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DEVELOPING DOMAIN-SPECIFIC SIMULATION OBJECTS FOR MODELING CLINICAL LABORATORY OPERATIONS

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ABSTRACT

Clinical laboratories play a critical role in patient diagnosis, treatment planning and prevention of disease, but, as with all elements of healthcare, they are under increasing pressure to improve performance and reduce costs. Although clinical laboratories reflect many aspects of traditional production systems, the medical profession is, as are most specialized areas of practice, much more willing to entertain analytical methods that describe their systems with domain-appropriate terminology and semantics. In this paper we discuss the development of a framework for creating domain-specific simulation objects for modeling clinical laboratories; we demonstrate their applicability in projects undertaken with the chemistry laboratory at Seattle Children's Hospital. The primary objective of our work is to improve the efficiency of building clinical laboratory discrete-event simulation models.

1 INTRODUCTION

The clinical laboratory plays an important role in the healthcare system by providing physicians and other healthcare professionals critical information needed to "detect and predict disease; confirm or reject a diagnosis; establish prognosis; guide patient management; and monitor efficacy of therapy" (Kurec 2000). The complexity of clinical laboratory systems lies in the volume and variety of specimens that must be processed, the range of analytical tests to be undertaken and the specialized lab equipment and instruments used to perform those tests. Effective management and use of the equipment, instruments and facilities requires laboratory technologists (LTs) with specialized skills.

With increasing test workloads, pressure to reduce costs and demand for quicker analytical results, laboratory leadership must consider a variety of ways to improve the performance of their operations. Potential avenues include purchasing newer instrumentation, which may include more automation; expanding the menu of analytical tests provided by their labs; increasing the number of reference clients served; revising/expanding the hours of operation; refining clinical laboratory work flow; and adjusting their lab technician staffing model. However, managers want to understand how the performance of their operations will be affected by potential changes in their laboratory configurations and operating policies.

As might be expected, when considering improvements to production systems, many organizations have employed Lean and Six-Sigma methodologies to improve clinical lab performance and reduce costs (Sunyog 2003). Rutledge, Xu, and Simpson (2010) at Seattle Children's Hospital (SCH) used Toyota production system strategies to reduce test turnaround time (TAT) and decrease handling errors. Marinagia et al. (2000) used a patient-wise planning and scheduling approach for managing patient tests in a hospital environment using a multi-agent blackboard-based architecture. Although simulation has been used extensively to model many aspects of the healthcare delivery system, there has been little use of simulation to investigate the

impact of changes to a hospital's clinical laboratories. We believe that the reasons simulation has not been used in clinical labs is an example of a common situation: the people with expertise in a particular area (in this case clinical laboratory operations) are unaware of simulation as a modeling technique and/or they do not have the technical expertise needed to use computer-based simulation.

It is time consuming and requires knowledge beyond just knowing how to use simulation software to develop simulation models for a specific domain (Sadowski and Grant 1999). Hiring a model builder to conduct a simulation study may not be efficient, since the model builder may not be familiar with important aspects of the particular domain. This may lead to a lack of confidence in the model, as well as misuse of the model by the domain experts who own the problem. The approach we have taken is to develop the resources that will help the domain experts build their own models. This can not only improve their confidence in the models, but help domain experts gain insights about their problems while building the model (Heim 2001). Furthermore, if skilled modelers are available, language constructs that reflect the unique and important aspects of the particular environment can significantly increase model building efficiency and experimentation as larger "chunks" of domain knowledge are encapsulated and associated modeling performance verified. Providing an improved set of language constructs, or components, to better represent the problem domain, has always been a fundamental driver in computer programming language development. That is our objective as well.

According to Setavoraphan and Grant (2008), conceptual modeling (CM) and domain specific simulation environments (DSSE) are recognized as critical steps to improve the quality and efficiency of discrete-event simulation (DES). The advantages of using DSSE, which is summarized by Valentin and Verbraeck (2005) includes better understanding of the simulation model by problem owner (Pater and Teunisse 1997, Kasputis and Ng 2000); easier generation of new simulation experiments (Pater and Teunisse 1997; Altiok, Xiong, and Gunduc 2001); easier validation of the model; less instances of model constructs (Kasputis and Ng 2000; Altiok, Xiong, and Gunduc 2001). Valentin and Verbraeck (2005) did an experiment to compare the DSSE and non-DSSE, which helped demonstrate the value of DSSE, as well as guidelines for constructing and using DSSE.

The immediate goal of our work is to develop a collection of clinical laboratory simulation objects that will provide laboratory professionals the means to quickly assemble models of their environment, at the level of fidelity required. The simulation objects should provide sufficient flexibility to analyze a variety of complex clinical laboratory configurations and evaluate alternative operation strategies and policies.

2 METHODOLOGY

2.1 Object-Oriented Programming

Our approach is based on a common engineering (and programming) concept: break down a complex problem into smaller problems that we can individually address. We applied object-oriented principles to the identification of critical components of the clinical laboratory environment and to the development of the allied simulation objects.

2.2 Conceptual Modeling

Laboratory activities were observed to determine which objects would be included in the initial collection. As the domain analysis was undertaken, information about each of the critical elements was captured in a standard format that would eventually be used to guide design and construction of the simulation objects. In this case, each laboratory analysis (test) and necessary instruments, resources and credentialed staff requirements were identified. One important part of the documentation is a fully annotated process flow diagram that identifies the major sequence of activities associated with each test; provides a description of the constituent activity tasks accomplished at each step; captures the distribution of processing times for each step; identifies the resources required for each step; and includes additional information such as results reporting requirements. The documentation was verified with laboratory experts to assure that it

was a good reflection of the process as performed in the laboratory. The flow diagrams and additional function explanations are, in effect, the conceptual models of the primary activities that occur in the clinical labs, the specifications for the simulation objects that will be created. One challenge was deciding the level of abstraction fidelity needed for decision making. Therefore, modelers and their partner experts have to decide which aspects of the domain are most important and how to implement them appropriately as simulation constructs (Wang et al. 2013). The resulting collection of objects created for a specific domain, which represent how the real systems operate, should be understood by both model builders and domain experts (Glassey and Adiga 1990).

3 DOMAIN DESCRIPTION

The clinical laboratory is at the core of a complex three-phase system that must smoothly and reliably integrate pre-analysis, analysis, and post-analysis activities. The pre-analysis phase refers to the activities from the time the laboratory tests are ordered by care providers and samples are collected from the patient and then transported to the labs under proper environmental conditions (e.g., room temp, frozen). The analysis phase refers to the laboratory activities to prepare the specimens, perform the tests, and produce results, such as chemical assays on one or more instruments. The post-analysis phase refers to patient reporting and result interpretation by health care professionals (McPherson and Pincus 2007). Although our objective is to develop a set of simulation objects for modeling clinical laboratories, the initial project focused on the chemistry laboratory at Seattle Children's Hospital (SCH), which is one of the more complex laboratory operations at SCH in terms of equipment, analytical processes, and reference client services. The work reported in this paper is concerned with the analysis phase of clinical laboratory operations.

3.1 Chemistry Laboratory at Seattle Children's Hospital

The chemistry laboratory at SCH provides a broad range of testing and analysis services for SCH patients and a number of external reference clients (i.e., other hospitals and clinics). Because of an increasing demand for services, the laboratory has experienced some difficulties in maintaining target TATs. The chemistry laboratory has considered how changes to configurations, space, resources, and test schedules could improve efficiency, meet TAT performance goals, and support continued expansion of services and reference laboratory clients.

3.2 Domain Analysis for Modeling

There were two objectives for the clinical laboratory domain analysis: 1) to create a shared language, or ontology, for modelers and lab professionals to communicate unambiguously about clinical labs and associated operations; and 2) map the important elements and features of the domain into an organizing structure that would guide modelers developing the clinical lab simulation objects. "In the context of computer and information sciences, an ontology defines a set of representational primitives with which to model a domain of knowledge or discourse" (Gruber 2009). Here, a clinical laboratory ontology is developed to identify the physical objects in the laboratory, as shown in Figure 1. The framework we used is an object hierarchy, or tree, and the process for constructing the ontology follows the work that was done by Wang et al. (2013).

At its most abstract levels of the ontology, the laboratory is seen as instances of staff, specimens that arrive for analysis, documented test procedures, and the variety of equipment necessary to store, prepare, and analyze the specimens. The equipment can be further divided into four categories. The most complex is test-essential equipment, which are generally complex instruments used to perform chemistry based analyses; storage equipment, where specimens are staged until analysis is initiated; administrative equipment, such as printers, scanners and computers; and laboratory furniture. While laboratory furniture seems an odd element to include, this category determines the amount of bench top space available for smaller lab instruments and preparatory operations. This study focused primarily on the analytical instruments

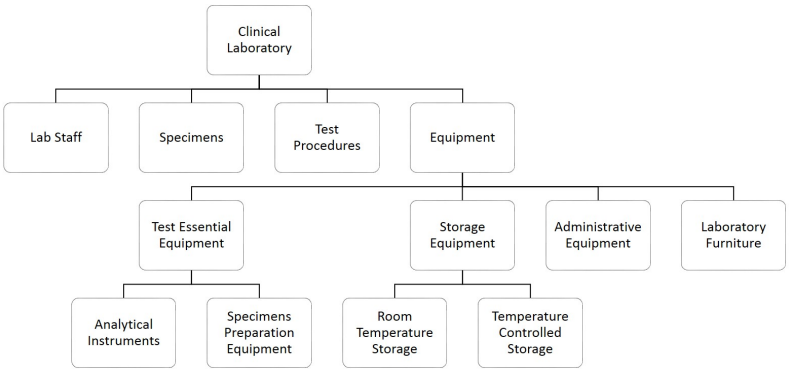

Figure 1: Ontology of the clinical laboratory.

because of the complexity, uniqueness, and modeling challenges they present as well as the opportunities they provided to improve the laboratory performance. Using the ontology as a guideline, a set of simulation objects for modeling clinical laboratories were defined. The simulation object tree is shown in Figure 2.

The simulation object tree reflects the set of the objects we developed for clinical laboratories and their class relationship: specimens, lab technologists (LT), test-essential equipment, manual tasks, storage equipment and the clinical lab process database. Several of the objects represent information sources (e.g., lab database) or ways of performing tasks (e.g., manual or automated). Test-essential equipment is categorized according to the four ways specimens are loaded on the equipment and the processing logic employed. The characteristics for each category are specified in Table 1.

Table 1: Test-essential equipment type based loading on processing logic.

	Input		Processing			Description
	Single	Batch	Single	Batch	Hybrid	
Type 1	✓		✓			Specimens are processed individually (single piece flow).
Type 2		✓			✓	Specimens are loaded as a batch. Each specimen may require different number of assays. The processing time may be different for each specimen.
Type 3		✓		✓		Specimens are loaded as a batch. All the specimens in the batch are processed identically. The processing time for the batch is generally independent of the batch size.
Type 4		✓	✓			Specimens are loaded as a batch. Specimens are processed individually (single piece flow).

4 OBJECT CONSTRUCTION

After domain analysis has identied the necessary collection of simulation objects, their relationships, and common functionalities, the next step is to translate those definitions into DES language constructs, which are our clinical lab objects. In this project we have used the Simio modeling language because of its

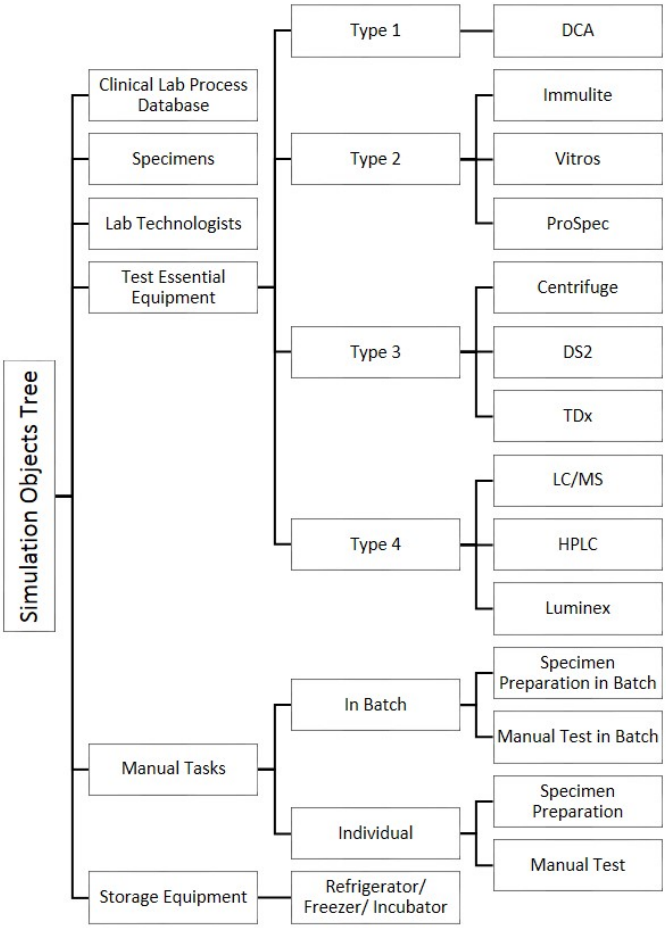

Figure 2: Simulation object tree.

strong object-oriented foundations and ease of developing domain specific environments. The verification and validation of the objects are obviously two critical steps in constructing simulation models. Before they are used, all object models are individually verified for correct results and validated for their ability to adequately reflect the important aspects of the problem domain. In this section, we will introduce the structure of those objects.

4.1 Simio as Foundation

Simio is an object-oriented simulation modeling framework that also supports a seamless use of multiple modeling paradigms including event, process, object, and agent-based modeling (Pegden and Sturrock 2010). We chose Simio because of its flexibility and facilities for building a family of domain specific objects.

4.2 Object Structure

Most objects include a unique icon for display in the model workspace and appropriately named input and output interfaces of the object (parameter names that correspond to the terminology used by lab professionals not modelers). Objects are configured by assigning the appropriate values to the object parameters. An example of the parameter fields for an object is shown in Figure 3.

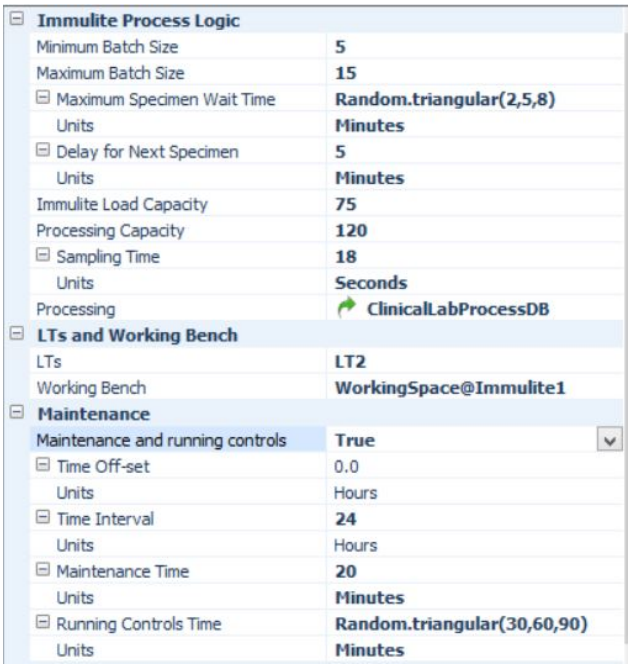

Figure 3: Processing parameters and process database references for an Immulite instrument simulation object.

4.2.1 Clinical Lab Process Database

The information associated with different kinds of tests and analyses are stored in a clinical lab process database object. Specimen objects are assigned information concerning the list of tests that will be performed on them as they arrive to the lab model. The specimens will carry the information through the system, and analytical instrument objects extract the necessary information from the database to process the TestIDs, which represent different tests, carried by the specimen objects (modeled as entities). There is some pre-defined information which is necessary for using the created objects. Additional information can be added into the database based on modeling needs.

The advantages of using a database is to reduce the work when new tests are added in the lab. All the domain experts need to do is to add another row which contains the information of the new test. Also, new columns can be added easily based on the modeler's need.

4.2.2 Test-Essential Equipment

Test-essential equipment is used to either prepare specimens, or analyze specimens during testing. The processes on test-essential equipment follow a similar flow, as shown in Figure 4. There is one exception. The centrifuge is not an analytical instrument, so for the centrifuge there are no verify and report results steps. Four different types of test-essential equipment has already been discussed in Section 3.2 (Table 1).

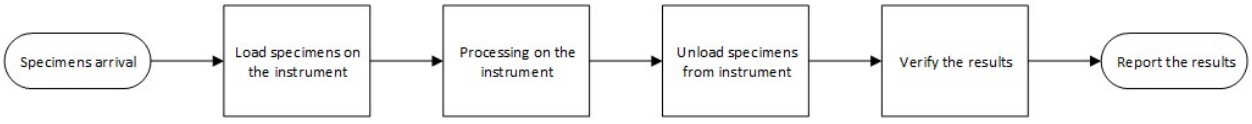

Figure 4: Process flow on test-essential equipment.

A very important part of modeling the test-essential equipment is to reflect the alternative methods of batching, which is the gathering and grouping of specimens to balance throughput, TAT, and laboratory resource utilization. Most of the clinical lab simulation objects (e.g., test-essential equipment) use batching logic to organize specimens for subsequent process/analysis. The objective of the lab object batching logic is to represent specific policies the LTs are supposed to follow while flowing specimens through the lab facilities. The batching logic uses four parameters to support exploration of a wide range of complex production control/dispatch strategies.

- **Maximum Batch Size**: this parameter determines the maximum number of specimens that may be in the same batch. This parameter may be a constraint of the instrument (its capacity), or the ability of LTs who are processing the batch. When the number of specimens reaches the maximum batch size, the specimens in the batch are processed.
- **Minimum Batch Size**: this may be a function of the costs associated with initiating a series of assays, such as reagents or other supplies. The LTs are encouraged to wait until that minimum number of specimens is available. Unless there is sufficient demand, LTs do not usually process a specimen when it first arrives to the lab. They wait for more specimens to process together.
- **Maximum Specimen Wait Time**: there may be situations when the number of specimens have not reached the minimum batch size and the specimens have been waiting for some period of time. Test procedures dictate how long specimens can wait. When the waiting time for any of the specimens exceeds the maximum specimen wait time, all specimens that are waiting are processed regardless of the number of specimens in the waiting queue.
- **Delay for Next Specimen**: specimens are not always batched right after the number of specimens available reaches the minimum batch size. If there is another specimen coming soon, then it is reasonable to assume that LTs will wait for that specimen. So, when the number of specimens reach the minimum batch size the last specimen will be given a time window. If this time window elapses and no specimen arrives then all the specimens waiting are processed.

4.2.3 Manual Tasks

Manual tasks are the processes that are done by LTs without the use of highly-automated analytical instruments. There are wide variations in the times for completing manual tasks; some may require as short as five minutes, while others may take several hours. In order to model the complexity and make the objects more flexible in reflecting different kinds of processes, we divide a manual task into a series of hands-on and hands-off processes. A hands-on process requires LT resources, while hands-off processes do not require LT resources to complete. Our manual task objects provide one unit of manual task activity, which includes one hands-on process and one hands-off process. The modeler can choose to combine multiple instances of the manual task object to model a complex manual task. Each of the two manual tasks, specimen preparation tasks and manual tests, has two types of process logics: batch and single piece flow.

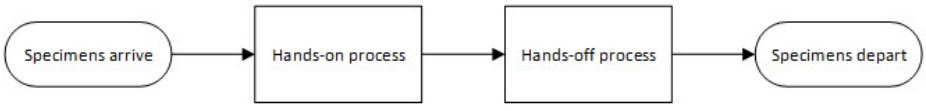

Figure 5: Process flow for manual tests and specimens preparation.

4.2.4 Storage

Refrigerators, freezers, and incubators are instances of the same simulation object since temperature is a parameter of the object and does not affect its function. When specimens arrive they are placed in a

storage unit. The storage object is modeled as a detached queue. An order (i.e., entity), which carries the information about what kind of specimens are to be analyzed, will remove the specimens which match the information. In some instances, LTs are required for storing and removing specimens. The tests are scheduled on specific days of the week. The orders can be controlled to model different working schedules.

4.2.5 Other Objects

There are a number of simulation objects in the simulation objects tree, illustrated in Figure 2, that are not discussed (e.g., specimen, and lab technologist). These objects are instances of fundamental constructs of Simio standard library.

5 CASE STUDIES

To demonstrate the applicability of the created simulation objects, we present three case studies used to investigate lab performance. Case 1 is a bench level model, which contains a small number of test instruments and associated preparation equipment. Case 2 is a more complex model. It reflects the complete SCH chemistry laboratory which includes additional instruments and specimen preparation equipment. Case 1 is embedded inside Case 2. Our third case demonstrates the ability to quickly construct enterprise models to investigate the impact on the chemistry lab of radically increased activity in another functional unit of the hospital. Case 2 is embedded inside Case 3.

5.1 Case 1: Bench Level Models

A laboratory is a collection of specialized benches or workstations. Each of which focuses on one or more types of tests. Each bench typically includes specimen preparation equipment and analytical instruments. Our use of the term "bench level" means that the model consists of a *limited* number of benches and instruments. In this case we demonstrate a bench level simulation model with three LC/MS instruments. Each of them has a different capacity. Several types of tests are analyzed using LC/MS instruments. These tests are scheduled on different days of the week. Lab managers wanted to study how to schedule these tests to make a better use of the three instruments and investigate how many LTs would be needed to operate three instruments.

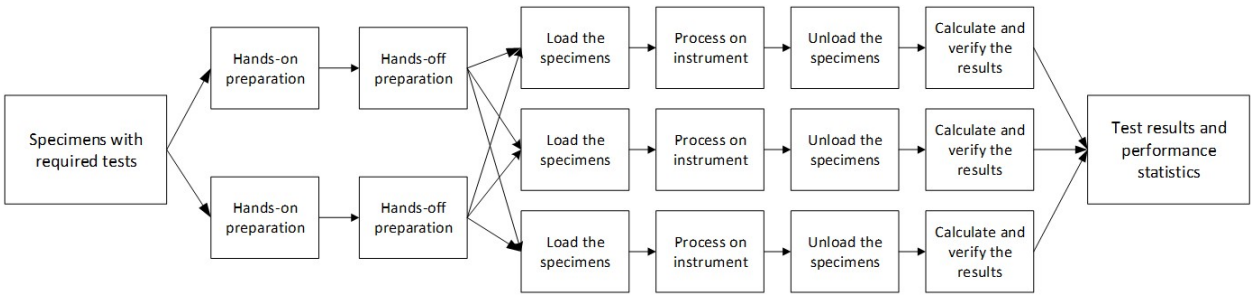

Figure 6: Case 1 model of the LC/MS bench constructed without benefit of the domain-specific objects.

Figure 6 shows a model constructed without the developed objects. In this model each step of specimen preparation and testing is modeled individually. In comparison, Figure 7 shows an alternative model constructed with the developed specimen preparation and LC/MS objects. The alternative model contains fewer instances of model constructs, which indicates that the alternative model takes less time to build. The fact that the objects in the model are mapped to real world equipment and processes help domain experts understand the model. With many functions pre-defined in the objects, less time is required to validate the model.

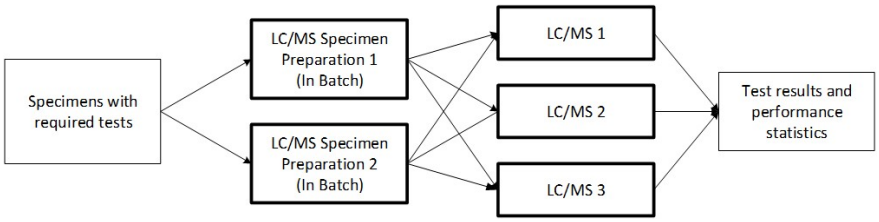

Figure 7: Case 1 model of the LC/MS bench using the clinical lab objects: specimen preparation in batch, LC/MS.

As currently configured, the standard set of statistics that are reported by the simulation environment, in this case, Simio, are used to evaluate the performance of the model system. We are currently adding performance metrics specific to clinical laboratories.

Simulation on a small scale is often difficult to justify since the outcome may not be significant enough when compared to the cost of developing the simulation. When the model objects are available, however, many of the domain experts can build adequate models without incurring the costs that result from involving IT and modeling experts.

5.2 Case 2: Laboratory Model

In this case, we discuss the SCH chemistry laboratory modeled with the clinical lab simulation objects we developed. The model is shown in Figure 8.

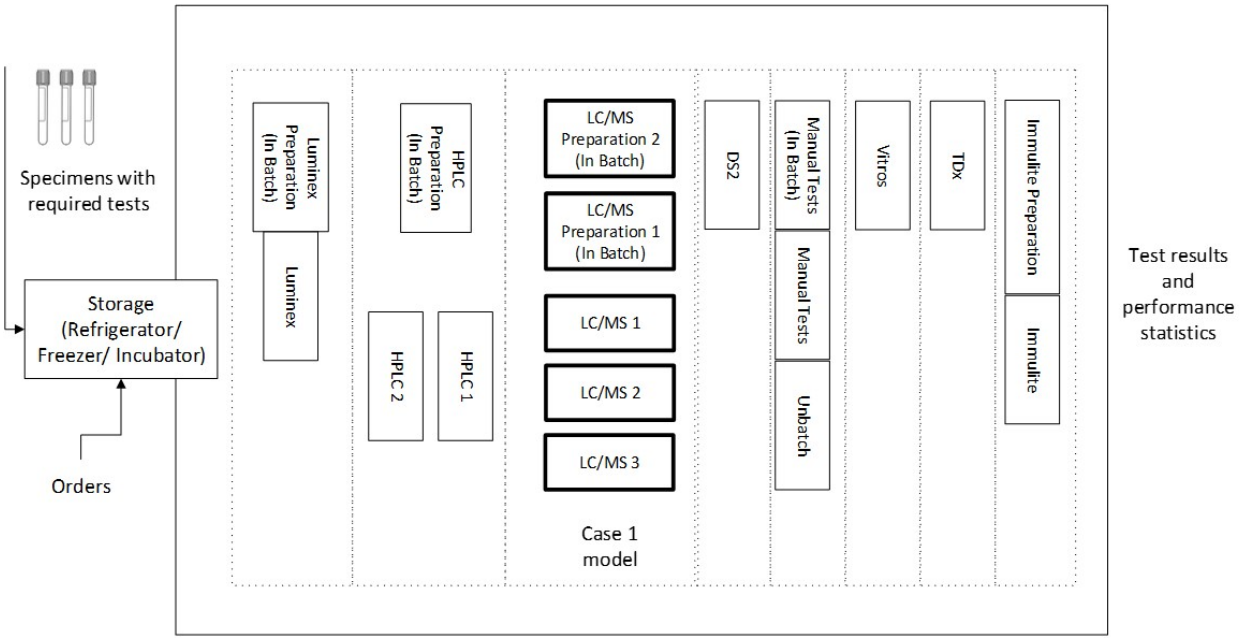

Figure 8: Case 2 model of the chemistry laboratory in SCH.

When specimens arrive, they are assigned with testing information from the database, including their route in the lab. They are then placed in a refrigerated storage facility. The specimens will not be processed until their scheduled day. An order entity is sent to storage with information on which specific tests to process. The specimens requiring these tests are removed from storage and move through the lab based on their particular route (obtained from the lab process database object). The model developed in Case 1 is embedded inside Case 2 as part of the lab model. This lab model is used in a number of ways to explore

the capacity and scheduling of the chemistry laboratory, as well as examine the consequences of changes in reference client demand. Modeler-specified metrics are used to determine the performance of the lab and evaluate operation policies, staffing levels, and service levels.

The model in Case 2 is more complicated in terms of the number of objects and tests involved compared to Case 1. Objects that represent instruments and processes are used in constructing the model which make it easier for the domain experts to map to the real world. If a method similar to the one used to construct the model in Figure 6 is applied to build this whole lab model, it is not only time consuming and difficult for model builders to construct, but because of its complexity, it is also hard for domain experts to understand and validate. Therefore, there is a higher possibility of making mistakes in the construction and application of the model.

5.3 Case 3: Occupational Health Services (OHS) Clinic and Laboratory Medicine

The final case illustrates the value of the developed clinical lab objects by quickly constructing simulation models and answering questions concerning the impact of one functional unit on the performance of another unit in the same organization. In 2011, SCH adopted a creative method for combining their annual flu immunization campaign with the tuberculosis (TB) screening required of each hospital worker (employees, students and volunteers). Instead of visiting the SCH Occupational Health Services Clinic twice during the year, the healthcare workers would visit only once to have their flu immunization shot and a blood draw for TB screening. The model is shown in Figure 9.

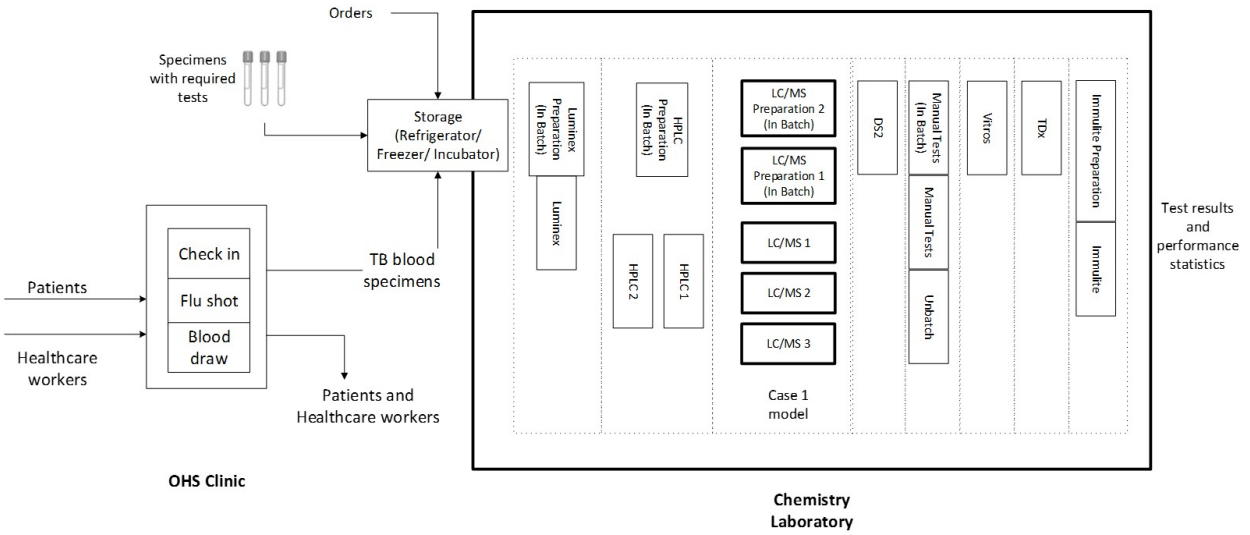

Figure 9: Case 3 model of occupational health services and chemistry laboratory.

The model contains two primary objects: the OHS clinic and the chemistry laboratory. Patients and healthcare workers arrive at the OHS clinic for flu shots. Healthcare workers also have a blood sample taken for the TB screen; the blood specimens are transported in batches to the chemistry lab several times during the day. The analytical instrument used for analysis is DS2. The TB specimens will impact the workload on DS2 and could potentially have an impact on the overall performance of the chemistry lab. The arrival of patients and healthcare workers is predicted in advance. SCH wants to know how many nurses and phlebotomists will be needed to perform the operations in the OHS clinic as well as how the campaign will impact the chemistry laboratory. The chemistry laboratory object in Figure 9 is simply the Case 2 model shown earlier. With this model, different resource allocation strategies can be tested.

6 DISCUSSION

Our primary objective has been to improve the efficiency of building clinical laboratory models, but we also want to make DES modeling accessible to the domain professionals who otherwise might not have the skills, time and motivation to construct models that would support data-driven decisions concerning their operations. We have begun assessing the usefulness of the laboratory simulation objects with the chemistry laboratory managers and domain-naive engineering students.

After a brief introduction to simulation modeling and the Simio language over a six week period, the SCH laboratory professionals successfully built smaller models, such as our Case 1. We have also evaluated the ability of undergraduate engineering students, who have taken an introductory course in simulation modeling, to quickly develop useful clinical laboratory models (a domain with which they have little experience). The feedback we received and the results of the modeling endeavors by the lab managers and students has helped demonstrate the value of high-level domain-specific constructs and also identified further object development needs.

We have also confirmed that the availability of these domain-specific objects can substantially improve the efficiency of modelers that are building more complex and comprehensive simulations of clinical laboratories, even when they have a good understanding of lab operations and testing procedures. The work we reported here is for a complex chemistry laboratory in a hospital environment. The demand for certain tests are high, but some tests are run only a few times per week, so turnaround time (TAT) *variance* is of greater concern than elapsed time from receipt of specimens until results reporting. We have also applied the same modeling approach to the SCH core lab, a much higher volume operation with intense demand for reducing TAT. The framework we have created provides a useful guide for developing additional instrument and domain specific objects as we expand the variety of clinical laboratories we are able to model.

ACKNOWLEDGMENTS

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