaled paper, the space projections can be compared to the different alternatives generated.

As with Step 1, the flows of the laboratory and the ideas and concerns of Stage 1 should be considered. Also, as in Step 1, a preliminary evaluation can add information. Probably in this step, there will be more assumptions that will need to be captured. This exploration is more detailed and more complex than Step 1, not only for the use of accurate measurements but since there are more things to consider in each section. The last activity of this step is to check the drawings and to group items into associated sets of components that will be used in Step 3. If bubble diagrams were generated, they can also be taken into account to generate the components that will be used as a unit of construction. The recommendation is to have open spaces for sections and the different rooms as components. They should be divided into smaller components only where specific reasons exist. This would serve as a preliminary space program that can even include the amount of linear bench needed.

Step 3: Fitting the pieces

In this step, the bubble diagrams from Step 1 and the components resulting from Step 2 are required. Other common components, not specific to laboratories, should be added to the design effort (e.g., restrooms, supply storage). It also is recommended to start with an initial discussion. Then, the bubble diagrams serve as a base to start placing the scaled components derived from Step 2 and to develop several fully functional clinical laboratory drawings (a preliminary design). Since many of these components do not have pre-defined shapes (only a footprint size), having cardboard pieces in conjunction with scaled paper, which can be cut to form components, is a recommended approach for a participatory design setting.

Depending on the detail wanted for the preliminary design, the smaller scaled pieces used in Step 2 can also be placed to add more detail to the designs and to understand the contact points between sections. This is always recommended since the micro arrangement could affect the macro design and it is better to realize that early in these preliminary designs rather than later during the overall design. Additionally, a grid of standard benches can be provided to visualize the overall space and standardize the allocation of clinical laboratory space.

This step, unless there is re-work, is the last step that can make a difference in the preliminary designs. Thus, it is even more important to include all the information generated from Stage 1. For example, this is the time to test big ideas like different handling systems or to solve specific concerns that have not been addressed. Additionally, if there is information about the construction aspects of the project, that information should act as constraint for this design step. For example, if there is a limit to the amount of space, or if a floorplate design has been completed, that information should be incorporated in the basis for the alternatives generated. Once several preliminary designs are generated, it is time to begin Stage 3, highlighted in the SADT diagram of Figure 3.9 and described in the next section of the thesis.

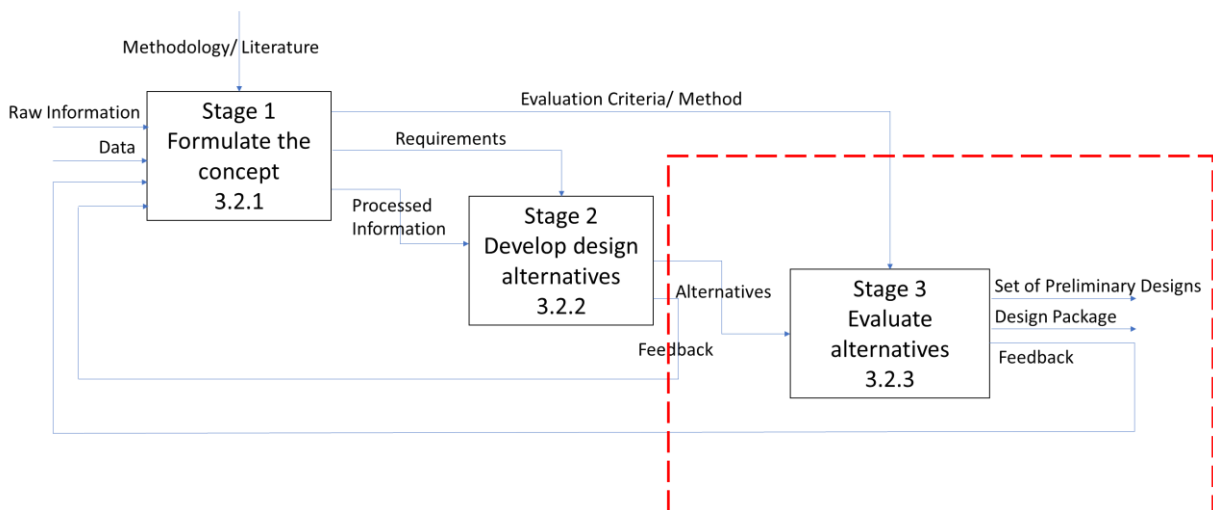


Figure 3.9: SADT diagram of the PDL methodology highlighting Stage 3

3.2.3 *Stage 3 Evaluate alternatives*

This stage is more straightforward than the first two, since it is the application of the evaluation methods already selected in Stage 1 and deciding whether, at this point, the project can be concluded or needs to re-visit one or more of the previous design stages. However, that does not make this stage less important than the other two. Adjustments of the evaluation method or criteria are still possible since it is likely that more information was collected in the previous activities; the overall form of the criteria and method should stay the same. The two steps of Stage 3 are shown in Figure 3.10.

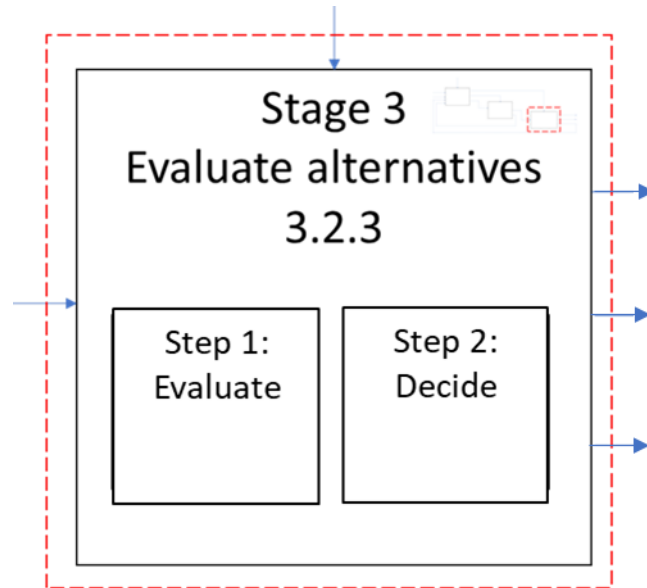


Figure 3.10: Stage 3 steps

Step 1 Evaluate

In stage 3 the several design alternatives created in stage 2 are evaluated by the method and criteria previously defined in the first stage. The objective is to generate and provide information that can show why an alternative is considered better than others, to understand the possible trade-offs and to determine if the project could be finished or re-work is necessary. The techniques used depend on the complexity of the designs and how far the overall construction project has progressed. It is extremely important to capture the evaluation process and results, since they are the justification of the design decisions that will be made.

Step 2: Decide

If the result of this evaluation is considered unsatisfactory, the next step is to go back to the first stage to perform additional work as shown in the thicker line of Figure 3.11. The information generated is processed in Stage 1 to re-formulate the concept and then used to generate newer alternatives that will also be evaluated. This process is repeated until the evaluation is considered satisfactory and the project has reached the end.

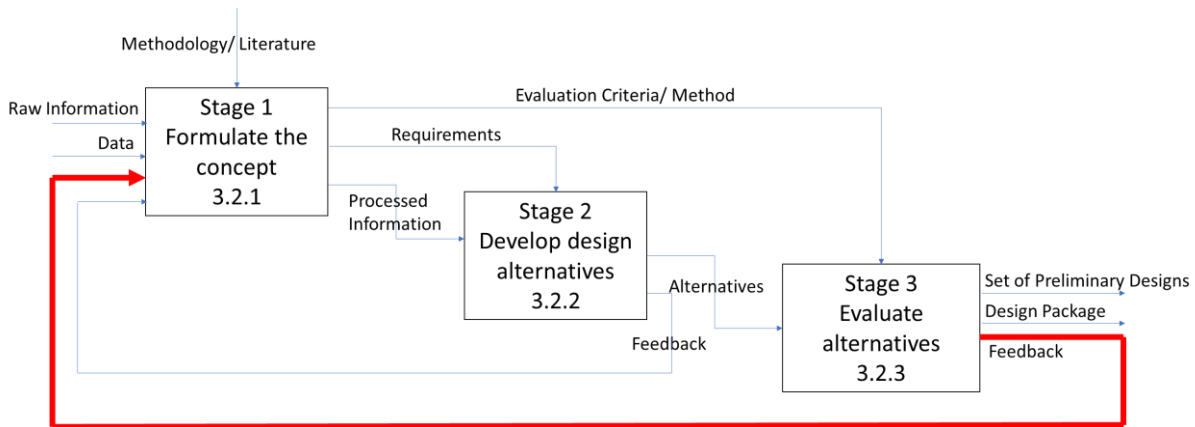


Figure 3.11: Feedback loop from Stage 3 to Stage 1

3.3 PDL METHODOLOGY DISCUSSION

The PDL methodology has stages defined and questions and steps identified for each stage. That provides the overall structure to execute this kind of project. The application of each stage provides flexibility to adapt to the contexts of each clinical laboratory. There is an important acknowledgement that each organization is unique and what works in one setting, does not have to work in another. Additionally, the feedback loop between Stages 1 and 2, provides the opportunity to revisit stages to improve, revise and add new information throughout the project. The feedback loop between Stages 3 and 1 is concerned with the decisions about selecting from among the alternatives developed, when there is not sufficient confidence in the final results. That reflects the criticality of the evaluation method and criteria.

The results of the methodology are not exclusive to the different preliminary designs but also provides value by delivering a design package containing useful information that reflects the thinking process of people involved. A summary of the design package content, which can be adapted to the specific context of the different clinical laboratories, is shown in Table 3.2. The PDL methodology may not provide definitive answers but it will motivate the owner or client to think hard about their needs and to *explore the alternatives* for the best clinical laboratory that could possibly be constructed. It is in this thinking process where breakthrough alternatives can be generated, providing the support to execute a participative and set-based design process. Usually more iterations encourage innovation (Coletta, 2012), thus providing a better result that the different designs will reflect.

Table 3.2: Design Package content

Item	Descriptions	Includes	Stage	Question/Step
Project Definition	Document summarizing the definitions for the PDL methodology application	-	-	-
Literature and experts	Journal articles, publications and expert's meeting minutes for the design of the new clinical laboratory	-	-	-
Organization	Documents and publications regarding the organization	History, other construction projects, organization charts, campus map, blueprints, clinical laboratory diagram, vision statement	1	1
Construction Project	Documents and publications regarding the construction project	Description, diagrams, team definition, schedule	1	1
Stakeholders	Document summarizing the stakeholders involved in the project	Map, definitions	1	1
Benchmarking	Documents and pictures of each visit to other laboratories	-	1	1
Design Principles	Document summarizing the definition of the design principles	-	1	1
Evaluation Criteria/Method	Document summarizing the evaluation criteria definition and the evaluation methods chosen	-	1	2
Clinical Laboratory Description	Documents that includes the relevant information for the clinical laboratory	Data, blueprints, flow chart/value stream maps, adjacency relationship chart, adjacency optimization model	1	3
Sections Description	Documents that includes the relevant information for each section of the clinical laboratory	Data, blueprints, flow chart/value stream maps, equipment lists, adjacency relationship chart, adjacency optimization model	1	3
External lab users and stakeholders	Document summarizing inputs from external lab users and stakeholders	-	1	3
High-level bubble diagrams	Diagrams of the overall configuration of the clinical laboratory	Preliminary evaluation	2	1
Sections Space Spreadsheet	Spreadsheet showing items for each section with sizes and quantities	-	2	2
Sections Designs	Scaled diagrams of the configuration of each section of the clinical laboratory	Preliminary evaluation	2	2
Components Spreadsheet	Spreadsheet showing items for the clinical laboratory with sizes and quantities separated by section	-	2	2
Preliminary designs evaluation	Documents summarizing the results of the evaluation of the preliminary designs and the decision about the PLD methodology application	-	3	1-2

After conclusion of the PDL-supported phase of the project, several significant milestones in the overall construction project remain, so it is important to continue with the schematic design with no setbacks due to lack of communication or unaligned goals. In these later stages there is opportunity to further refine the alternatives (and to discard unfeasible ones) and to include more aspects of the clinical laboratory in the design process. If the designs are changed, that does not mean that the preliminary designs had no value; quite the opposite. It is because that process was executed that an improved final result was achieved.

Chapter 4. CASE STUDY

The PDL methodology was adapted and applied to a real project of the Department of Laboratory Medicine at Seattle Children's Hospital (SCH). SCH will open a new building in 2021 in which the clinical laboratories and other departments will be located. This case study provides useful examples of a practical nature and served as a test for the PDL methodology. Information about the hospital, the clinical laboratory and the construction project are included as part of the project's activities. In the following section a brief description of the origin of this case study is presented.

4.1 CASE STUDY ORIGIN

This case study arises from the alliance that the Industrial and Systems Engineering (ISE) Department of the University of Washington has with the Department of Laboratory Medicine of Seattle Children's Hospital. They have been working together since 2010 on projects where many undergraduates and graduate students had the possibility to work in a healthcare setting.

The clinical laboratory was interested in giving more time than was allocated by the hospital to the planning of their new facility and to be prepared when the overall project starts. That was translated into the need for starting the pre-design. The project was started in October 2017 and ended in May 2018. In the following sections the case study is described, following the same structure as Chapter 3.

4.2 CASE STUDY DESCRIPTION

Before the application of the PDL methodology, the project milestones were roughly set since the deadlines depended on the hospital's larger project. The design team was formed including ISE and SCH, with the ISE portion being the responsibility to apply the PDL methodology to the clinical laboratory. Lastly, the work schedule was defined, and the literature was reviewed as part of this thesis. In the following sections, the application is explained providing information and results when appropriate. For a reminder of the PDL methodology description, refer to Section 3.2.

4.2.1 *Stage 1 Formulate the Concept at SCH*

In the first stage, three questions are answered, as shown in Figure 3.2. They were answered concurrently with no particular order except for the portions of the context that it is recommended to answer first (a minimum understanding of the organization, the construction project, the stakeholders and the definition of the design principles). Extracts of the results and the process to determine those results are presented in the following sections.

4.2.1.1 Question 1: What is the context at SCH?

There are several divisions of the context, as shown in Figure 3.3. In this case, the starting point was to understand the organization and the key stakeholders of the project. It is clear that division boundaries are artificial, for management purposes, since everything is interrelated.

Organization

Seattle Children's Hospital was founded in 1907 as Children's Orthopedic Hospital Association. Today they deliver patient care, advance new discoveries and treatments through pediatric research and serve as the pediatric and adolescent academic medical center for Washington, Alaska, Montana and Idaho. Along with Fred Hutch and the University of Washington Medicine, they form the Seattle Cancer Care Alliance (SCCA). More than a decade ago, SCH underwent a major cultural shift by adopting Toyota Production System principles or lean management. Additionally, in the last ten years they have built several new facilities with a special focus on having an operational transformation while doing that. Here is a description of the new facilities:

- 2010: Seattle Children's opens a clinic and outpatient-surgery center in Bellevue's hospital district. The Bellevue Clinic and Surgery Center covers 79,000 square feet and features 32 exam rooms, two operating rooms and an MRI imaging room. The case study is presented in Wellman (2017).
- 2013: Building Hope (officially "Forest A") opens, adding 330,000 square feet of new space to the hospital's main campus including a larger emergency department with a new process that allows patients to be seen by a triage nurse right away.
- 2017: Building Cure construction starts. Building Cure is a new research building that will be dedicated to developing cell-based therapies for childhood diseases such as diabetes,

cancer and sickle cell anemia. It is located in downtown Seattle and will expand Seattle Children’s Research Institute to over 1,000,000 square feet.

The clinical laboratory has 220 employees. They are looking forward to moving, since their current installation is outdated and there is no space for growth (they continually grow as does the hospital). A map of Seattle Children’s Hospital current campus is given in Figure 4.1. The clinical laboratory is currently in the Ocean building in a portion of the 8th floor and the 10th floor. The different sections and the way the people in the laboratory tend to group the different functions is shown in the different concentric circles of Figure 4.2, courtesy of Angela Vetch, Manager of Pre-analytical Clinical Laboratory Operations. For the clinical laboratory at SCH, the specimen volume is always an issue since they deal strictly with pediatric specimens. This has several implications (e.g., automation is not always possible).



Figure 4.1: Seattle Children’s Hospital main campus

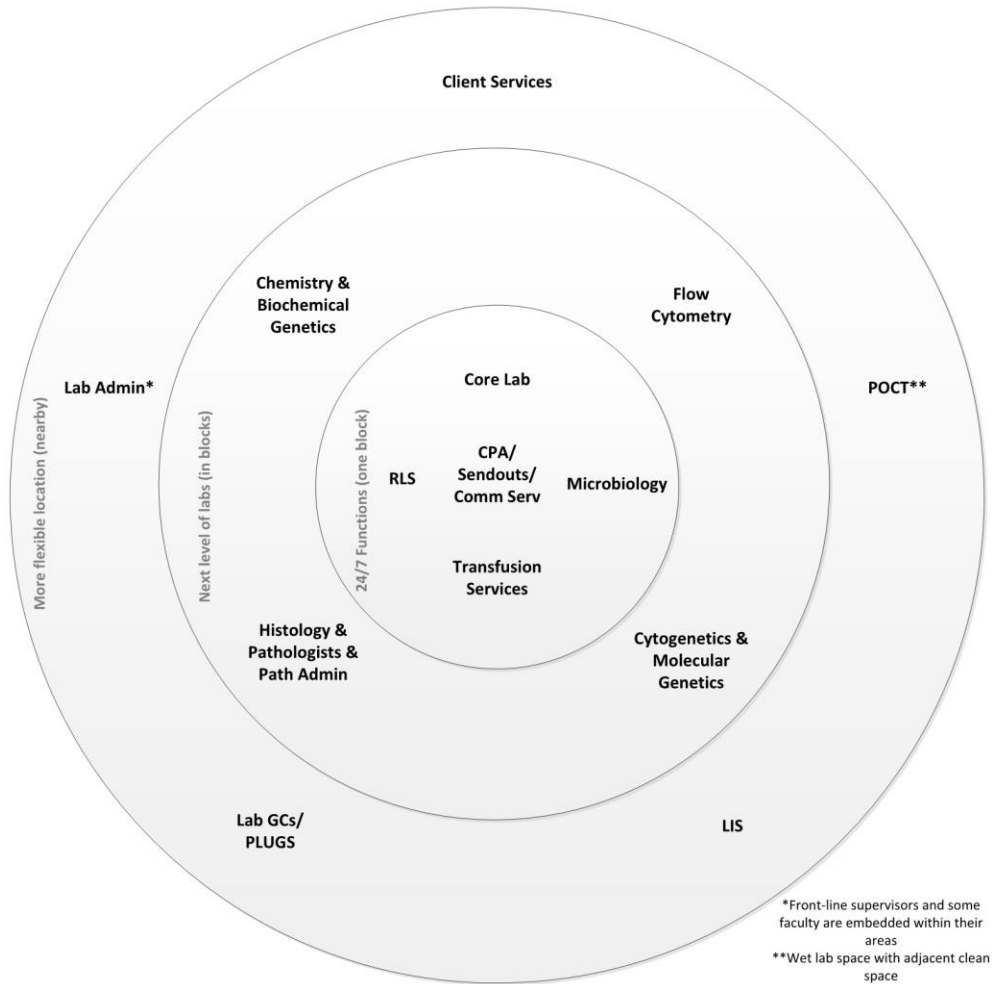


Figure 4.2: SCH clinical laboratory grouping

The vision statement for SCH clinical laboratory is:

- Support patient care by providing clinician requested diagnostic results with precision and accuracy
- Provide great experience for services that directly interface with patients and family
- Support hospital mission of research and education
- Provide state of the art testing to SCH and other regional, national, internal institutions
- Comply to future regulations requirements
- Maximize throughput, reduce lost samples and reduce turnaround time
- Reduce cost per test and unnecessary tests
- Allow rapid reconfiguration with a highly flexible laboratory

The management structure of the clinical laboratory follows a common structure for healthcare, where there is an organization for administrators and another for the faculty. This can be seen in Figure 4.2 and Figure 4.3. SCH labs have a large menu of approximately 750 tests and serve as a reference laboratory for other laboratories (some tests are only performed at Seattle Children’s Hospital) as well as SCH’s patients. Their current volume is almost one million tests a year and more than 70% are processed by their CORE laboratory (the section of the laboratory that performs the tests that are ordered with increased frequency and that have the shorter turnaround times).

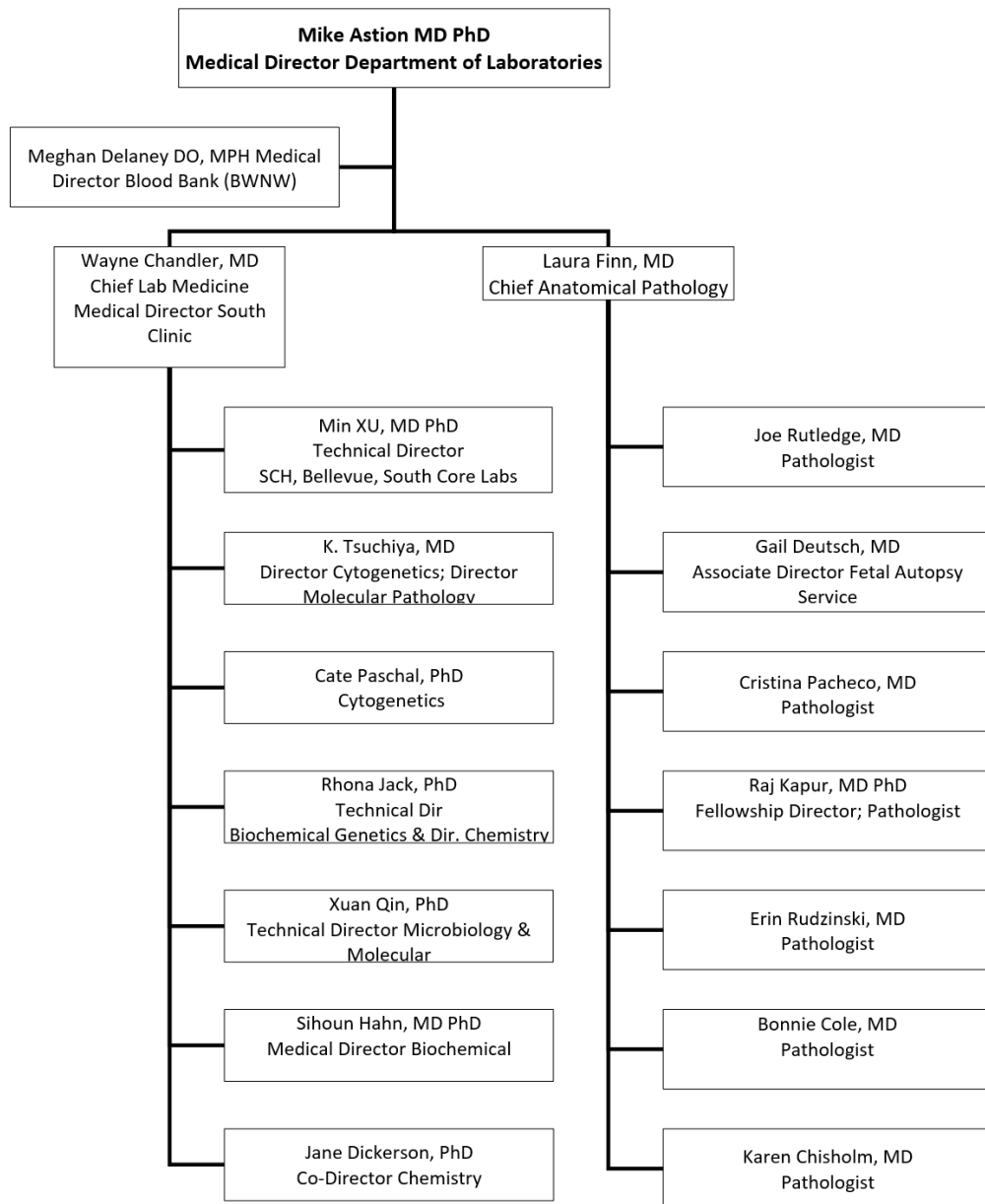


Figure 4.3: Faculty organization chart

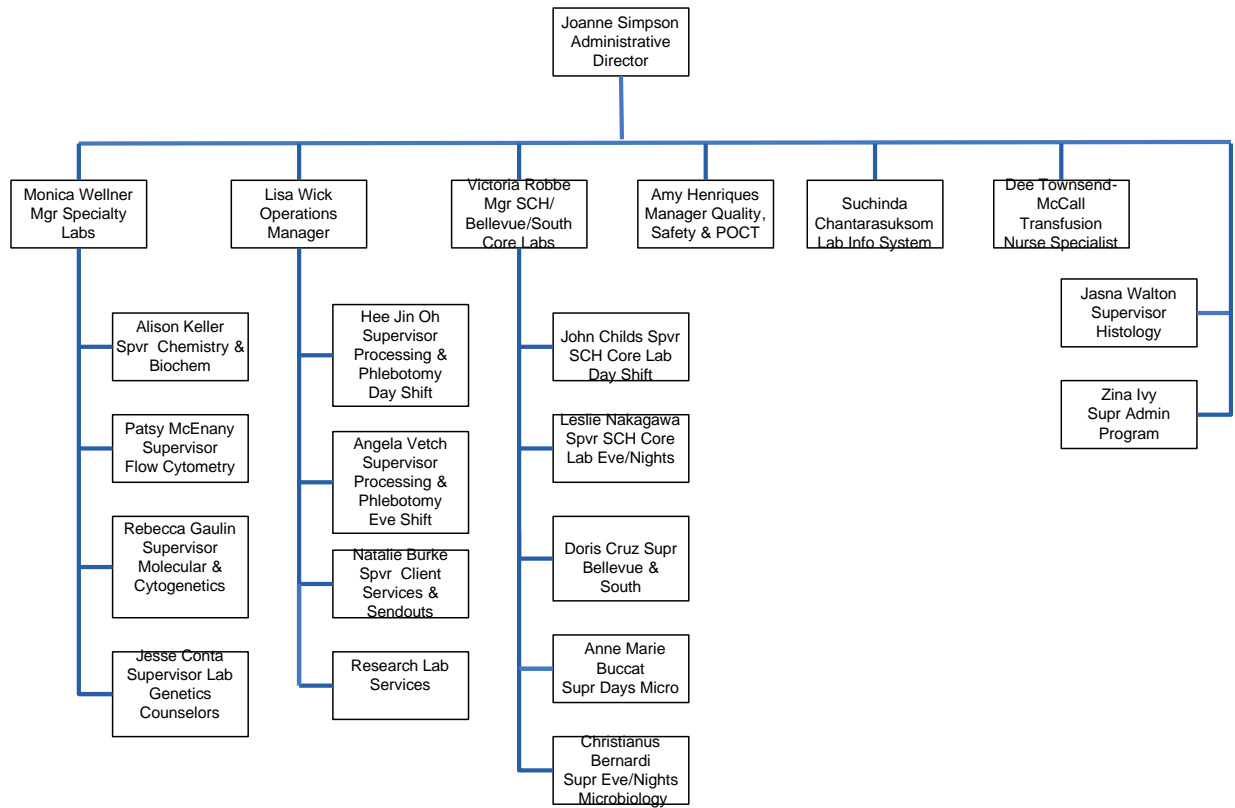


Figure 4.4: Administration organization chart

Construction Project

The project for the building, where the new clinical laboratory will be housed, is called Building Care (officially “Forest B”) and is being developed for three main reasons (Seattle Children’s Hospital, 2017)³:

1. As the population of the region continues to grow, the hospital should be prepared to meet the needs of all families in its region. Building Care supports the strategic plan through clinical capabilities, expanding their facilities, and growth and integration.
2. Conducting research is at the center of SCH’s mission. Clinical facilities must be designed to transform research advances into real therapies and allow for the integration of research and patient care. The hospital should have sufficient capacity to treat patients who are participating in clinical trials and research studies.

³ Source derived from the intranet (not publicly available) of Seattle Children’s Hospital.

3. Because the hospital campus has been built-out over time, some older areas are not designed to support today's care practices and improving technology. New space will allow them to build flexible, state-of-the-art spaces to serve their patients and care providers for the future.

The building is scheduled to open in 2021 and the design phase started in 2017. The new building will be an expansion of the Forest building as seen in Figure 4.5. The same design and construction team that built Forest A (Building Hope) has been hired: Seneca Group as the development manager, ZGF (Zimmer Gunsul Frasca) as the architect and Sellen Construction as the general contractor. The building will have approximately 300,000 square feet with eight levels above ground and one level below ground, plus two levels of underground parking. The building envelope was designed first with no possibility of changes. Along with the clinical laboratory, it is supposed to be the home to a new hematology/oncology clinic, infusion center, operating rooms, procedural suites, heart center clinic, inpatient pharmacy, inpatient beds and imaging. At the beginning of the project there was no certainty in what would be built in the near-term and what will be left for future build-outs.



Figure 4.5: Seattle Children's Hospital main campus expansion

In this context, while a hospital team is focused on designing the building for every area involved, the clinical laboratory initiated a project to develop different preliminary designs that could serve as an input (along with the information generated, the design package) to the overall construction project (that will be called the Forest B project). Thus, the clinical laboratory project should be undertaken in coordination with the Forest B project. The Forest B project has the following teams in place:

- Core team: Facilities, architects, general contractor, development manager and lean consultants. They are the people that lead the project.
- Forest Innovation Team (FIT): Contains one representative from each department that will be located in the new building (including the lab). Their mission will be to explore new high-level approaches for providing patient care by using 7 flows, including waste reduction, simulations and modeling.
- Care Strategy and Change Management Team (CSCM): Physicians on a “care strategy” team will develop and recommend strategies for healthcare of the future (long term view). The laboratory has one representative on the CSCM Team.
- The Home Advisory Team (HAT): This refers to different teams assembled from the various areas that will be located in the new building. For the laboratory, the HAT team is composed of approximately twenty people from the different sections. They will advise and provide input on future state designs, test mock-ups at the Ballard warehouse, and help with communications and change management with the other teammates.

For the Forest B project, they are using as their design process the Integrated Facility Design (IFD), a form of lean design and project delivery where there is a collaborative approach between the teams having a warehouse in Seattle as their headquarters. This process was used in SCH Bellevue Clinic and Surgery Center and it is described in Wellman (2017). In IFD, space and design is driven by data, full scale mock-ups are used to test the designs and front-line staff and families are included early in the design process.

For the particular case of the clinical laboratory, the schematic design will start during the spring of 2018. Currently, there is no clarity on the space that will be designated for the clinical laboratory and if they will be split across two or more locations (e.g., floors). As a consequence of the future space and schedule uncertainties, the preliminary design phase serves the purpose of preparing the clinical laboratory to take into consideration all possible options. In the last weeks of the application of the PDL methodology, the team structure of the Forest B project changed, but that is not described since it did not affect the execution.

Stakeholders

Stakeholder information defines who will be important for the design. Figure 4.6 is a stakeholder map for the project. This map provides a wide view of the entire construction project. For the preliminary design of the clinical laboratory, the focus will be on each stakeholder of the “SCH

Lab” figure. The other stakeholders will not be directly addressed (those will be considered as external inputs from other sources such as the Forest Innovation Team).

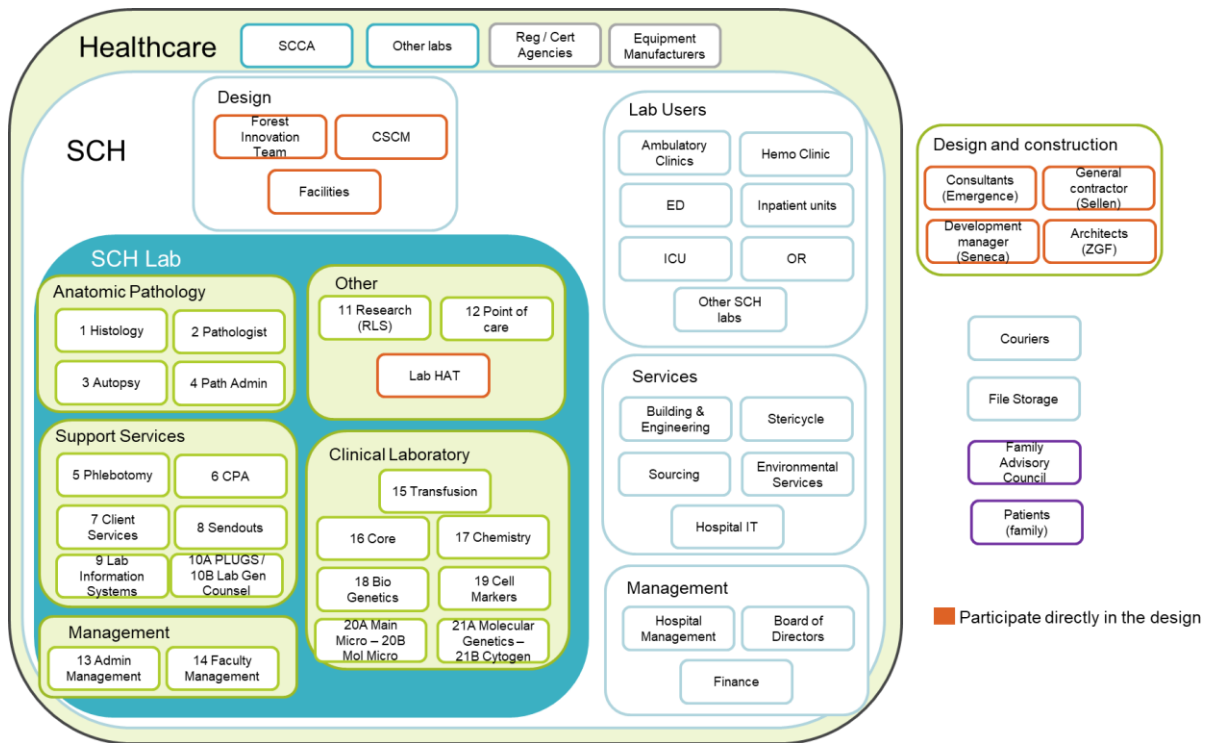


Figure 4.6: Stakeholder map

Benchmarking

Several laboratories were included in benchmarking efforts University of Washington Medical Center (Seattle), University of Washington Harborview (Seattle), Virginia Mason Medical Center (Seattle), Mayo Medical Laboratories (Rochester) and Seattle Children’s Bellevue Clinic (Seattle). These organizations were kind enough to open their doors to show their facility and share their processes. Several ideas were taken into account, especially in terms of the movement of specimens between sections and different visions on how to design a new facility. A summary document was created of each visit.

Design Principles

Another important part of the context are the design principles. These were chosen with the management and supervisors of the clinical laboratory in several meetings. Although they are specific for this context, they could be defined as general principles for the clinical laboratory. Here is the list of the principles and their definitions:

- Flexibility: The only thing constant in the lab is change. No one exactly knows the future is going to be, so the recommended process is to design a flexible clinical laboratory that can be changed every time that is needed with only laboratory staff. The concept of an open lab is the goal because it allows more flexibility than fixed walls (the current state of Seattle Children’s Clinical Laboratory).
- Human Factors: Design to optimize the staff well-being and optimize their relationship with their environment. Include them every time possible in the design process.
- Lean/CPI: Seattle Children’s Hospital is a lean organization and the clinical laboratory is one of the “leanest” areas of the hospital. Lean principles should be considered by designing to eliminate waste, staff overburden and process variation.
- Quality and Safety: Although this principle encompasses many disciplines and it is related to the previous principles, the inclusion was thought to explicitly have a focus on the clinical laboratory quality (reducing errors and, increasing accuracy and precision) and safety to patients and the staff.

All of this information was used as a part of the concept formulated and provided the basis for what could be undertaken. In the next section the next question is answered.

4.2.1.2 Question 2: What are the evaluation criteria and the evaluation method at SCH?

For the evaluation criteria, the first concept that was chosen was the adjacency score to evaluate the critical adjacencies of the alternatives. This comes from the several relationship charts that will be developed to evaluate the desired adjacencies between sections of the laboratory and between the different items present in a particular section. Additionally, there were several qualitative factors that were important for the clinical laboratory. This came from several meetings and interviews with the people from the laboratory. Since they already had experience with the Analytic Hierarchy Process (AHP), a decision was made to define the factors, share them with the people (in case something is missing) and then utilize AHP as the method to evaluate each design with the chosen criteria. Since the adjacency score and the AHP ranking depends on the subjective measures defined, if necessary a sensitivity analysis will be performed to see how the result changes if those values change.

Additionally, it was decided that as a first step in the evaluation process, a list of pros and cons of each design will be developed. This, along with stakeholder requirements and concerns verification for the final preliminary designs, will serve to provide more information for each design with no specific criteria in mind. This way, there is an explicit relation with the concepts generated and the final alternatives that are chosen. In summary, the agreed evaluation methods have four steps that will be applied to each preliminary design:

- Clearly list the pros and cons of each design alternative
- Stakeholder requirements and concerns verification
- Adjacency score (adjacency importance criteria)
- AHP (qualitative criteria)

In the third stage (evaluate design alternatives), a group decision process will be performed to review the results and to provide conclusions that can serve as an input to the schematic design phase. As for the evaluation criteria that will be incorporated in the AHP model, the factors were defined without the hierarchy. After the factors were defined, they were grouped as shown in Figure 4.7.

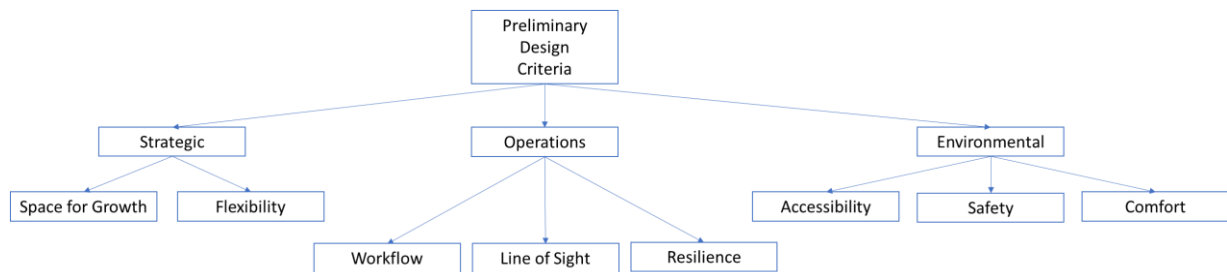


Figure 4.7: Preliminary design criteria

These are the factors defined:

- Category: Strategic
 - Space for growth: Is there space for future growth?
 - Flexibility: Is there enough flexibility to make changes?
- Category: Operations
 - Workflow: Is the workflow efficient and interrupted?
 - Line of Sight: Is there adequate line of sight between sections and inside each section?

- Resilience: Is the lab prepared for malfunctions or rare events (e.g. tube system not operational)?
- Category: Environmental
 - Accessibility: Is there appropriate access for every person (staff, courier, instrument maintenance)?
 - Safety: Are there any safety concerns?
 - Comfort: What is the level of staff comfort?

There were other factors that were identified but were not applied since they were included as part of factors already defined. Additionally, *cost-to-build* was a factor at first where architects would be consulted. At the end, cost-to-build was not considered necessary, since there were not any major structural differences among alternatives and it was too early to start with cost quotes. With that, Question 2 is answered. In the next section Question 3 will be addressed.

4.2.1.3 Question 3: What are the characteristics of the clinical laboratory at SCH?

In this section, the content of Question 3 (shown in Figure 3.5) at SCH is explained. The first part regarding the Clinical Laboratory and its section description was directly answered and the second part regarding the laboratory users and other stakeholders was answered through the participation of people from the clinical laboratory in the Forest B project and in similar instances.

Clinical Laboratory/Sections Descriptions

To develop the description of the clinical laboratory and the descriptions of each section, a standard document was created (one for the clinical laboratory and one for the sections). These documents have the important information and reference other documents that complements the information gathered. This way, the information can be added incrementally, and the access is easier. In Appendix A and B the document templates are presented. Basically, each document is self-contained and self-explanatory helping the sharing of information. Also, it can serve as an input to the schematic design. Several activities were performed to fill the descriptions and they were available for everyone in a shared project folder (with the rest of the design package). Some aspects of the descriptions should be explained in more detail:

Space estimates

The footprint and the blueprints (architectural renderings) of the current facility were the starting point. The basic thought was that the new clinical laboratory should be at least the same size as the current facility. The Forest B project team was in charge of requesting these estimates and then deciding how much space would be allocated for the clinical laboratory. The first estimate is how much space each section needs (including amenities) for the near term; this is based on their current space problems and the potential for growth. A proper analysis was made of the section space requirements based on their test volume and/or their test menu. Additionally, the Forest B project asked for a space estimate for the year 2040 (their planning date). This was based in the same information. There will likely be some uncertainty in these estimates and they should be revised in Stage 2.

Equipment list

A spreadsheet was created incorporating the fields proposed by the Clinical Laboratory Standards Institute (2016). It was intended to include all of the equipment that has a considerable size. Each section was asked to provide the Model, Maker, Quantity and the name of the bench or section that utilize the equipment. All other fields on the spreadsheets were left to be filled with the manufacturing information or by mechanical and electrical engineers. Some of the sections already had some of that information and were kind enough to provide it. Appendix C contains an example of the equipment spreadsheet.

Sub-Categories

Several sub-categories were created to organize the information and to ensure that the descriptions are self-explanatory. They were chosen according to the information that was retrieved in the first encounters with the key stakeholders of the clinical laboratories.

Physical Arrangement

The first activity performed was an education workshop with a representative of each section of the laboratory to teach them how to construct a relationship chart based on the critical adjacencies and how to evaluate a particular layout. This workshop will be described in Section 4.2.1.4. After the workshop, each section was asked for their adjacency values to every other section. Then an activity was performed to ensure that each value is the same from every pair of sections (if not the bigger value prevails) and that every value makes sense. Some sections were combined to reduce the complexity, since they need to stay together, no matter what. Phlebotomy and the Morgue were

discarded since the first is not moving and the second will be located in the basement of the new building. The result is the model shown in Figure 4.8.

Section	Histology	CPA/Send/CS	Core	Transfusion	Micro	Mol Micro	Client Ser	RLS	Chemistry	Bio Genetics	Cell Mark	Cyto/Array/MG	LGC/PLUGS	POCT	LIS
AP & Path Admin	A	I	I	U	U	U	O	U	U	U	I	O	U	U	U
Histology		E	I	U	E	E	U	O	U	U	I	O	U	U	U
CPA/Send/CS			A	E	E	E	E	I	I	O	I	O	O	U	I
Core				E	E	E	I	O	E	O	I	I	U	O	I
Transfusion					I	U	U	U	U	U	U	U	U	U	O
Microbiology						E	O	U	I	U	U	U	U	U	U
Mol Micro							O	U	I	U	U	I	U	U	U
Client Ser								O	U	O	O	U	I	U	U
RLS									O	U	O	U	U	U	U
Chemistry										E	U	U	U	O	U
Bio Genetics											U	O	O	U	U
Cell Mark												I	U	U	U
Cyto/Array/MG													I	U	U
LGC/PLUGS														U	U
POCT															U

- A: Absolutely Essential (need to be right next to each other, have line of sight, etc.)
- E: Essential (need to be closely co-located, within ~10-15 feet or so)
- I: Important (need to be easily accessible/walkable)
- O: Marginally Beneficial (nearness is helpful; no specific location requirements)
- U: Unimportant
- X: Should not be adjacent

Figure 4.8: Relationship chart of the critical adjacencies

The information provided was used to solve the optimization model that was presented in Chapter 3 having as an input a hypothetical space with sixteen locations. The software used was the student version of AMPL, the solver chosen was CPLEX. The optimal value was determined to be 378 after 11,298,808 MIP simplex iterations. The resulting layout is shown in Figure 4.9. After this process, each section was asked to develop the relationship chart for their own physical space with special emphasis on the items to be included and their potential sizes.

Histology	Mol Micro	Micro	LIS
AP	CPA	Core	Chemistry
C Markers	C Services	Transfusion	Biochem
RLS	Cyto/MG	PLUGS	POCT

Figure 4.9: Resulting layout

Queueing Models

The clinical laboratory had specific questions about the number of stations or monuments needed for sections of the new facility. The basic assumption is that specimens have Poisson arrivals, since they are unscheduled, and, for simplicity, the service time behaves exponentially. The same assumptions were presented in Bruin et al. (2007). From this, an M/M/s model was implemented in Microsoft Excel where the number of servers is representing the number of processing stations of CPA (Central Processing Area, SCH pre-examination area). A set of data was collected to represent how this would be used in their particular applications. The graph of Figure 4.9 shows the evolution of samples arriving to CPA at different days and at different hours of the day. From that figure and a detailed analysis of the data, three periods were defined:

- Period 1: Normal operations
- Period 2: AM Spike (morning rounds)
- Period 3: Weekday outpatient clinic operations

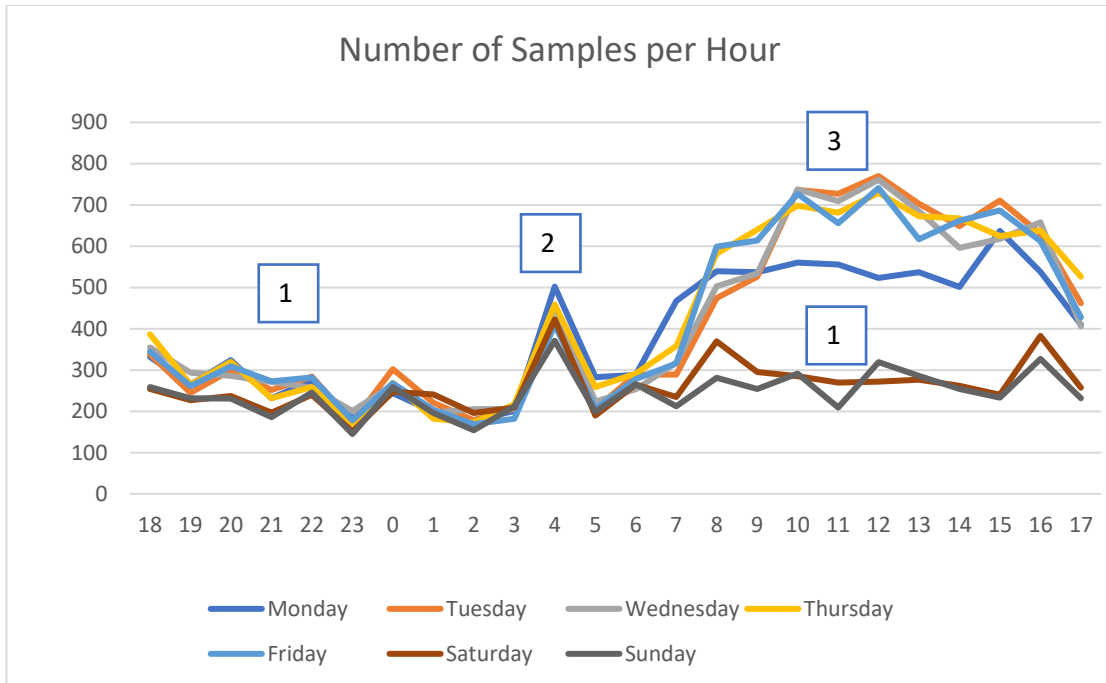


Figure 4.10: Number of samples arriving at CPA per hour at different days

The summary data for each period is presented in Table 4.1. Since the data obtained was the sum of samples arrived for each day at different hours, this was converted to a daily average for each period and will serve as the arrival rate (per hour). As for the service time, 5 minutes was used⁴. With a goal of having a utilization rate greater or equal than 0.5, a sample expected time in the system less or equal than six minutes and the probability of a sample waiting less or equal than 0.4, the numbers of servers should be 3, 4 and 5 for periods 1, 2 and 3 respectively. Thus, the processing area should have at least five processing stations and should be prepared to operate with only three open. The results are presented in Table 4.2, Table 4.3 and Table 4.4.

Table 4.1: Periods summary data of samples per hour

	Average	Std	Min	Max	Daily Average
Period 1	263	70	145	502	18
Period 2	434	42	371	502	29
Period 3	615	95	406	770	41

⁴ For demonstration purposes only. It was obtained from conversations with SCH clinical laboratory staff.

Table 4.2: Period 1 performance metrics

Performance Metrics	Servers			
	2	3	4	5
Utilization	0.75	0.5	0.375	0.3
Probability that the system is empty	0.14	0.21	0.22	0.22
Expected number in queue	1.93	0.24	0.04	0.01
Expected number in system	3.43	1.74	1.54	1.51
Expected time in queue	0.11	0.01	0.00	0.00
Expected total time in system	0.19	0.10	0.09	0.08
Probability that sample waits	0.64	0.24	0.07	0.02

Table 4.3: Period 2 performance metrics

Performance Metrics	Servers			
	3	4	5	6
Utilization	0.81	0.60	0.48	0.40
Probability that the system is empty	0.05	0.08	0.09	0.09
Expected number in queue	2.72	0.45	0.11	0.03
Expected number in system	5.14	2.86	2.53	2.44
Expected time in queue	0.09	0.02	0.00	0.00
Expected total time in system	0.18	0.10	0.09	0.08
Probability that sample waits	0.66	0.29	0.12	0.04

Table 4.4: Period 3 performance metrics

Performance Metrics	Servers			
	4	5	6	7
Utilization	0.85	0.68	0.57	0.49
Probability that the system is empty	0.02	0.03	0.03	0.03
Expected number in queue	4.08	0.76	0.21	0.07
Expected number in system	7.50	4.18	3.63	3.48
Expected time in queue	0.10	0.02	0.01	0.00
Expected total time in system	0.18	0.10	0.09	0.08
Probability that sample waits	0.70	0.35	0.16	0.07

Once the descriptions of the clinical laboratory and the sections were in place, it was still necessary to have the external lab users' and stakeholders' inputs, to tie the characteristics of the new clinical laboratory directly to the wellbeing of patients.

External lab users and stakeholders

The following is a summary of the conclusions drawn from the FIT and CSCM teams (hospital teams defined in the context section):

- Faster and increase testing: Genomic testing and expanded neonatal exome. Molecular Genetics is likely to grow.
- Decrease turnaround for Phlebotomy: Reduce travel distance for patients, need for specialized phlebotomy expertise and need for specialized phlebotomy rooms.
- Decrease turnaround for acute programs: Evaluation of changes (e.g.: satellite labs, rapid focused transport of samples, processing fast lane)
- Problem orders: Bedside barcode order improvements, better communication with ordering location for problem samples and real time location
- Transfusion: Support during massive transfusion protocol and adding a cell bank to support immunotherapy program and space for apheresis equipment.
- OR Frozen Sections: Location of histology (frozen sections) and Anatomic Pathology faculty offices relative to the OR.

4.2.1.4 Methods to answer the questions at SCH

There were several activities that were performed to answer the questions. They happened in a continuous iterative process where the different needs dictated what was executed. Here a description of the more important tasks:

- Bi-weekly meetings: A presentation was made every two weeks to the laboratory leadership. It helped to discuss key topics and to show the current progress.
- Visit to other institutions: As presented in the description of Question 1, several institutions were visited as part of the benchmark of other clinical laboratories.
- Section tours and structured interviews: The first contact with each section was to schedule a tour of their facility (with an explanation of their services) and a structured interview. The questions for these interviews is in Appendix D.
- Adjacency workshop: This workshop lasted three hours and was divided into two periods. The first one was an educative presentation of the things that are important in a relationship chart and what are the key features of thinking of critical adjacencies. The

second period was practical and with the help of a spreadsheet, the people could try the development of a model.

- Coordination with Forest B project: During the entire project, the coordination with the Forest project was crucial to the lab project success. Several visits were made to the warehouse that served as the workplace for the Forest B project and the participation in the HAT meetings provided the nexus between projects.
- Shared folder: A shared folder was put in place to store the information that could be accessible for the people in the laboratory. This information was also combined and used for the Forest B project.
- Regular contact: It was always important to maintain the contact with everyone in the laboratory and the other activities provided the contacts necessary to keep the information flowing. This served the purpose of formulating the concept while maintaining the alignment with the laboratory.

When the deadline for Stage 1 was close and all three questions were almost answered, the planning for Stage 2 started. In the next section, the execution of Stage 2 is explained.

4.2.2 *Stage 2 Develop design alternatives at SCH*

Stage 2 has three steps that can be seen in Figure 3.7. At SCH this was adapted to their specific context where information released from the Forest B project affected how it was executed. Several feedback loops to Stage 1 were necessary to re-formulate concepts and to add information generated in the different steps.

Step 1: Explore critical adjacencies

The first step of Stage 2 focused on exploring critical adjacencies and different configurations for the clinical laboratory. This step undertaken in a workshop including one representative from each section of the laboratory. Since the Forest B project has not decided on which floor the clinical laboratory will be located, or if is going to be on more than one floor, the process for the workshop was to develop alternatives for three scenarios (one floor, two floors and three floors). This way, work can be performed without having to wait for the Forest B decision. One of the crucial steps for this workshop was to incorporate the information generated in the previous stage; the adjacency model was provided as a guide and other pieces of information from the context and the

descriptions were used to design the workshop or were incorporated in the instructions. The instructions of the workshop are presented in Appendix E. This activity lasted 3 hours, and twenty-five different layout configurations were developed. These layouts were used in a final workshop that combines the results of this workshop with the designs of each section. A picture of the people working in the workshop can be seen in Figure 4.11.

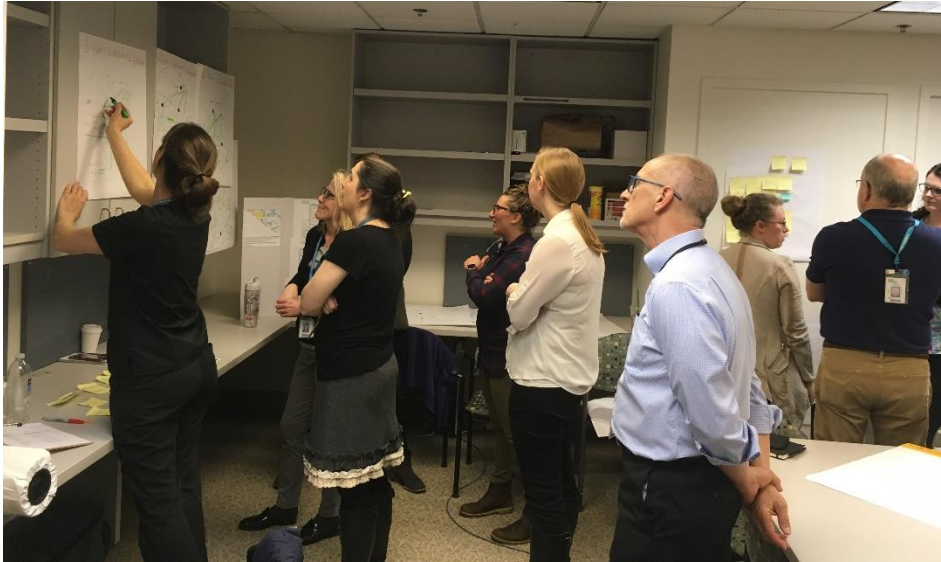


Figure 4.11: Design workshop I

At the end of that workshop each team was asked to rank their alternatives for each scenario and to list the pros and cons of each alternative (an example of a resulting configuration is shown in Figure 4.12). Additionally, after the workshop was concluded, all the alternatives were digitalized, put in a standard format and placed on the wall of the laboratory. Then, the clinical laboratory staff was asked to choose their favorite for each scenario (by adding a color dot sticker) and to list their pros and cons. This served the purpose of discarding the “bad” alternatives, to give everyone a chance to participate in the design and to capture useful information that otherwise could be lost. The preliminary analysis of the results was positive with adequate participation. It served to confirm the mental models of the people of the laboratory and provided useful comments about the alternatives. It even provided a design that matches the current configuration given the Forest B current scenario (Figure 4.13). Figure 4.14 shows the designs posted on the clinical laboratory walls.

2 FLOORS SCENARIO 2 (70/30) *favorite*

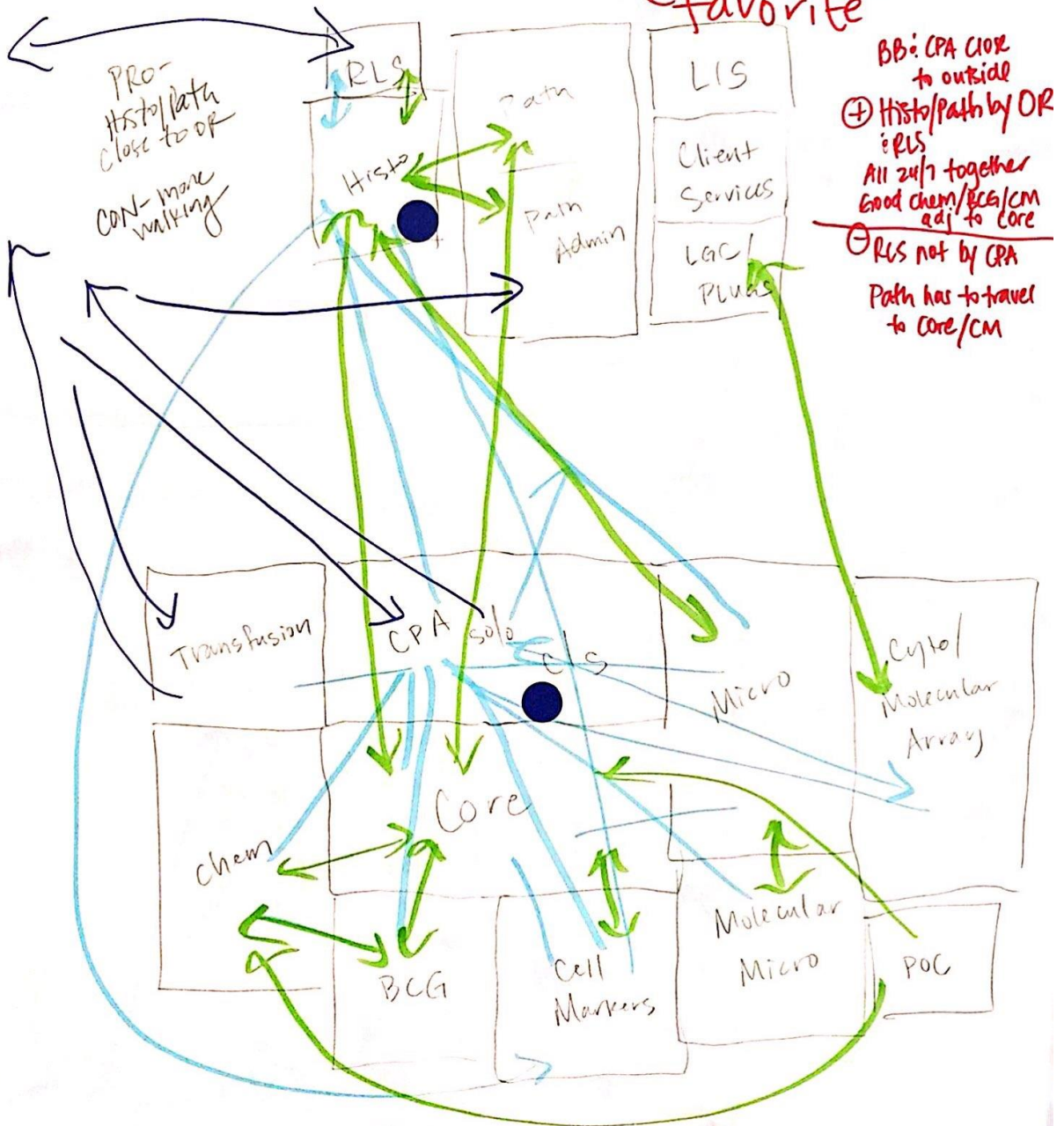


Figure 4.12: Result example

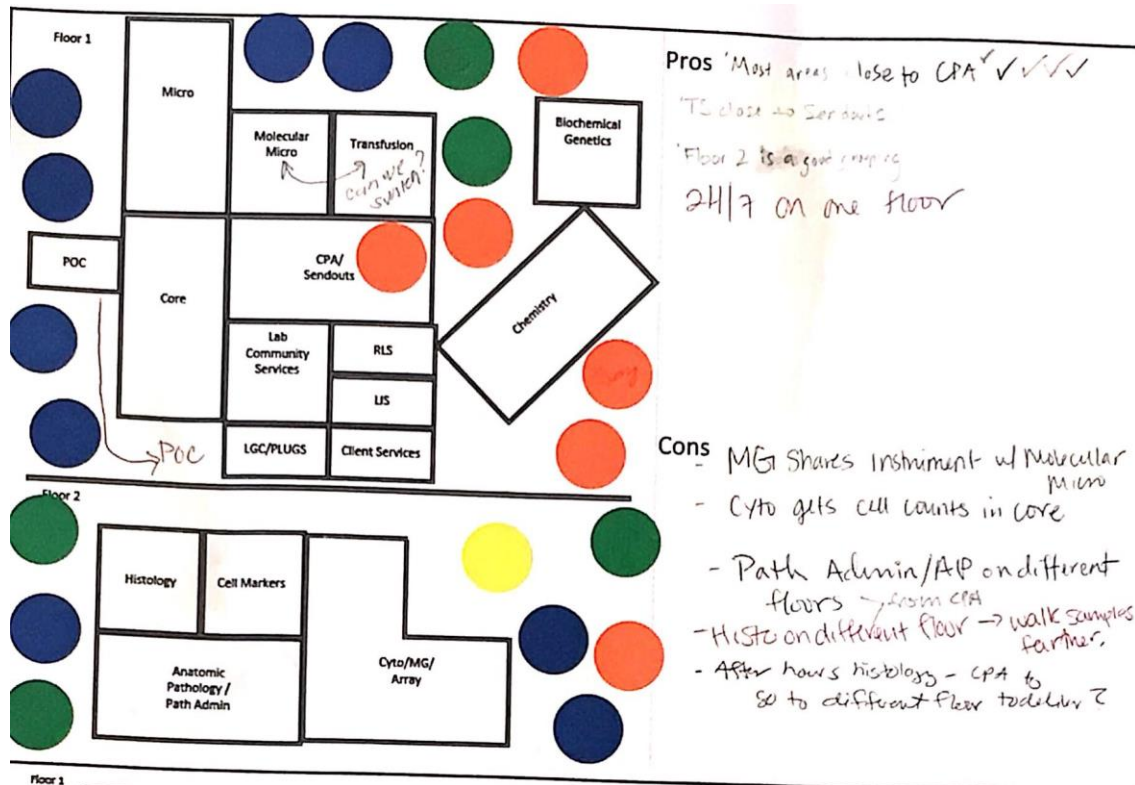


Figure 4.13: Current configuration design

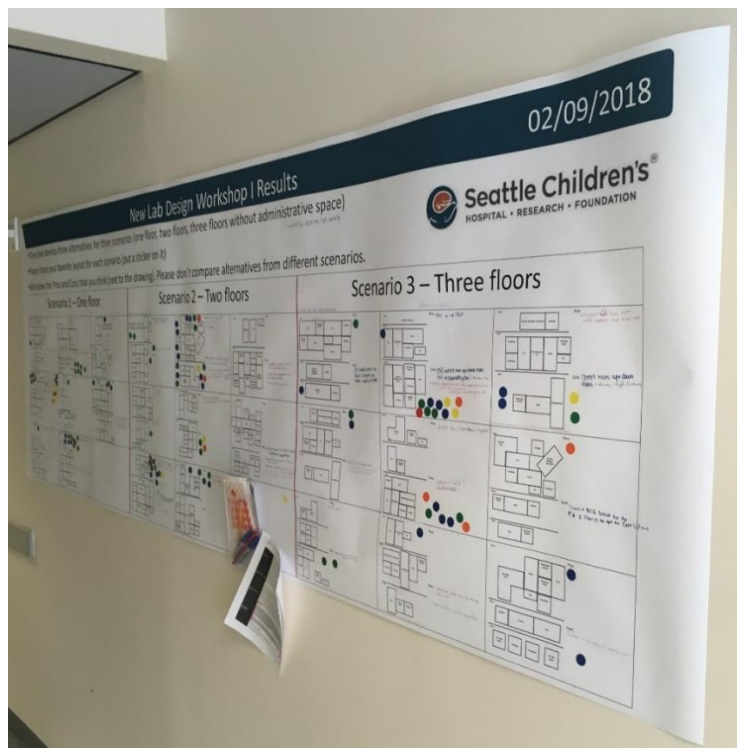


Figure 4.14: Design workshop I results

While the results were posted for revision and comment, the planning for Step 2 started. The biggest problem was that the numbers of sections required a considerable effort for the staff and the facilitators if the goal is to design each section's space. This was mitigated by clearly defining the process, the required staff attendance and the objectives for the different workshops were undertaken as part of Step 2.

Step 2: Design sections space

To design each section-specific workplace, more planning is necessary, since it is a more complex situation: each section is moving different pieces and the sizes are very important. At this point, the Forest B project still has not decided the final location of the labs in the new wing (changes are still on the way). The process will be to design each section using their current space and the projected space as a guide, but to design it with a given scale and with several examples of benches, equipment and monuments. Information from the descriptions should be provided (in the form of a friendly summary or graphic) and the ideas and concerns will be used as themes to develop alternatives. These activities serve the purpose not only of developing the preliminary designs but also to see if the clinical laboratory has everything ready to enter the schematic phase. It will also serve the purpose of building the internal capabilities to design their workplace, something very valuable given the constant change in the laboratory.

With proposed space on floors L1, 2 and 4, a preliminary calculation was made to see what can be allocated between floors while respecting critical adjacencies, the need for Histology close to the operating rooms and thinking about their future configuration for the next twenty years (a new building is going to open along the way, Forest C). L1 is available but due to its characteristics, it cannot be utilized for laboratory or administrative functions (having the Morgue as an exception). The administrative space was not included, since there is not sufficient space; the hospital needs to provide a solution to their location. The result was the following configuration:

- 4th floor: Histology, Anatomic Pathology, Pathology Administration, Cell Markers, Cytogenetics and Molecular Genetics
- 2nd floor: CPA, Send-outs, RLS, Transfusion, Core, Chemistry, Biochemical Genetics, Microbiology and Molecular Microbiology.
- L1: Morgue and support area.

Since the 4th floor was originally scheduled to start the schematic design phase sooner than the 2nd floor, a decision was made to have three workshops to design the following sections:

- Workshop 1: Cytogenetics, Molecular Genetics and Cell Markers.
- Workshop 2: Histology, Anatomic Pathology, Pathology Administration, Chemistry and Biochemical Genetics.
- Workshop 3: Central Processing Area (CPA), Sendouts, Research Lab Services (RLS), Transfusion, Core, Microbiology and Molecular Microbiology.

The planning process included a checklist of activities that should be done beforehand (available in Appendix F). One key aspect was to define the components for each section that they will use to move and develop different designs of their individual space. This was addressed in a pre-workshop meeting with each individual section to review the components and the information available from Stage 1. Each workshop lasted approximately three hours with each individual section working as a team developing at least four different layouts using pre-defined cardboard components. Figure 4.15 shows people working in the last of the three workshops of this step. Each section had to make different assumptions about their surroundings and their relationship with the other parts of the clinical laboratory. The overall process is presented in Appendix G.



Figure 4.15: Design workshop II

After the workshop the projected space was compared to the different designs and some adjustments were made (feedback loop to Stage 1). Additionally, the smaller components were grouped into larger components as a preliminary space program and to serve as the unit of

BIOCHEMICAL GENETICS

11-2

1/ sample
1/ staff

PROS - whether team has clear
even "space" to work
into 2/3 structures
- placement of some people is
very important - good

CONS - could be limited results
regarding if work on
2 sides

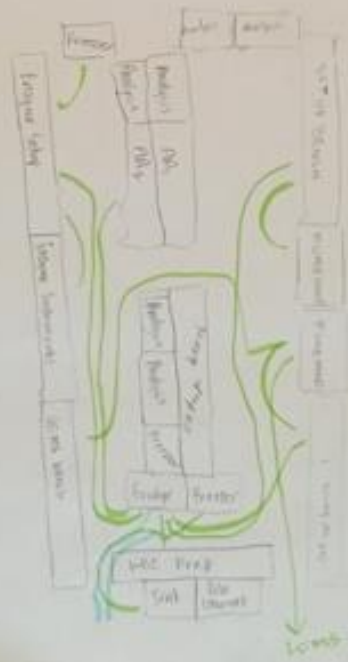


Figure 4.17: Biochemical Genetics design

Rank

BEST CASE SCENARIO #1

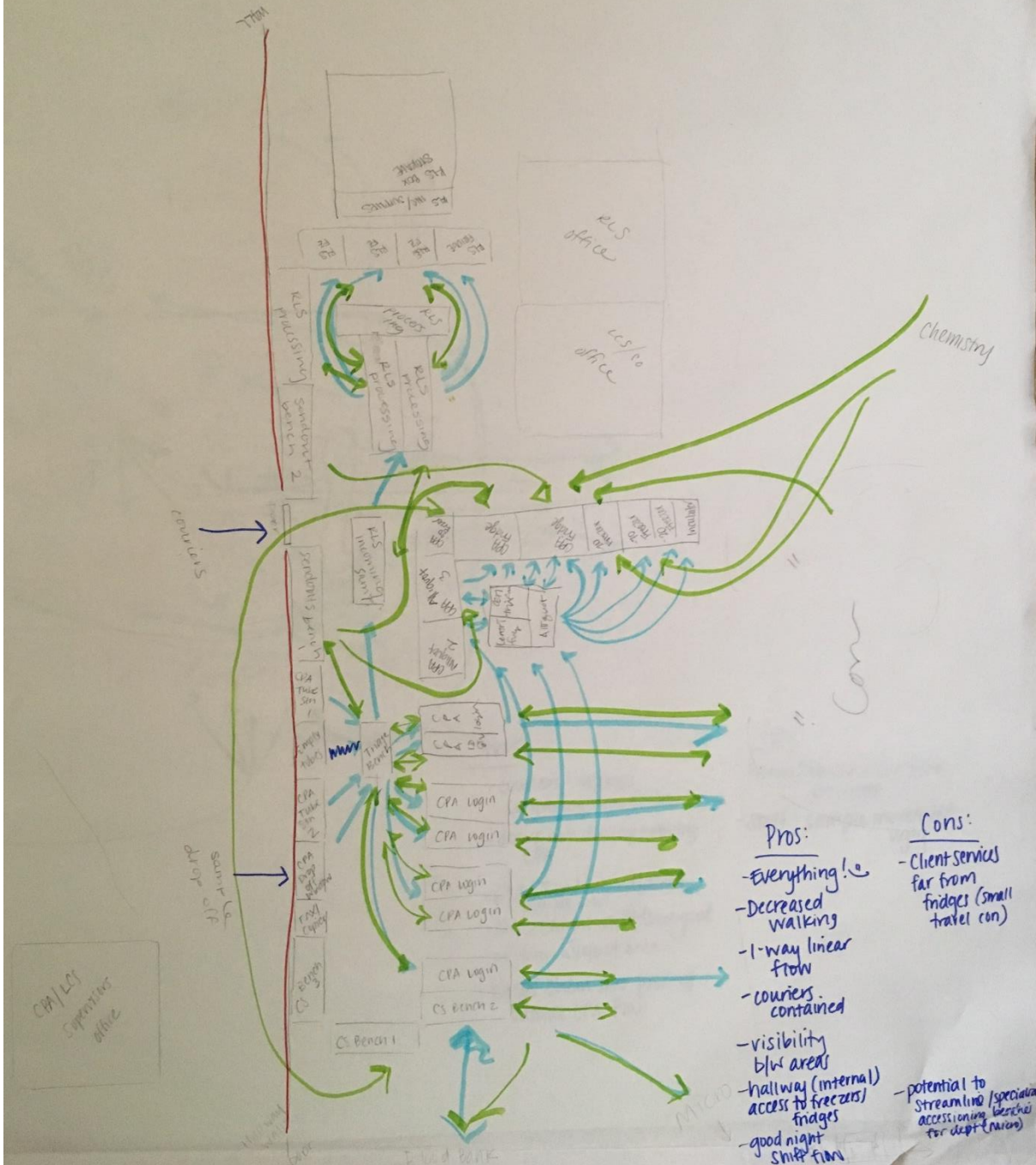


Figure 4.18: CPA/Sendouts/CS/RLS design

Some discussion has started about having a final workshop to combine all the information and the designs to a set of final preliminary designs. At this point the Forest B project has changed the schedule and the schematic design for the different floors of the clinical laboratory will be completed in the same week. It is not clear if all the new clinical laboratory will be constructed or a portion will be left as shell space, but the decision was to design the overall space and then adjust if changes are made.

Step 3: Fitting the pieces

For this last workshop, the actual floorplates of Forest B were used as a constraint for the space of the clinical laboratory. The original plan was to have two teams of people designing different options for the overall configuration of the clinical laboratory with the components defined from the last step. Since there were not enough people to have two teams, it was decided that one team design level 4 and another team design level 2, constantly communicating when needed. Ideas and thoughts about L1 were captured. This workshop lasted approximately three hours.

Although each team had available the different configuration from Step 1, it still was needed to start with bubbles diagrams since now the separation of floors it is defined. Placing these bubbles was the start, as seen in Figure 4.19 and 4.20. Then each component was placed or drawn to develop a design. In this case, each placement took time since several stakeholders participated and the constraint of the floorplate made it necessary to make several adjustments along the way. In Figure 4.21, people are discussing one alternative arrangement.

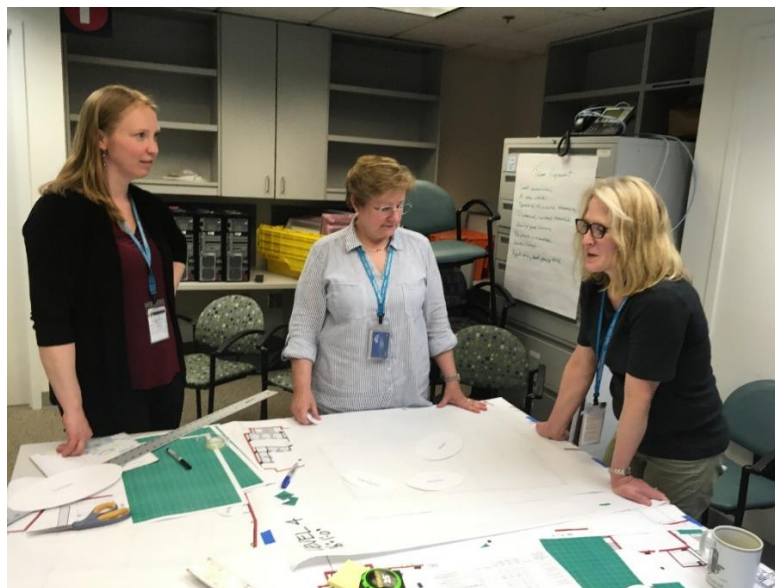


Figure 4.19: Placing bubbles

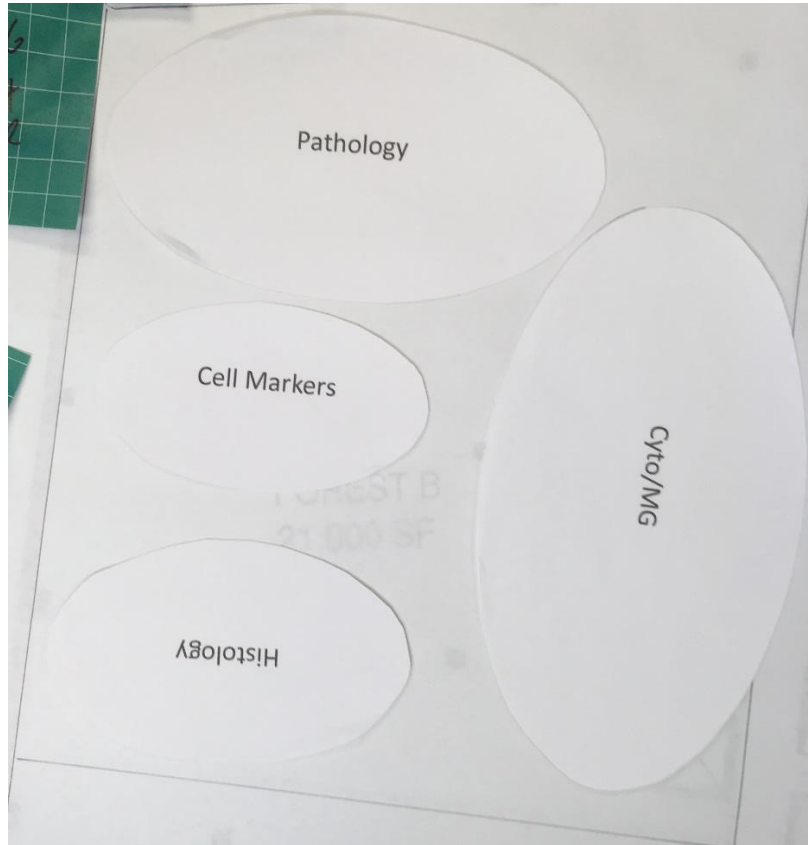


Figure 4.20: Bubble diagram of the 4th floor

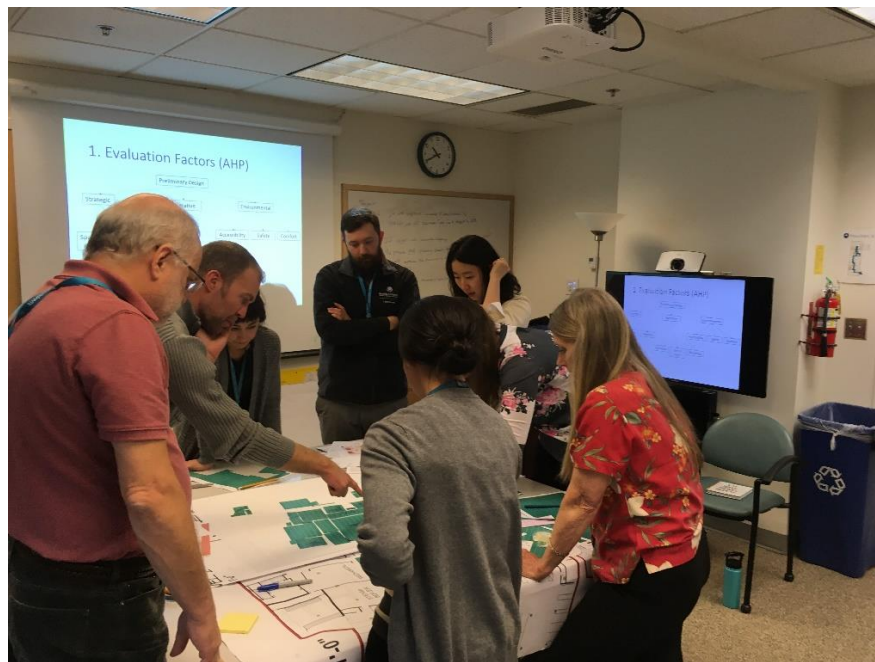


Figure 4.21: Design workshop III



Figure 4.26: L1 configuration

4.2.3 Stage 3 Evaluate alternatives at SCH

The evaluation method planned in the first stage was used to evaluate the final preliminary designs and then decide if the project has come to an end or if there is a need to re-formulate the concept and develop more alternatives (feedback loop). As a reminder, the agreed evaluation method has four aspects: pros and cons; stakeholder requirements and concerns verification; adjacency score; and AHP.

Step 1 Evaluate

The final workshop presented in the last section was also the beginning of this step where a list of pros and cons was developed by the staff and they incorporated their initial thoughts about each design. Additionally, it was the opportunity to weight the AHP factors (at the beginning of the workshop) and then evaluate the alternatives (at the end of the workshop). The weight values give a great penalty to environmental violations; the underlying thought is that environmental factors are the basis for the clinical laboratory current and future operations. Then, the strategic are more important than operations, since the current operations change constantly in the clinical laboratory. Once the alternatives were developed, they were compared for each low-level factor. In Figure 4.27 the AHP hierarchy with their weights are presented. Given that there are only two alternatives

and each comparison provided clear results, it was decided that the sensitivity analysis was not necessary. The AHP results are presented in Figure 4.28 and 4.29 showing the table used in the workshop to evaluate each alternative for each factor. The number highlighted in yellow next to each alternative reflects the preference (a higher number next to the alternative shows a stronger preference for that alternative, 0 is neutral). The AHP calculations were performed with the Super Decisions software.

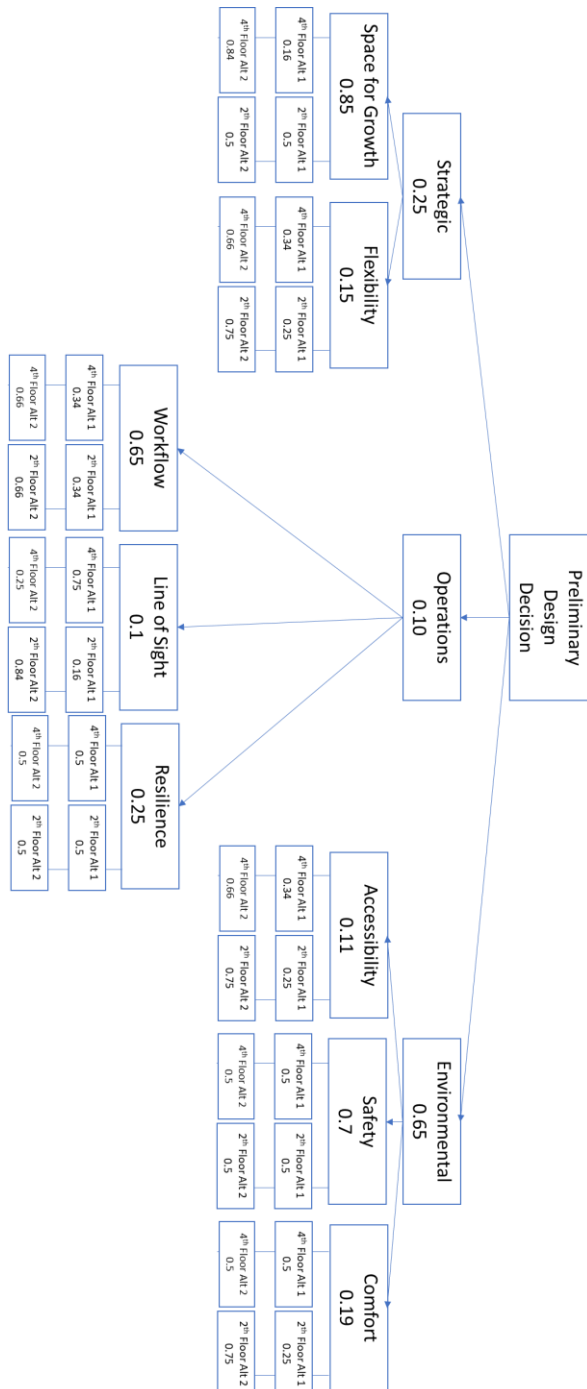


Figure 4.27: AHP hierarchy

Space for Growth								
3	2	1	Alternative 1	0	Alternative 2	1	2	3
Flexibility								
3	2	1	Alternative 1	0	Alternative 2	1	2	3
Workflow								
3	2	1	Alternative 1	0	Alternative 2	1	2	3
Line of Sight								
3	2	1	Alternative 1	0	Alternative 2	1	2	3
Resilience								
3	2	1	Alternative 1	0	Alternative 2	1	2	3
Accessibility								
3	2	1	Alternative 1	0	Alternative 2	1	2	3
Safety								
3	2	1	Alternative 1	0	Alternative 2	1	2	3
Comfort								
3	2	1	Alternative 1	0	Alternative 2	1	2	3

Ranking:

- Alternative 2: 0.6
- Alternative 1: 0.4

Figure 4.28: 4th floor AHP evaluation

Space for Growth								
3	2	1	Alternative 1	0	Alternative 2	1	2	3
Flexibility								
3	2	1	Alternative 1	0	Alternative 2	1	2	3
Workflow								
3	2	1	Alternative 1	0	Alternative 2	1	2	3
Line of Sight								
3	2	1	Alternative 1	0	Alternative 2	1	2	3
Resilience								
3	2	1	Alternative 1	0	Alternative 2	1	2	3
Accessibility								
3	2	1	Alternative 1	0	Alternative 2	1	2	3
Safety								
3	2	1	Alternative 1	0	Alternative 2	1	2	3
Comfort								
3	2	1	Alternative 1	0	Alternative 2	1	2	3

Ranking:

- Alternative 2: 0.6
- Alternative 1: 0.4

Figure 4.29: 2nd floor AHP evaluation

After the workshop, the adjacency scores were calculated. The adjacency importance codes used in Figure 4.8, were transformed into numerical values according to Table 4.5. These values were

used as an input to calculate the adjacency score for each alternative. The results are presented in Table 4.6 and the ranking is the same that the one derived from AHP. Additionally, the requirements and concerns from Stage 1 were validated and reviewed to understand if something is missing and to judge the overall quality of the designs. With all this information, it was time for the next step, to decide if the project as come to an end or if another iteration is required.

Table 4.5: Adjacency importance numerical values

Importance	Value
A	64
E	16
I	4
O	1
U	0
X	-64

Table 4.6: Adjacency scores

Floor	Alternative	Score
4	1	6
4	2	10
2	1	140
2	2	172

Step 2: Decide

Analyzing the preliminary designs and their evaluation, there is still room for improvement. However, the clinical laboratory was confident that they could be refined in the next stages of the construction project (schematic design and detailed design), particularly since the design package is robust enough to provide the basis for future improvement. Thus, the PDL methodology was executed entirely and the preliminary design project was concluded without another feedback loop to Stage 1.

4.3 CASE STUDY DISCUSSION

The SCH case study was a great experience for the clinical laboratory and the ISE. Together they prepared the clinical laboratory to design their new workplace in an orderly manner with the application of the PDL methodology providing different preliminary designs and the design package as a result. In Appendix H, the design package items (shown in Chapter 3) is linked to the

specific activities that required planning and a collective effort. The different tasks were executed successfully having as a crucial factor the level of engagement and preparation of the clinical laboratory staff; they know what is best for their workplace and are continually looking for ideas to keep improving. They mastered engineering aspects like workflow, capacity constraints and other lean concepts. That in turn, simplified the application considerably. The PDL methodology provided a framework for collaboration between sections reducing the silo thinking, so common in a clinical laboratory.

The PDL methodology set the overall direction for the project. It helped to plan accordingly and to respond to the constant changes due to the environment and the information generated. It is important to acknowledge that in this type of project, uncertainty plays a major role and the PDL methodology acknowledges that factor and is flexible enough to leave space for unexpected circumstances. At the beginning of this case study, there was no clarity on where the clinical laboratory was going to be located and on how many floors. Then, information was released and changed frequently but this did not affect the PDL methodology application; it continued without major setbacks. Of course, for the clinical laboratory to be distributed across three locations is far from ideal; there is a negative impact on turnaround time and lost samples.

The evaluation method and criteria used for the different preliminary designs demonstrated that different points of view are necessary when a project of this type is executed. That helps to understand the trade-offs and the different visions of different stakeholders. The application of AHP helped to understand how the front-line staff saw the overall operation of the clinical laboratory. If necessary, managers and faculty could be asked to weight the factors and the results would likely be different. The important conclusion is not the resulting number but the overall analysis of the situation. In this case, AHP provided a sufficient analysis of the different designs; in other cases other metrics could be added if necessary.

After the PDL methodology execution, the schematic design process, led by the Forest B project, was started. As a way to evaluate the overall results of the PDL methodology, the first weeks of the schematic design phase were followed closely. Once the first version of the schematic design was completed, several conclusions were drawn about the application of the PDL methodology at SCH clinical laboratory:

- The biggest problem was the insufficient space to allocate all laboratory functions, something already acknowledged throughout the PDL methodology execution. This was

exacerbated by construction constraints such as columns and building access. It is hard to move things or to try different alternatives when there is not sufficient space.

- Although the final design is not a reflection of a specific preliminary designs, the PDL methodology results were the basis for the successful design of the clinical laboratory. It provided the starting point and the necessary resources, demonstrating that it is an important step to ensure stakeholder satisfaction.

With the case study description complete, in the next chapter an overall discussion of the PDL methodology and its application is presented including the proposed benefits and some guidelines for future work.

Chapter 5. DISCUSSION

Constructing a preliminary design of a system of integrated clinical laboratories is not a trivial task. The complexity is explained by the characteristics of clinical laboratories and the uncertainty of the future. The actual result will depend on how the problem is approached. The PDL methodology serves this specific purpose of managing the complexity in an orderly way and creating several preliminary designs that increase the chances of a successful process and an efficient physical configuration of the clinical laboratory where the stakeholders are satisfied with the result. This is achieved by the three stages considered: Stage 1 formulate the concept, Stage 2 develop design alternatives and Stage 3 evaluate alternatives. The feedback loops between Stages 2 and 1 and between Stages 3 and 1, reflect the need to add more information or to re-formulate the concept. The deliverables are the different preliminary designs and the design package. Additionally, there is value in the thinking process performed by all the people involved.

In the case study presented, the PDL methodology was tested in a real setting of a large pediatric hospital in the U.S. Since the methodology has space for flexibility, the specific context of Seattle Children's Hospital was a good example of how to use it. The ISE team and the hospital healthcare workers were quite satisfied with the results and felt they were much better prepared to continue the construction process led by the Forest B project.

It is important to acknowledge that success will always depend on the actual execution of the PDL methodology. Thus, the overall definitions and organization of the project should be carefully examined and if possible, tested beforehand (that includes the abilities of the people leading the PDL methodology application). There will always be people that cannot see the value of preliminary design and will want to wait for more concrete stages of the design process. The recommended approach is to explain the value of a preliminary design and how it relates with what comes after, particularly in these cases is where good planning is necessary, to minimize people's frustration.

5.1 BENEFITS

The benefits can be considered by thinking of an alternative path of not following a structured process. What would be the result? Although it is hard to think of hypothetical realities, there is a tendency to replicate older facilities and just give the space to each section of the laboratory with

the implicit instruction “just make the best of it”. Furthermore, if the architects do not have the appropriate skillset, the end result can be far worse and can be noticed by the following aspects:

- More time to execute the process
- Focus on generic concepts and not specific to the clinical laboratory
- Less collaboration and staff satisfaction
- Less space to re-evaluate process and think alternatives
- Not applying “form follows function”
- Increase cost of design changes
- Less transparent evaluation process
- In the end, a less efficient configuration at a higher cost

Another benefit of using the PDL methodology is that several methods and theories can be used in a structured process to help the construction of a preliminary design (e.g., AHP, CBA, SLP, 3P, queueing theory, optimization). Instead of choosing one, the best alternative is to have the flexibility to use each one when appropriate. Most of the approaches presented in this work can be used as complements, although that is not so clear while reviewing the specific domain literature. Furthermore, there are many other models and tools available that can also be incorporated if the specific context is appropriate.

In the preliminary design, where ideas can flow freely, it is important to use thoughts to formulate the concept for the clinical laboratory and achieve a better design. That makes the generation of alternatives a team effort, where all of the different perspectives should be incorporated. An idea could be a great contribution, but, if is not managed adequately, chances are that it will have the proper support. That and the fact that clinical laboratories are complex, is why every alternative generated should be in a workshop setting involving several people with different backgrounds and expertise. This also prevents the clinical laboratory of working in silos, increasing communication and disseminating ideas across sections.

There is additional value in generating the internal capabilities and training the clinical laboratory staff since they are likely to change their layout configuration multiple times in the future in response to technological changes and continuous process improvement. The case study provides a good example of how to plan and execute different workshops, where one of the largest difficulties was to react to the constant changes decided by the Forest B project.

And finally, the generation of information and the different ways to provide documentation and easy access created great value throughout the whole process. The information served to engage the different stakeholders and to track the advances made. The focus is on the quality rather than quantity, so that the information can be used to help inform decisions and can serve for the future projects of the clinical laboratory.

5.2 FUTURE WORK

One interesting question is what comes after the preliminary design. This work can be continued and incorporate the whole construction process and follow the same logic throughout the different stages. An evaluation could be made about the final design and how that relates to the different preliminary designs. Changes should be properly addressed and a description of how to react to those should be incorporated. Additionally, it would be interesting to quantify the value of the PDL methodology (e.g., money, time). It not an easy task, since the base scenario is not completely clear and several assumptions should be considered. Nevertheless, it can provide useful figures that can serve the purpose of showing the merits of a well defined process.

Additional cases studies and investigations could provide more evidence on the value of the methodology. Specifically, a case study where the clinical laboratory is its own construction project without depending on coordinating with other entities. Other modeling techniques could be applied to those case studies (e.g., ALDEP, discrete event simulation) as well as a more rigorous project management approach (RBS and WBS).

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APPENDIX A: CLINICAL LABORATORY DESCRIPTION TEMPLATE



Seattle Children's
HOSPITAL · RESEARCH · FOUNDATION

Clinical Laboratory

New Lab Design Description

Date: 01/25/2018

I General Information

N°	Category	Information
1	Description	<ul style="list-style-type: none"> A. <u>Services provided:</u> <ul style="list-style-type: none"> ○ <i>Service 1: Description</i> B. <u>Current Area:</u> <i>X sqf</i> C. <u>Projected Area:</u> <i>See annex N°1</i> D. <u>Current space:</u> <i>See annex N°2</i>
2	Sections	A. <u>Section 1:</u> <i>X sqf</i>
3	Other	A. <u>Administration/Management:</u> <i>X sqf</i>
4	Interactions	A. <u>Department 1:</u> <i>Description</i>
6	Workflow	<ul style="list-style-type: none"> A. <u>Inputs:</u> B. <u>Outputs:</u> C. <u>High-Level workflow:</u> <i>See annex N°3</i>
7	Employees	A. <u>Type:</u> <i>(X) Description</i>
8	Design Principles	A. <u>Design Principle 1:</u> <i>Description</i>
9	Metrics	<ul style="list-style-type: none"> A. <u>Metric 1:</u> <ul style="list-style-type: none"> ○ <i>Description</i> ○ <i>Data</i>

II Requirements

N°	Category	Information
1	Common Areas / Structure	<ul style="list-style-type: none"> A. <u>Tube system:</u> <i>Description</i> B. <u>Break rooms:</u> <i>How many? Size?</i> C. <u>Conference rooms:</u> <i>How many? Size?</i> D. <u>Locker rooms:</u> <i>How many? Description</i> E. <u>Supply delivery area:</u> <i>Description</i>

		F. <u>Huddle area</u> : Description
		G. <u>Restrooms</u> : How many?
		H. <u>Emergency showers</u> : How many?
		I. <u>Emergency eye wash stations</u> : How many?
		J. <u>Autoclave station</u> : Description
		K. <u>Glass washing station</u> : Description
		L. <u>UPS</u> : Universal or local?
2	Storage	A. <u>Chemicals</u> : Description B. <u>Long-term File Storage (Iron Mountain)</u> : Description
3	Refrigeration	C. <u>Fridges</u> : Description D. <u>Freezers</u> : Description E. <u>Cold rooms</u> : Description
6	Accessibility	A. <u>Couriers (Send-outs)</u> : Description B. <u>Drop-off Samples</u> : Description C. <u>Iron Mountain</u> : Description D. <u>Staff</u> : Description E. <u>Visitors</u> : Description F. <u>Emergency exits</u> : Description
7	Waste	A. <u>Solvent</u> : Description B. <u>Biohazard</u> : Description C. <u>Radiological</u> : Description
9	Schematic Design Requirements	A. <u>Emergency power</u> : For what? B. <u>Connectivity</u> : Type C. <u>Windows</u> : Description

III Concerns

N°	Category	Information
1	Preliminary Design Concerns	A. <u>Space</u> : Description B. <u>Category 2</u> : Description
2	Schematic Design Concerns	A. <u>Category 1</u> : Description
3	Future State	A. <u>Category 1</u> : Description

IV Ideas

N°	Category	Information
1	Common areas	A. <u>Category 1</u> : Description
2	Storage	1. <u>Category 1</u> : Description
3	Space	A. <u>Category 1</u> : Description
4	Transportation	A. <u>Category 1</u> : Description

5	Monuments	A. <u>Category 1:</u> <i>Description</i>
6	Future State	A. <u>Category 1:</u> <i>Description</i>
7	Schematic Design	A. <u>Category 1:</u> <i>Description</i>
8	Continuous Process Improvement	A. <u>Category 1:</u> <i>Description</i>

APPENDIX B: SECTIONS DESCRIPTION TEMPLATE



Clinical Laboratory

New Lab Design X Description

Date: 01/25/2018

I General Information

N°	Category	Information
1	Description	<ul style="list-style-type: none"> A. <u>Explanation:</u> Services offered B. <u>Operations:</u> How are the services executed? C. <u>Hours of Operation:</u> X AM to X PM M-F D. <u>Current Area:</u> X sqf E. <u>Current Space:</u> See annex N°1 F. <u>Projected Area:</u> X sqf G. <u>Driver for Space Requirements:</u> Test menu / Volume? H. <u>Other Limitations for Scaling Up:</u> People / Equipment?
2	Sections / Benches	<ul style="list-style-type: none"> A. <u>Section 1:</u> Description
3	Interactions	<ul style="list-style-type: none"> A. <u>Stakeholder 1:</u> Interaction description
4	TAT	<ul style="list-style-type: none"> A. <u>Rapid diagnosis:</u> X min (range) B. <u>Routine:</u> X hours (range)
5	Workload	<ul style="list-style-type: none"> A. <u>Test Menu:</u> Number of tests B. <u>Volume:</u> Number of tests in a period of time (description) C. <u>Forecasting:</u> Description D. <u>Evolution:</u> Description E. <u>Future growth:</u> Description F. <u>Special features:</u> Other
6	Other metrics	<ul style="list-style-type: none"> B. <u>Metric 1:</u> <ul style="list-style-type: none"> ○ Description ○ Data
7	Workflow	<ul style="list-style-type: none"> A. <u>Inputs:</u> What's coming in? B. <u>Outputs:</u> What's coming out? C. <u>Current workflow:</u> See annex N°2 and N°3
8	Staffing	<ul style="list-style-type: none"> A. <u>Designation:</u> Rotation? Fixed? B. <u>XAM to XAM:</u> X
9	Employees	<ul style="list-style-type: none"> A. <u>Type of Employee:</u> X
10	Equipment	<ul style="list-style-type: none"> A. <u>List:</u> See annex N°4

		B. Software: X
10	Services / Usage	A. Long-Term File Storage (Iron Mountain): Yes / No. Description B. Courier: Yes / No. Description C. Conference room: Yes / No D. Break room: Yes / No. E. Lockers: Yes / No F. Office supplies: Yes / No

II Requirements

N°	Category	Information
1	Monuments	A. Fume Hood: X B. Biosafety Hood: X C. Negative Pressure Room: X D. Tube Station: X E. Drain: X F. Sink: X
2	Physical Separation	A. Separation 1: Why? Description
3	Sections / Benches / Room Specifics	A. Section / Bench – Wet or Clean Bench / Room: Specifications
4	Visual Signs	A. Whiteboards: Description B. Category 2: Description
5	Chemicals	A. Nitrogen: Yes / No. For what? How much? B. Argon: Yes / No. For what? How much? C. CO2: Yes / No. For what? How much? D. Helium: Yes / No. For what? How much? E. Storage: Yes / No. For what? How much?
6	Storage	A. Samples: Yes / No. For what? How much? B. Solvent: Yes / No. For what? How much? C. Reactant: Yes / No. For what? How much? D. Blocks: Yes / No. For what? How much? E. Slides: Yes / No. For what? How much? F. Flammable: Yes / No. For what? How much? G. Vented: Yes / No. For what? How much? H. Demand flow: Yes / No. For what? How much? I. Record: Yes / No. For what? How much? J. Glassware: Yes / No. For what? How much? K. Coat Racks: Yes / No. For what? How much? L. Other materials: Yes / No. For what? How much?
7	Refrigeration	A. Fridges: Yes / No. For what? How much? B. Freezers: Yes / No. For what? How much? C. Cold room: Yes / No. For what? How much?

8	Waste	B. <u>Solvent:</u> Yes / No C. <u>Biohazard:</u> Yes / No D. <u>Radioactive:</u> Yes / No E. <u>Sharp:</u> Yes / No
9	Others	A. <u>Deionized water system:</u> Yes / No. For what? B. <u>Glass wash:</u> Yes / No C. <u>Autoclave:</u> Yes / No D. <u>Huddle Area:</u> Yes / No
10	Future State	A. <u>Category:</u> Description
11	Schematic Design Requirements	A. <u>Emergency Power:</u> Yes / No. For what? B. <u>Category 1:</u> Description

III Concerns

N°	Category	Information
1	Preliminary Design	A. <u>Space:</u> Description B. <u>Workflow:</u> Description C. <u>Category 3:</u> Description
2	Schematic Design	A. <u>Category 1:</u> Description
3	Operations	A. <u>Category 1:</u> Description
4	Desired Adjacencies	A. <u>Section:</u> Why?
5	Internal Adjacencies	A. <u>Bench X-Bench Y:</u> Why?

IV Ideas

N°	Category	Information
1	Space	A. <u>Idea 1:</u> Description
2	Continuous Process Improvement	B. <u>Idea 1:</u> Description

APPENDIX C: EQUIPMENT LIST SPREADSHEET

Equipment				
Maker				
Model				
Quantity				
Weight				
Size				
Volts				
Amps				
Watts				
Network Connection				
UPS				
Emergency Power				
Special Plug				
BTU				
Ven Out				
Gas				
Vacuum				
Drain				
Water				
Notes				
Bench / Section				
Use				

APPENDIX D: STRUCTURED INTERVIEW QUESTIONS



Clinical Laboratory

New Lab Design 1st Interview

Date: _____

Section: _____

Participants: _____

Number of people: _____

Shifts: _____

N°	Category	Question
1	Problems	A. What problems do you want to solve with the new design? B. What are your current physical space constraints that limit expansion or adding new services? C. What other resources limit your ability to scale up [to meet increasing demand, add new technology and new testing]? (People? Equipment?) D. What are the biggest problems that your staff experience in the current space?
2	Subsections	A. Does your section have different benches? What do they do? B. Does your section have sub-sections or different areas that perform different tasks? What do they do? C. Do you need physical separation for some processes or subsections?
3	Special features	A. What's unique about this section of the lab compared to other sections?
4	Building infrastructure	A. Do you have special building infrastructure needs? For the lab sections: 1) Fume Hood(s)? 2) Biosafety Hood(s), 3) Separate Room (e.g. PCR)?, 4) Negative Pressure Room, 5) Drains, 6) Chemical Storage, 7) Gas Storage, 8) Cold Room, 9) Nitrogen Generation, 10) Flammable storage, 11) short and long term record or materials storage
5	Performance	A. What aspects of the overall lab design are critical to your performance? B. How do you measure the performance of the section?
6	Innovation	A. What new ideas do you have for the future space (think out of the box)?
7	Change	A. What changes would you like to see in the new lab? B. What new technology [or new instruments] do you plan to add to the lab by 2025? What are its anticipated special needs (e.g. connectivity, drain, water)?

Comments: _____

APPENDIX E: DESIGN WORKSHOP I INSTRUCTIONS



Clinical Laboratory

New Lab Design Workshop I Guide

Date: 02/09/2018

Scenarios:

1. One floor
2. Two floors (70%, 30%)
3. Three floors (60%, 20%, 20%). Do not consider administrative functions (Client Services, LGC/PLUGS, POC, LIS)
- 4.

Sections (required):

Named Spaces to be Included in Layout Candidates	Approximate Current Size	Represent with # and Size of Post-Its	For team use
1. Anatomic Pathology/Path Admin	3000 sqf.	2 big post-it	
2. Histology	1420 sqf.	1 big post-it	
3. CPA/Sendouts/CS	2275 sqf.	2 big post-it.	
4. Core	2200 sqf.	2 big post-it.	
5. Transfusion	920 sqf.	1 big post-it.	
6. Microbiology	2300 sqf.	2 big post-it.	
7. Molecular Micro	1000 sqf.	1 big post-it.	
8. Client Services	450 sqf.	1 small post-it.	
9. RLS	468 sqf.	1 small post-it.	
10. Chemistry	2730 sqf.	2 big post-it.	
11. Biochemical Genetics	1180 sqf.	1 big-post-it.	
12. Cell Markers	1300 sqf.	1 big post-it.	
13. Cyto/Molecular Genetics/Array	4328 sqf.	3 big post-it.	
14. LGC/PLUGS	400 sqf.	1 small post-it.	
15. POC	320 sqf.	1 small post-it.	

16. LIS	280 sqf.	1 small post-it.	
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Other areas (optional) :

Other Named Spaces that may be Included in Layout Candidates	Represent with # and Size of Post-Its	For Team Use
1. Administration/Management.	1 big post-it.	
2. Break rooms.	1 small post-it.	
3. Conference rooms.	1 small post-it.	
4. Locker rooms.	1 small post-it.	
5. Supply delivery area (box breakdown).	1 small post-it.	
6. Huddle.	1 small post-it.	
7. Restroom.	1 small post-it.	
8. Storage.	1 small post-it.	
9. Iron Mountain.	1 small post-it.	
10. Freezer Farm.	1 big post-it.	

Tube System (required):

Pneumatic Tube Drop. **1 dot**

Other (optional):

Incorporated as notes or drawings (i.e. in-lab transportation system, centralized sample storage)

7 flows of the laboratory (optional):

1. Samples: Light blue
2. Laboratory Staff: Light green
3. Equipment/Glassware: Yellow
4. Supplies: Red
5. Information: Black
6. Couriers/Visitors: Blue
7. Waste: Pink

Pros and Cons (required): Examples of Evaluation Criteria

1. Space for growth
2. Flexibility
3. Workflow

4. Line of Sight
5. Resilience (e.g. tube system down)
6. Maintenance
7. Accessibility
8. Comfort
9. Safety
10. Cost

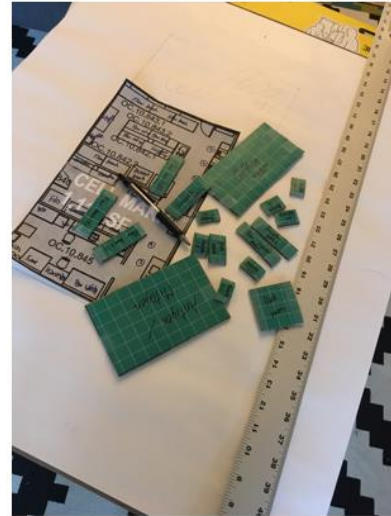
APPENDIX F: DESIGN WORKSHOP II CHECKLIST

Cell Markers	MG/Cyto	
		1-Materials and tools
X	X	Define scale
X	X	Current layout
X	X	Projected Space
X	X	Building Blocks
X	X	Green Sheets
X	X	Instructions
X	X	Components Spreadsheet
X	X	Print Themes
		2-Section information
X	X	Description (document)
X	X	Equipment List
X	X	HR list
X	X	Current volume and projections
X	X	Components Spreadsheet
X	X	Internal Adjacency
X	X	3-Define themes
		4-Attendees list and confirmation
		X
		5-Pre-workshop meeting
X	X	Scheduled
X	X	Topics Reviewed
X		6-Conference room booked
X		7-Presentation

APPENDIX G: DESIGN WORKSHOP II INSTRUCTIONS

Overall process

1. Design your lab using cardboard pieces.
See the themes for each lab.
2. There's space to change sizes and shapes
by creating new pieces or adding notes
3. Think about your current process but think
also in the future growth (What if the test
volume doubled?)
4. Capture information with notes (space for
further changes)
 - I. Things to pay attention
 - II. Things missing
 - III. Things that should be bigger
 - IV. Etc.

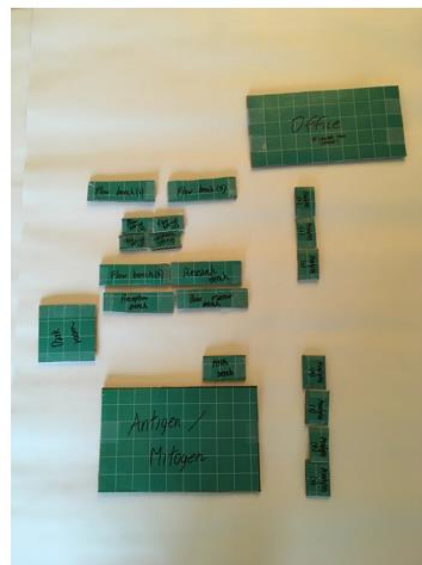


Step 1: Place

1. Place the objects in the post-it pad
2. Use pencils to simulate the flow of people
and specimens

*If you need to, you can go the current lab to
measure objects.

**To make changes to the shapes or sizes, or
to aggregate items (Core/Micro), go to the
facilitator station or wait until you draw them



Step 2: Draw

1. Capture the arrangement by drawing a box around each defined space (you can change the size or shape)
2. Within each box, write the name of the space and make a reference in **red** to doors or walls (if any)
3. Label the layout with a title (name) for the alternative
4. Notes concerning your layout that you believe are important to capture
5. Add references or drawings of subcomponents (e.g., tube station, Biosafety cabinet, instruments) [Optional but recommended]

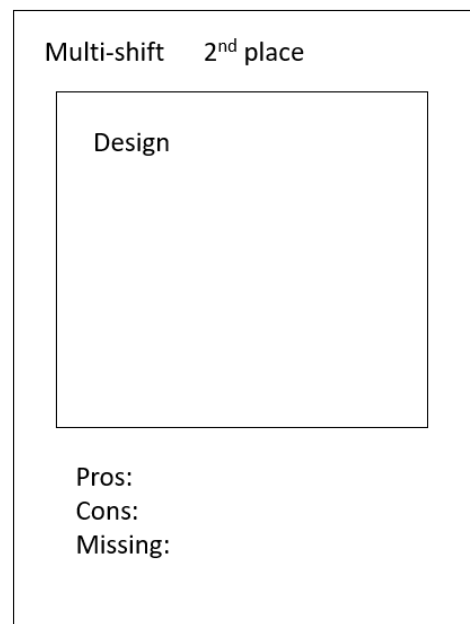


Step 3: Evaluation (at the end)

1. Rank alternatives (number on top)
2. Draw the flows of the laboratory
3. Pros and cons (try to include explicit evaluation of the alternatives for expansion)
4. What is missing or what we don't know that can influence the design

Flows of the laboratory:

1. Samples: Light blue
 2. Laboratory Staff: Light green
 3. Couriers/Visitors: Blue
- Use red over the other color to indicate increase flow rate



APPENDIX H: SCH'S DESIGN PACKAGE SPECIFIC ACTIVITIES

Item	Specific Activities
Project Definition	-
Literature and experts	-
Organization	-
Construction Project	-
Stakeholders	-
Benchmarking	Laboratory tours (2017-2018)
Design Principles	-
Evaluation Criteria/Method	-
Clinical Laboratory Description	Structured Interviews (12-2018) Facility Tours (12-2018) Adjacency educational workshop (12-2018)
Sections Description	Structured Interviews (12-2018) Facility Tours (12-2018)
External lab users and stakeholders	-
High-level bubble diagrams	Workshop (02-2018)
Sections Space Spreadsheet	-
Sections Designs	3 Workshops (04-2018)
Components Spreadsheet	-
Preliminary designs evaluation	Workshop (05-2018)