The Clinical Chemical Laboratory

Internship Report

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1. INTRODUCTION

This thesis is the final report of our internship at the clinical laboratory of the Academic Medical Center (AMC) in Amsterdam. This internship was performed for our study, Medical Information Engineering, at the University of Amsterdam.

During this internship, we closely studied two different, but connected hospital systems: the clinical laboratory and the DIO project (Data Integration for Research). The clinical laboratory performs various analyses of bodily fluids, to support the diagnostic processes in the hospital. The DIO project is an initiative of the AMC and IBM, and integrates several of the hospital's clinical databases, of which the laboratory database (LABZIS) is one of many, and is meant to support scientific research by enabling researchers to collect data from all these databases with a single query.

The results of our study are presented as (Three Layer Graph Models) 3LGM models. 3LGM is a meta-modeling technique especially created for the modeling of Hospital Information Systems (HIS), and is focused at three layers of information management: a domain layer with enterprise functions, a logical tool layer with application components, and a physical tool layer with physical devices running the application components. All components are described, along with their function, their communication with other components, and the ways in which the functions and application components map on their underlying layers.

We used the 3LGM model to identify two problems with the processing of information. These problems are described, together with a possible solution. An overall quality assessment of the laboratory information system is also included.

We would like to thank the laboratory staff and the DIO project managers for their support in completing our internship, especially our supervisor Dr. J. Dols at the department of Clinical Chemistry.

2. METHODS

During our internship we studied two separate but connected hospital systems, as stated in the introduction. We used the same methodology to analyze both the clinical laboratory and the DIO project, but for the second part of our assignment, the creation of activity diagrams and the analysis of the quality of the information system, we focused on the clinical laboratory.

We acquired the necessary information mainly through interviewing people working on the DIO project and people working on the clinical laboratory. For the DIO Project, we interviewed Ms. E. Honig van Den Bossche (Project Leader), Mr. R. Verheij (IBM IT Architect) and Mr. R. Poppen (ETL Specialist). For the clinical laboratory we interviewed Mr. J. Dols (Clinical Chemist) and the laboratory's dedicated IT specialists, Mr. M. Regeling, Mr M. van Bemmel and Mr. P. Wissink.

These interviews resulted in the identification of Enterprise functions (Business functions), application components, and physical data processing tools. We used this information to create 3LGM models of the DIO project and the clinical laboratory, which we confirmed in new interviews with the abovementioned persons. Suggestions made during these interviews were incorporated in the final versions of our models. For the creation of the 3LGM models we used the 3LGM^2 Tool released by the Institute for Medical Informatics of the University of Leipzig, version 3.1.0.

We analyzed one particular laboratory process in detail. This process, the analysis of a sample, is modeled as a UML Activity Diagram in the StarUML program version 5.0.2.1570.

We used both models to perform an assessment of the quality of the information processing systems used by DIO and the clinical laboratory. The criteria for this quality assessment are listed in Haux, chapter 4 – What are Good Hospital Information Systems?

We compared our model of the clinical laboratory with the model made by the students from the universities from Braunschweig, Heidelberg and Innsbruck. The results from this comparison are described at the end of this report.

2.1. PLANNING

The Strategic Information Management module had a timeframe of four weeks. During these weeks we studied DIO and the Clinical Chemical Laboratory. In order to complete the exercises we made the following work plan.

Week 1

- Interviewing DIO Project Leader
- Creating DIO 3LGM model
- Completion DIO 3LGM model
- Modeling Clinical Chemical Laboratory

Week 2

- Introduction at the Clinical Chemical Laboratory by our supervisor
- Making additional appointments with the laboratory staff
- Refining our 3LGM model of the Clinical Chemical Laboratory
- Starting orientation for the quality assessment

Week 3

- Finishing our 3LGM model of the Clinical Chemical Laboratory
- Additional appointments with the laboratory staff
- Start Quality Assessment using our 3LGM models
- Write thesis

Week 4

- Finishing touch, we finished all our exercises and finalized our thesis
- Describe the differences between the Medical Centers participating in the Frank – van Swieten Lectures
- Give presentation at the Frank – Van Swieten lectures

Week 5

- Give presentation at Clinical Laboratory meeting

During these weeks we informed the other – Dutch – students about the progress we made during our internship at the Clinical Chemical Laboratory. Every week we presented our progress on Thursday. We kept our supervisor informed about the progress we made.

3. RESULTS

This chapter contains the results from our study of the DIO project and the Clinical Laboratory. The DIO project and the Clinical Laboratory are presented as 3LGM models, which are explained in detail. In the next chapter we present the results of our analysis of the quality of the information system at the Clinical Laboratory.

3.1. DIO 3LGM MODEL

The following paragraphs present the 3LGM model of the DIO project. A general, three-layer overview is presented first. In this overview, the mapping of the enterprise functions on the application components, and the mapping of the application components on the physical data processing components are clearly visible. However, these mapping is also presented when the individual layers are discussed.

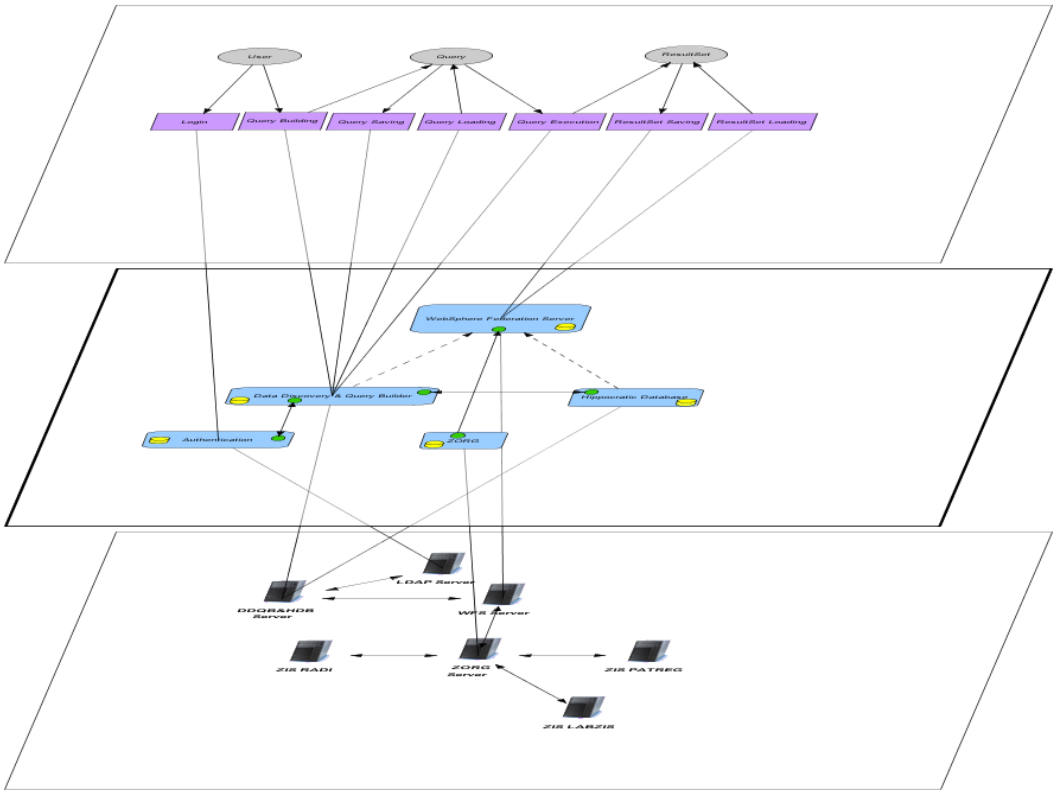

Figure 1 – Three layer overview of the DIO 3LGM Model

3.1.1. DIO 3LGM DOMAIN LAYER

The domain layer of the DIO project contains 3 entity types, and 7 enterprise functions. The enterprise functions deal with the authentication of users, the creation of queries, and the execution of queries, which leads to results that can be saved (downloaded) for further statistical analysis, for example in SPSS. DIO itself provides only very limited statistical functionality. Each enterprise function is explained in the table following the image.

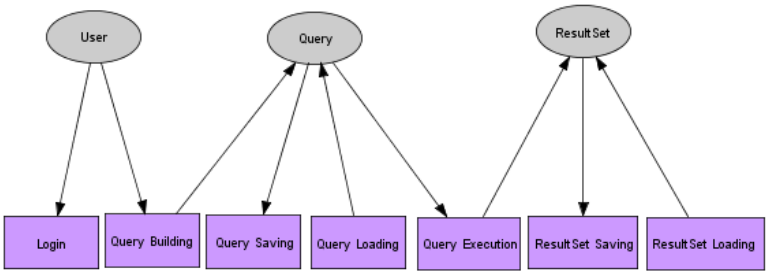

Figure 2 – The Domain Layer of the DIO Project

Enterprise Function	Description
Login	The user enters his credentials (username, password) to login into the DIO web application.
Query Building	The user uses the DIO web application to select the various items he wants in his result set, and enters the different criteria upon which must be selected.
Query Saving	A built query is saved for later use.
Query Loading	A saved query is loaded for use.
Query Execution	The user sends the query to the DIO application for execution.
Result Set Saving	The user saves the result set produced by the execution of a submitted query. The result set can be saved to desktop, or in the

	DIO system itself.
Result Set Loading	A result set saved in DIO itself is loaded for use

Table 1 – Enterprise functions of the DIO Project

3.1.2. DIO 3LGM LOGICAL TOOL LAYER & PHYSICAL TOOL LAYER

The next two images depict the DIO logical tool layer and the physical tool layer. The Logical Tool Layer consists of 5 application components, of which the Data Discovery & Query Builder and Hippocratic Database are parts-of components of the Websphere Federation Server. These two components are modeled as separate components because of their clear and distinct functionality. The Websphere Federation Server communicates with the Zorg component, which contains a database with integrated data from LABZIS, ZIS RADI and ZIS PATREG. These three ZIS components are not modeled in the logical tool layer because DIO only uses the Zorg database, but the communication between these three HIS components and the Zorg component is based on ETL (Extraction, Translation and Load) processes.

On the Physical Tool Layer, the ZIS RADI, ZIS LABZIS and ZIS PATREG are modeled because their physical servers do communicate with the Zorg Server, updating it with the latest information every night. The rest of the components and their mappings are described in the table following the table describing the application components.

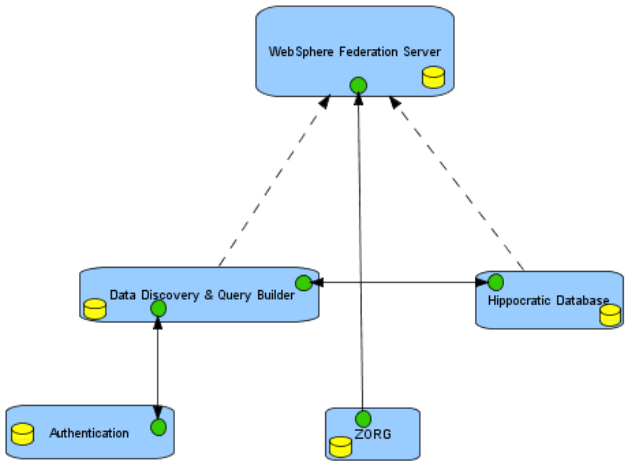

Figure 4 – The Logical Tool Layer of the DIO Project

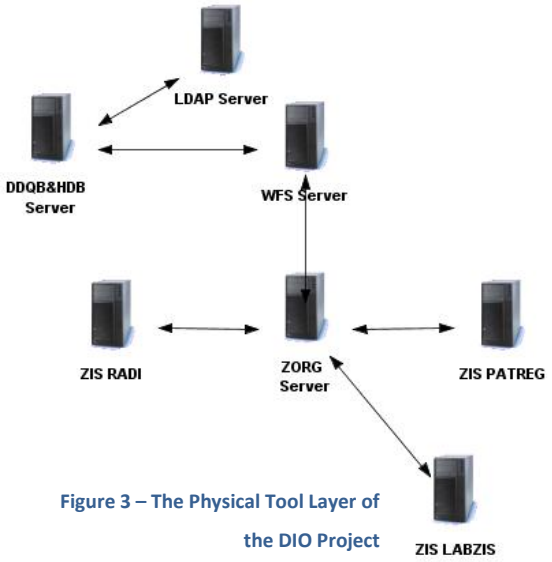

Figure 3 – The Physical Tool Layer of the DIO Project

Application Component	Description
Websphere Federation Server (WSF)	The IBM Software which is the heart of DIO. Consists of the DDQB and the HDB.
Data Discovery & Query Builder (DDQB)	WSF Part that enables the user to build and execute queries
Hippocratic Database (HDB)	WSF Part that contains rules to de-personalize patient data returned in a result set
Authentication	Application component that checks a user's credentials
Zorg	Component running the Zorg database with combined ZIS Data

Table 2 – Application Components of the DIO Project

Physical Component	Description
WFS Server	Runs the Websphere Federation Server
Zorg Server	Runs MS-SQL Database into which RADI, LABZIS and PATREG data are loaded by Extraction, Translating and Loading (ETL) processes
DDQB&HDB Server	Server running the DDQB and HDB Components
LDAP Server	AMC Server running an LDAP Database with user credentials and departmental information
ZIS RADI, ZIS LABZIS, ZIS PATREG	Components of the Hospital Information System.

Table 3 – Physical Components of the DIO Project

3.1.3. DIO 3LGM INTERLAYER RELATIONSHIPS

The following matrices describe the interlayer relationships for the DIO Domain Layer and the Application Components, and the DIO Logical Tool Layer and Physical Tool Layer. As can be seen in the first image, most enterprise functions are supported by the Data Discovery & Query Builder application component. The Zorg Server supports no enterprise functions, but is nevertheless modeled in our Logical Tool Layer, because of its communication with the

Websphere Federation Server, and its database into which the ZIS databases are copied. The functions 'Result Set Loading' and 'Result Set Saving' run on three application components (DDQB, HDB and WFS) because the DDQB and the HDB are both needed in this process and the WFS takes care of converting the Result Set data into a useable format (an SPSS format, for example).

In the matrix of the Logical Tool Layer and the Physical Tool Layer, the ZIS LABZIS, ZIS PATREG and ZIS RADI are not supporting any application components. The databases contained on these physical components are copied to the Zorg Server, and because of this process, the ZIS servers are modeled as well.

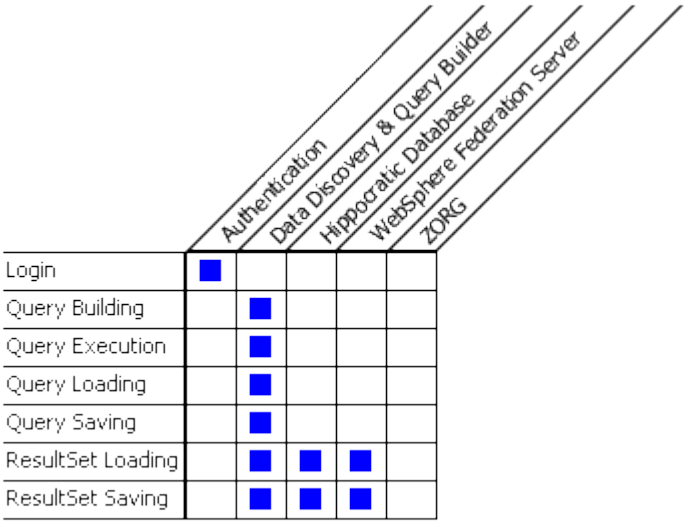

Figure 5 – The Interlayer Relationship [Domain Layer and the Logical Tool Layer]

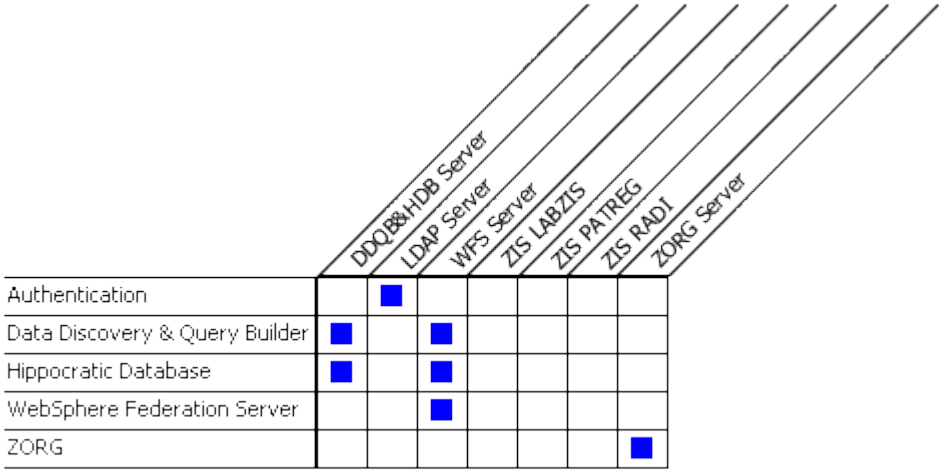

Figure 6 – The Interlayer Relationship [Domain Layer and the Logical Tool Layer]

3.2. CLINICAL LABORATORY 3LGM MODEL

The following image is a three-layer overview of the 3LGM model of the Clinical Laboratory. For many of the interlayer relationships this model shows clearly what maps on what, but for clarity this information will also be provided in the matrices following the tables describing each enterprise function, application components or physical data processing component in detail.

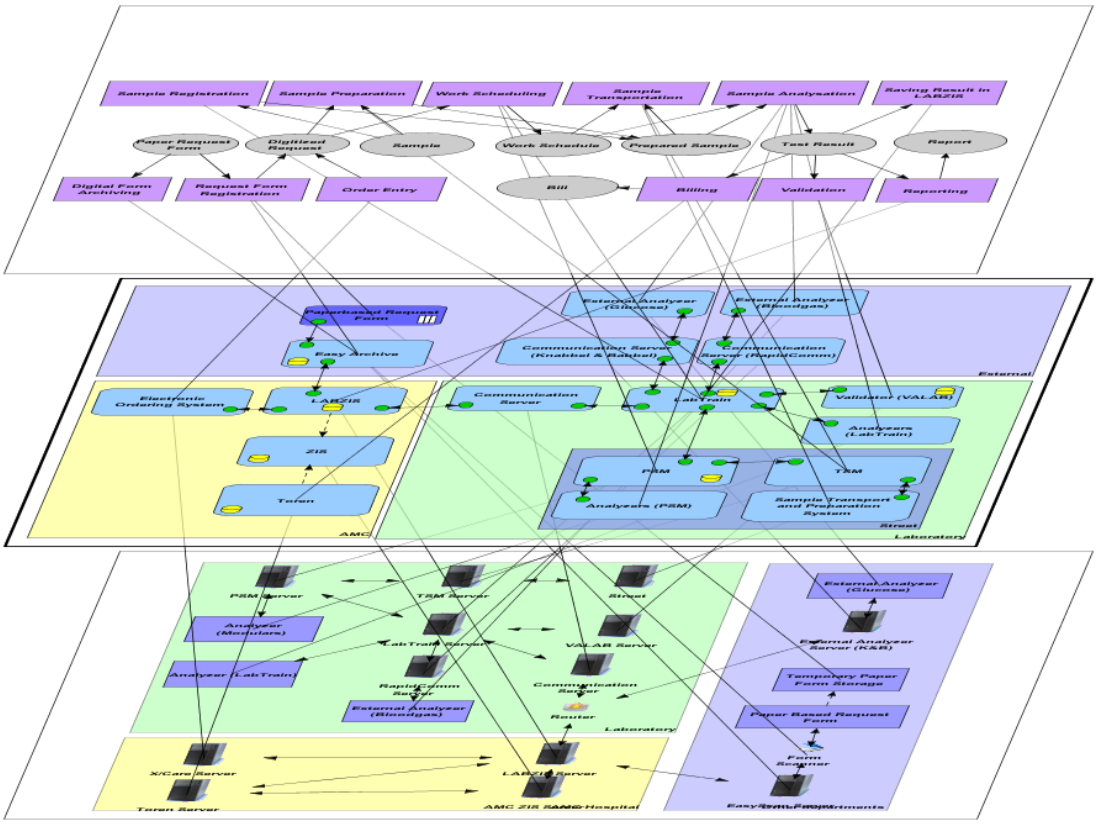

Figure 7 – The three layer overview of the Clinical Chemical Laboratory 3LGM Model

3.2.1. CLINICAL LABORATORY 3LGM DOMAIN LAYER

The domain layer of the Clinical Laboratory consists of 12 enterprise functions, which deal with 8 entity types. As it is the main process of the laboratory to analyze incoming samples

and to produce results according to what the requestor has asked for, many enterprise functions deal with this request and the sample that has to be analyzed. Billing and reporting functions has also been added, even although these functions are not really carried out by the laboratory (billing is carried out by the financial department based on the amount of successful analyses, and reporting is carried out by, for example, the AMC Zorgdesktop (not modeled), using the result information stored in LABZIS).

The enterprise functions are described in detail in the table following the graphic representation of the domain layer.

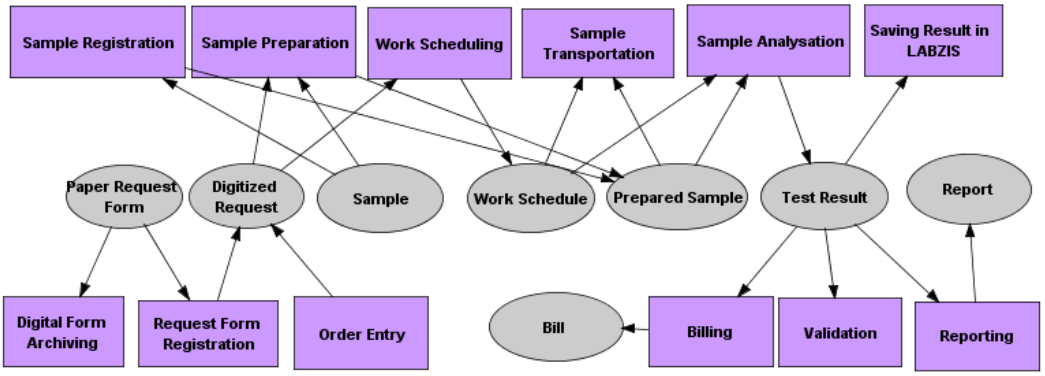

Figure 8 – The Domain Layer of the Clinical Chemical Laboratory

Enterprise Function	Description
Sample Registration	The LabTrain Analyzers register the arrival of a sample for tracking
Sample Preparation	Some samples need preparation, like de-capping, distributing in more vials, or re-labeling. This leads to a sample ready for analysis
Sample Transportation	Samples are automatically transported to the dedicated analyzer(s)
Sample Analyzing	Running the actual analysis of the sample, producing results (like glucose-level, Ht, wbc count, etc)

Work Scheduling	A computerized request for analysis is added to the controller's work schedule
Digital Form Archiving	A paper-based request form is scanned using Easy Archive, and saved in its archive. Also used for archiving of administrative documents.
Request Form Registration	A scanned-in paper form is transformed into a computer-based request for analysis
Order Entry	Automatic Electronic Ordering, an X/Care component (ELord)
Billing	Generation of a bill (for DBC), based on performed analysis
Validation	Automatic validation of analysis results that are communicated through LabTrain.
Reporting	Generation of report, through the AMC Zorgdesktop.
Saving Results in LABZIS	All test results are saved into LABZIS

Table 4 – The enterprise functions of the Clinical Chemical Laboratory

3.2.2. CLINICAL LABORATORY 3LGM LOGICAL TOOL LAYER

The Logical Tool Layer of the Clinical Laboratory consists of 18 application components. All of these, but the Paper-based Request Form, are computerized. The application components are put into different boxes, representing their various locations in the hospital. This separation is made on where the functionality offered by the application components (and connected components) is used. The external communication server (RapidComm), for example, runs in the IT room of the laboratory, but offers functionality to the blood gas analyzers used on other departments. This is why both this communication server and its connected analyzer(s) are modeled in the 'External' box.

The components Electronic Ordering System, LABZIS and the other relevant parts of the ZIS are modeled in the AMC box because they are AMC components. PSM, TSM, Analyzers (PSM) and the Sample Transport and Preparation System are modeled in a 'Street' box in the

'Laboratory' box because together they form the automated analyzing street clearly present on the laboratory floor.

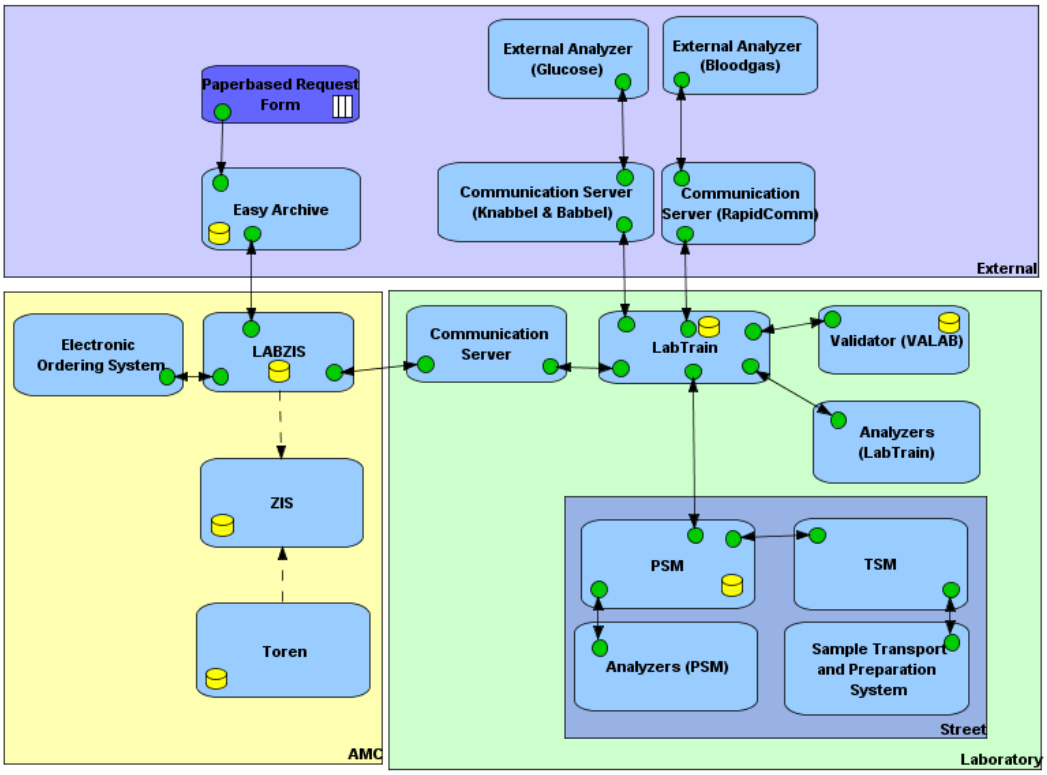

Figure 9 – The Logical Tool Layer of the Clinical Chemical Laboratory

Application Component	Description
LabTrain	LabTrain controls the LabTrain based analyzers, and communicates test results to LABZIS
PSM	PSM controls the PSM based analyzers (in the street), controls the TSM component, and communicates test results to LabTrain
TSM	TSM Manages the preparation and routing of a sample.
Analyzers (PSM)	The analyzers controlled by PSM, analyzing the samples
Sample Transport and Preparation System	The components responsible for the preparation and conveying of samples

Analyzers (LabTrain)	The analyzers controlled by LabTrain, analyzing the samples
Validator (VALAB)	Many test results are automatically validated by VALAB. Erroneous results are flagged and need checking by human.
Communication Server	Component that communicates and translates patient and test data from LABZIS to LabTrain, and test result data back.
Communication Server (Knabbel & Babbel)	Communication servers between external glucose analyzers and LabTrain
Communication Server (RapidComm)	Communication server between external blood gas analyzers and LabTrain
External Analyzers (Blood gas)	External Blood gas Analyzers
External Analyzers (Glucose)	External Glucose Analyzers
Easy Archive	Scanning and Archiving Software
Paper-based Request Form	A paper form on which (mainly) external users can tick which test needs to be performed
Electronic Ordering System (X/Care)	Electronic Ordering Component of X/Care
LABZIS	The Laboratory component of the Hospital Information System
ZIS	The Hospital Information System
Toren	The financial component of the Hospital Information System

Table 5 – Enterprise functions of the Clinical Chemical Laboratory

3.2.3. CLINICAL LABORATORY 3LGM PHYSICAL TOOL LAYER

The Physical Tool Layer of the laboratory contains 20 physical data processing tools. Similar to the laboratory Logical Tool Layer the processing components are grouped together, but here the criterion for grouping is the position of a component relative to the laboratory router. As a consequence, the External Blood Gas Analyzers are modeled in the laboratory box, even although they are physically present at different departments.

The Clinical Laboratory runs its own network, separated from the rest of the hospital's networks through a router. All devices outside of this network, like the AMC HIS servers, external glucose analyzers (and their communication servers Knabbel & Babbel) communicate with the LabTrain server through this router. The EasyScan Server directly communicates with LABZIS.

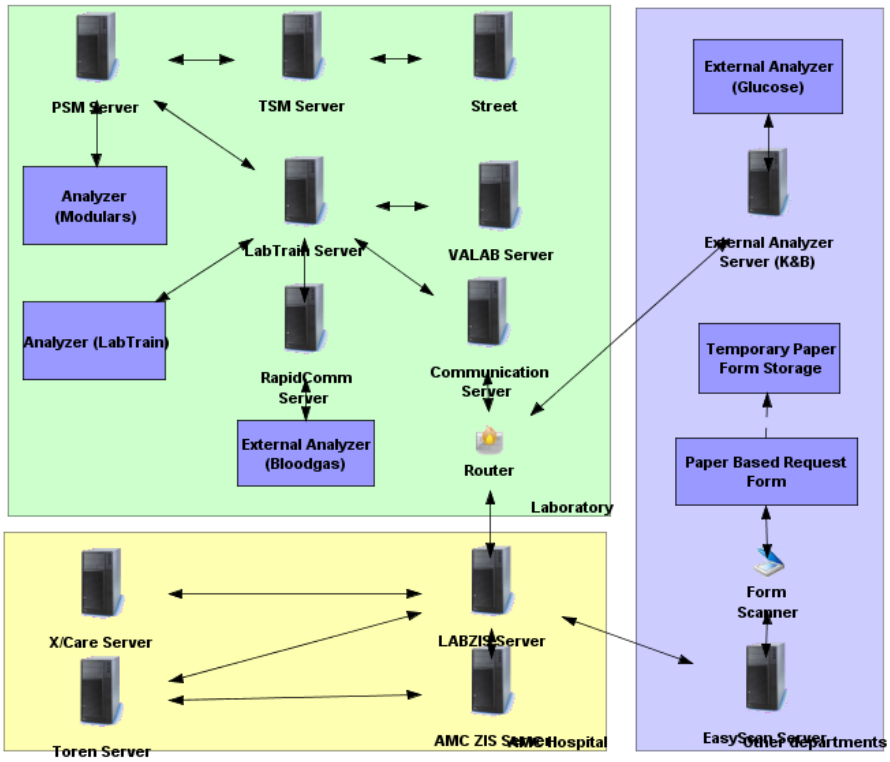

Figure 10 – Clinical Chemical Laboratory Physical Tool Layer

3.2.4. CLINICAL LABORATORY 3LGM INTERLAYER RELATIONSHIPS

The following two images, figure 9 and 10, show the interlayer relationships for the 3LGM model of the Clinical Laboratory. In figure 9 can be seen that all Enterprise Functions are supported by one or more (computer-based) application components, and that many application components support only one Enterprise Function. The communication servers and the ZIS do not support any Enterprise Function at all, because the communication servers only transport data to and from other application components. The ZIS does not support any Enterprise Function, because the parts of it that do, are modeled as parts-of the ZIS (LABZIS and Toren).

The Sample Analysation process appears to run on four application components. This is because we chose to model the four different types of available analyzers separately.

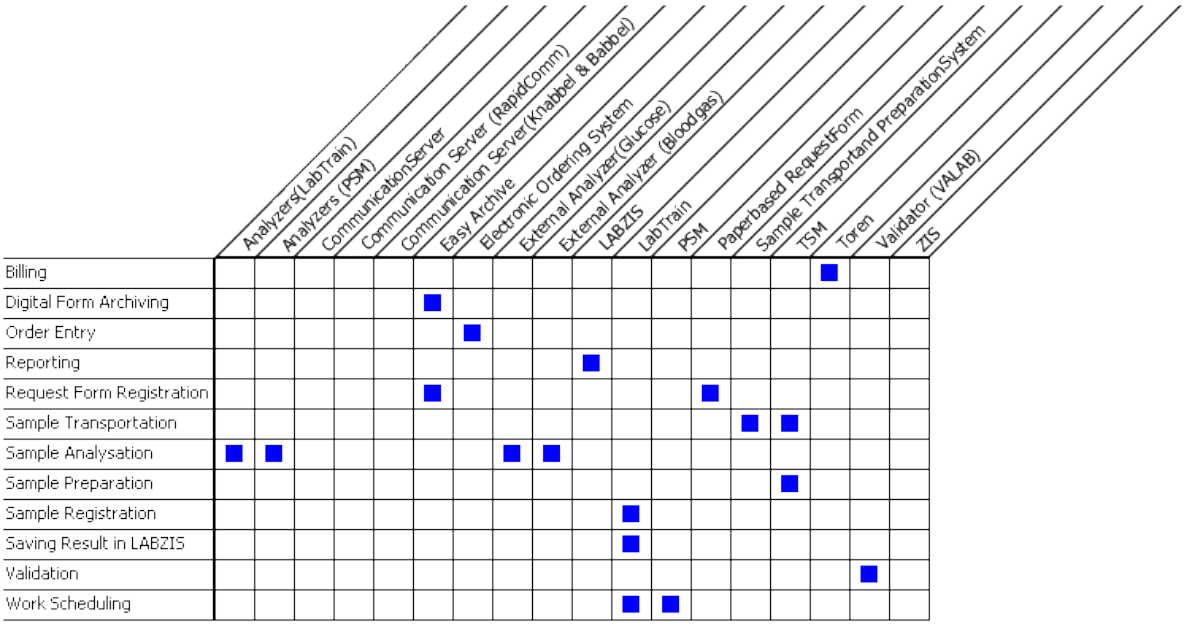

Figure 11 – Interlayer Relationship between the Domain Layer and the Logical Tool Layer

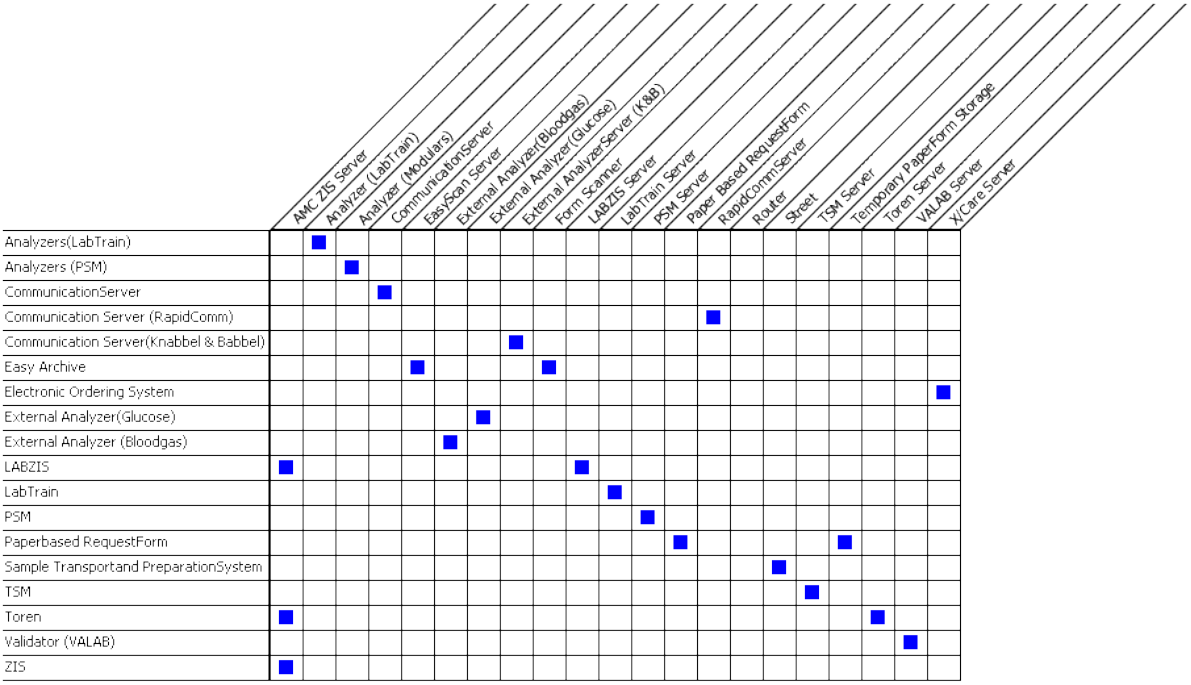

Figure 12 – Interlayer Relationship between the Logical Tool Layer and the Physical Tool Layer

Figure 10 shows the interlayer relationship between the Logical Tool Layer and the Physical Tool Layer. All application components are supported by one or more physical data processing tools, and except for the router, all application components support one or more application components.

Several application components are supported by more than one physical processing tool. The EasyArchive component is supported by both the EasyArchive server and the Form Scanner, but this is a consequence of the decisions we made modeling the physical layer. The LABZIS component is supported by the LABZIS server and the AMC ZIS server, but this distinction is merely artificial; the LABZIS component is an integral part of the AMC ZIS, but in the physical tool layer, we modeled the two servers separately for clarity.

3.3. ACTIVITY DIAGRAM SAMPLE ANALYSIS

We described one typical process of the department of Clinical Chemical Laboratory. The specified process is the routing of a sample in the laboratory; the routing supports the analysis of the sample and when the routing is finished the sample has been analyzed and the results have been made available to the entire hospital by storing the results in LABZIS.

The activity diagram starts when a sample has been received and then there are two options; the first option is that an external sample analyzer will analyze the sample and the second option is that the analyzers that are connected to 'the street' will do the analysis.

The first activity in 'the street' is the preparation of a sample. The sample will be prepared for analysis and therefore the vial with the sample will be centrifuged and/or distributed over other vials. When a sample has been prepared; the sample will be transported to the dedicated analyzers for analysis.

The etiquette on the vial with the sample is scanned and 'the street' knows which analyzers have to analyze the sample. This is the third activity of 'the street' after this activity the sample is properly analyzed.

These activities are somewhat different for the external analyzers, but the activities are the same for each external analyzer. These activities are the preparation of a sample and the analysis of a sample. The preparation of a sample can differ between the different external analyzers, but every external analyzer will prepare a sample which they have to analyze. After the preparation the sample will be analyzed, this is a specific process which can differ between the different external analyzers.

In case of external analysis of a sample the sample will be authorized by a human authorizer (the physician who required an analysis of the sample). In case of authorization the results of

a sample are stored directly in LABZIS via LabTrain (for external analyzers it is not common use that VALAB is used for authorization of the sample). When a human authorizer does not authorize the sample there are two options; the first option is that a different analysis will be done and the second option is that a new analysis will be done with a (new) sample.

In case of all other analysis the provisional results of a sample are stored in LABZIS, via the communication between LABZIS and LabTrain. There are two possibilities after the storing activity; the first possibility is that a sample will be validated by VALAB and the second is that a sample will not be validated by VALAB. When the sample is not selected for validation, the sample will be stored in LABZIS.

When a sample is selected to be validated, the activity 'VALAB Validation' will be executed. Again there are two possibilities; it is possible that a sample will be authorized and the other possibility is that the sample is not authorized. In case of authorization of a sample, the results will be stored in LABZIS. When a sample fails the authorization procedure than it will be reviewed by a second analyzer; the second analyzer is a human analyzer. The human analyzer can confirm the action of VALAB or ignore it and authorize the sample. When a sample has been authorized by a human analyzer the results will be stored in LABZIS. In case of the confirmation the sample will not be authorized.

There are three routes when a sample is not authorized by a human analyzer. The first way can be contacting and/or consulting the physician who requested the analysis, in this case the physician can authorize the results of the analysis or not. When he authorizes the sample the results will be saved and stored into LABZIS. In case of not authorizing the sample the physician has to decide what to do next.

The second way can be to perform another analysis. It is possible that the first analysis was not the right one for the sample that has been analyzed this way. So it is possible to do some other analyses and the sample has to start all over again (start at the begin point of the activity diagram). The third (and last way) can be to do a new analysis with a (new) sample.

This could be the same analysis that has been done before with the non-authorized sample or an entirely different analysis of the new sample. In both cases the sample has to start all over again (start at the begin point of the activity diagram).

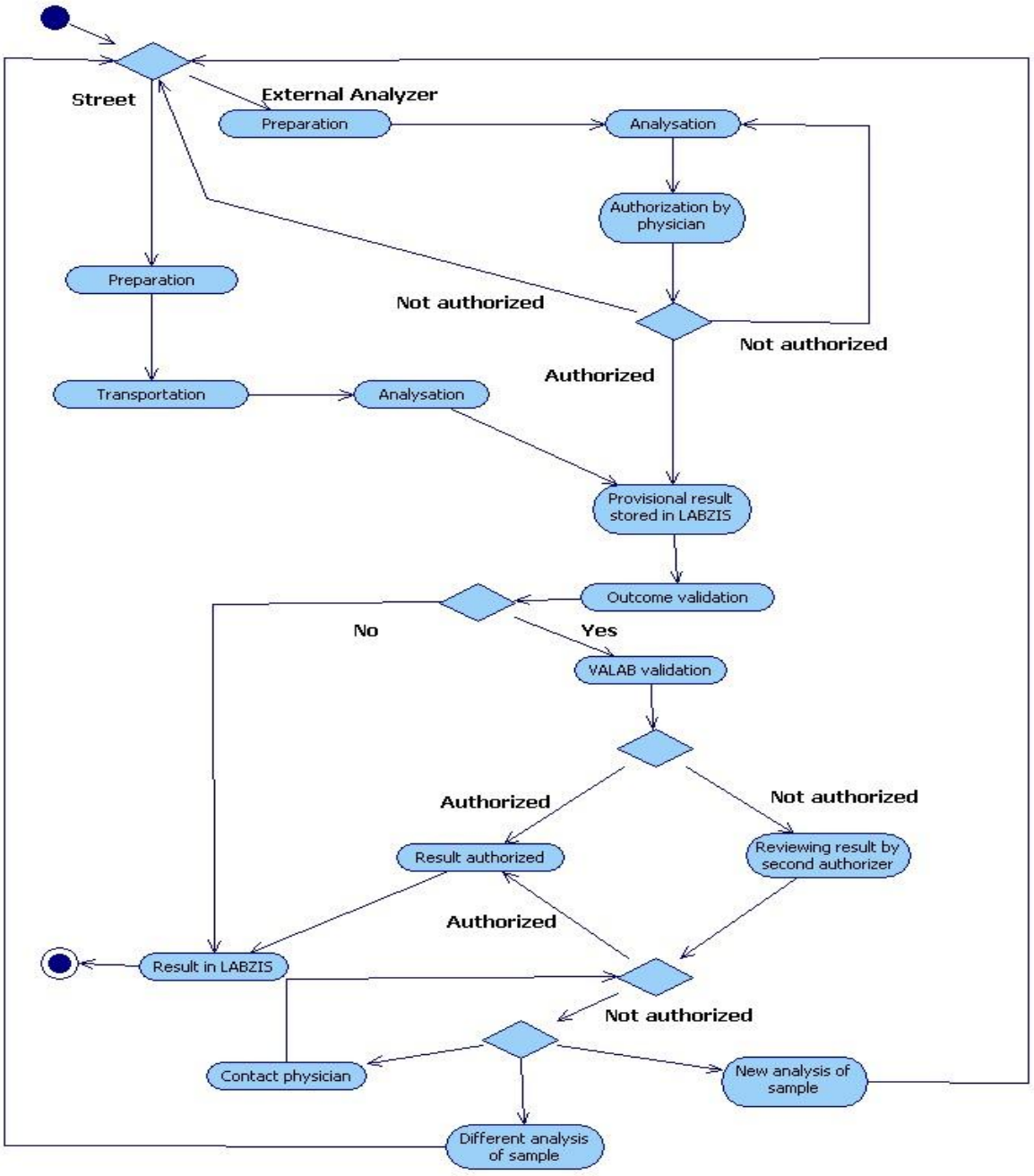

Figure 13 – Activity Diagram of the activity Sample Analysis

3.4. DIFFERENCES BETWEEN THE AMC AND BRAUNSCHWEIG

We compared the models we made during our research at the Clinical Chemical Laboratory of the AMC with the models made by the students from the Braunschweig Medical Center.

The laboratory of the Braunschweig Medical Center uses paper-based forms for ordering and reporting back the results. The main difference with the AMC is that the AMC laboratory has an electronic ordering system through which tests can be ordered. The consequences for Braunschweig are that in 50 percent of the cases one or more mistakes are made. Lab workers have to check every form for mistakes and in case of a wrong form they have to contact the requesting physician.

Another difference is that, although the test results in Braunschweig are stored in an SAP database, these results are not electronically available to the requesting parties. The laboratory sends the results to the requesting department, where they are automatically printed.

Also, test results in Braunschweig are manually checked by a lab worker, where the results in the AMC go through VALAB, the automatic validation system. This system only calls for a control check by a human if it detects an error in the test results. This automated way of checking saves a lot of human labor.

The laboratory in Braunschweig does not have an automated analyzing street. All samples are registered, prepared, transported and manually, while at the AMC laboratory the bulk of this work is done automatically. Even although not all the samples at the AMC laboratory are dealt with automatically, the AMC way of handling bulk work is much more efficient.

We concluded that much of the work done at both laboratories is the same, with more or less the same application components and communication servers. The largest differences

are found in the level of automation at the Braunschweig laboratory, which compared to the AMC laboratory, still uses a lot of paper-based application components. The result of this difference is that, with the request forms, a lot of errors are made, and that, overall, the work process at the AMC laboratory is more efficient, which results in much faster delivery of results (< 60 minutes in the AMC, and much longer at Braunschweig). Also, because of this, the AMC is able to handle higher loads of tests per hour.

4. QUALITY ASSESSMENT

We used Haux Chapter 4 to assess the quality of the architecture and infrastructure of the laboratory's information systems. We summarized the quality assessment into the strengths and the weaknesses of the information systems. These information systems are modeled in the 3LGM model. The Quality assessment is based on the 3LGM model, the activity diagram, the interviews we took and the observations we made. We used the Quality of Structures, Quality of Processes and Quality of Outcome analysis, of which we skipped the Quality of Outcome part, because this information cannot be obtained by our 3LGM models. We only assessed the quality of the laboratory and not of DIO, because we focused on the laboratory.

The laboratory does not seem to have any real problems. However, we did defined several smaller problems; the first problem is the communication service between LABZIS and LabTrain, the second problem is the router, the third problem is the communication with external services (meaning: general practitioners from the outside of the AMC) and the fourth problem are the media crack that still exists (scanning paper-based forms into a computerized form). Alongside these problems we describe some problems that (can) occur when DIO is fully operational. It was not easy to do some recommendations for DIO, because our timeframe was limited and the problems where complex and therefore not easy to solve.

4.1. QUALITY OF STRUCTURES

Quality of Data

The only three aspects of quality of data that can be analyzed with our methods are availability, confidentiality and security and safety. All results of the analyses of the samples are almost directly available to every site within the AMC. Some external sites have to wait for the results on paper. The availability of the information system is very good. The

availability cannot be assessed with help of the 3LGM model, so we observed the processes and interviewed some of the laboratory IT staff.

Confidentiality and security have been assessed with help of observing and interviewing. It came to our attention that the results are stored in LABZIS and that every physician, who can login to the LABZIS (and is authorized to see the patient data), can see the information about the results of a patient while they may have not anything to do with the patient. The confidentiality and security are not so good.

The third and last aspect of the quality of data assessment is the safety. When we looked at our 3LGM model we can see two main problems; the first problem is the communication service between LABZIS and LabTrain, the second problem is the router. When one of these services fails the data is not available until the service has been restored. There are enough spare parts available (there are three backup devices for the communication service between LABZIS and LabTrain), but they have to be plugged in before the backup. This communication service will not last forever, because in the near future LabTrain and LABZIS will communicate directly. At the moment the safety is good (the department makes periodically backups of the data), but the communication service and the router have to be watched carefully.

Quality of Information Processing Tools – Quality of Application Components

There are six quality characteristics according to the ISO 9126. These characteristics are; functionality, reliability, usability, efficiency, maintainability and portability. The only characteristic that can be assessed with the help of our 3LGM model is the functionality. Every function is supported by an application component, in other words, it is possible to execute all the functions of the laboratory with help of one or more application components. The functionality of the application components is good.

Quality of Information Processing Tools – Quality of Processing Components

There are several characteristics that can be assessed. These characteristics are; availability, multiple usability, security, standardization. The characteristic availability is not easy to assess, because of the interpretation of this characteristic. To assess this characteristic we used our 3LGM model and we interviewed some of the laboratory staff. It is possible to request every test that has been made available to the hospital by the laboratory. The request can be made by using the electronic ordering system (is a part of X/Care) and this system is available throughout the entire hospital, in this case the availability is very good. Another interpretation of availability is that the analyzers are mobile and not restricted to a certain place. In this case the availability is low, there are some external analyzers (blood gas and glucose), but all the other analyses have to be done at the department of the Laboratory.

The characteristic multiple usability can be assessed with the use of the 3LGM model. In our model it is clear that all physical information processing tools are dedicated. There is only one application component mapping on a physical information processing tool. Poor multiple usability will not necessarily lead to bad quality. Dedicated tools are easier to maintain (and there function is more clear, because of supporting only one application component) than tools that have multiple usability.

Security has been mentioned earlier in case of the data quality assessment. The security of the data is good, but on the physical tool layer there are two tools that have to be watched carefully. These two components are the communication service between LABZIS and LabTrain and the router. When these components fail the IT staff has to plug in the backup components to restore the functionality of the information system, these parts of the system are a little bit insecure. The Laboratory network is secured. The router knows which tools have access to the Laboratory network and the only communication with the Laboratory network is possible via the router.

Many processes at the Laboratory are standardized. Standardization reduces errors; for example, the paper-based forms are standardized so physicians know which forms they have to use for a specific case and know what the specific layout of the form is and know where to find what. The analyzers are also standardized; in case of the blood gasses the measurement (how to measure chloride for example) is every time the same. The standardization of the Laboratory is good.

Quality of Information Processing Tools – Quality of Component Integration

The Laboratory information systems are flexible and adaptable. It is very easy to connect an extra analyzer to LabTrain. The only constraint is that LabTrain is able to communicate with the new analyzer; in that case the analyzer could be added to the system. Most of the analyzers are able to communicate with LabTrain.

Redundant data storage should be avoided, but sometimes data redundancy is valuable. In case of the Laboratory some of the data has been stored redundantly in different sites (backup servers for example) in order to avoid data loss in case of system failures. It is very clear which component is the master source of the data and data redundancy is planned, monitored and directed.

4.2. QUALITY OF PROCESSES

Efficiency of Information Logistics

We cannot assess the quality in case of the information logistics with the use of the 3LGM model. We interviewed and observed the processes at the Laboratory and the information logistics are very efficient. In most cases the information is correct, available at the right time (when the physician needs it), it is available at the right place (the results can be accessed via LABZIS) and the information is also in a usable format for the physician.

Leanness of Information Processing Tools

Seven of the thirteen enterprise functions are lean, in other words, they are supported by only one of the physical information processing tools. The other five enterprise functions are not lean; they are supported by more than one physical information processing tool. The enterprise function Digital Form Archiving is supported by EasyScan Server and Form Scanner, the form scanner will digitalize the paper-based form and the computerized form will be stored on the EasyScan Server. Four physical information-processing tools support the Sample Analysation enterprise function, because four different analyzers can analyze a sample. There are good reasons why the other three enterprise functions are supported by more than one physical information processing tool.

Single Recording, Multiple Usability of Data

All the data that is produced in the Laboratory is stored only once. There are a few application components which have a database. For example VALAB has a databases which store rules (and tolerances) when a sample may not be authorized and LABZIS stores the results coming from LabTrain. The only redundancy occurs when a backup is made of a database.

Controlled Transcription of Data, no Media Cracks

Unfortunately there is one media crack; scanning the paper-based form into the Easy Archive. Some of the data on the form will be unreadable when it is transferred to the Easy Archive and the Laboratory staff has to update or fill in the missing or unreadable data. A possible solution is a web based interface.

4.3. STRENGTHS & WEAKNESSES

Strengths

- (Almost) no paper
- Results in LABZIS are available for the entire hospital
- Department is supported by dedicated IT staff
- The laboratory has its own physical sub-network, independent of the hospital network

Weaknesses

- Communication service between LabTrain and LABZIS (LabTrain and LABZIS will communicate directly in a short period of time)
- ELORD (Electronic Ordering) has not yet proven to be an advantage from the perspective of the physician

4.4. ANALYSIS AND RECOMMENDATION OF SOME PROBLEMS

As has already been mentioned, the clinical laboratory has a very efficient data processing infrastructure, and at first sight there appears little to improve. However, the few minor issues that could be addressed are the following:

- Central communication server runs old software and on old hardware
- The central router is a single point of failure
- Communication with external stakeholders is not digitalized
- Paper ordering forms are still used by several internal departments
- DIO

Central communication server runs old software and on old hardware

The communication server connecting the laboratory's application components to the LABZIS component, forming part of the backbone of the laboratory's infrastructure, runs old software. Because of this, the hardware required to run this software is also very old. The communication software, communicating test results to the LABZIS, and patient data from the LABZIS, has been written by one of the members of the laboratory IT staff, and has originally been developed for a DOS (Disk Operating System)/Windows 3.11 based environment. With great difficulty this software has also been ported to Windows XP. The current communication server is a pre-1995 Intel 486 machine, running Microsoft Windows 3.11.

If this setup were to break, the laboratory would be cut off from the rest of the hospital (lab results would still be visible, because they are stored in LABZIS), which would effectively stop the flow of patient information from the LABZIS to the laboratory. This would stop the analysis processes, because the analyzers the do not receive information on what to do with which sample. There are a few spare servers, which are setup like the original server, but hot-plugging them would require some configuration changes, which takes time.

The laboratory IT staff has also noted this problem, and a project has been started to remove the communication server. This would require a direct interface between LabTrain and LABZIS, on which the manufacturer of LabTrain is working. However, until this new setup is complete, this communication server remains a vulnerability.

The central router is a single point of failure

As can also be seen in the laboratory's physical tool layer, not only the communication server between LabTrain and LABZIS is a single point of failure, but the router/firewall connecting the laboratory's internal network to the AMC network is also a single point of failure. Any disturbance in the operation of the router would cause the same problems as a

break in the functionality of the communication server. However, the router is maintained by the central AMC IT department, which guarantees its continued operation.

Communication with external stakeholders is not digitalized

External stakeholders, like general practitioners, communicate with the laboratory through paper forms and letters. The letters are automatically generated, and the paper forms are scanned automatically, but this process does involve some media cracks and therefore causes problems every so often. Paper forms that are not filled out correctly are an example of such a problem. This would require somebody from the laboratory staff to call the external stakeholder, and ask about the meaning of the form, and the needs of the external stakeholder. This generates extra, and possible unnecessary work**.**

A possible solution to this problem could be to give the external stakeholders access to the electronic ordering system, for example through a web interface. This would cause problems of its own, because the patient, or the sample, send to the laboratory by the external stakeholder, has to be identified. With a paper-based form, this identification comes with the patient or the sample, carrying the form. When sample (or patient) and order would be separated through some kind of electronic ordering, the external stakeholder would have to print out a label that he could place on the sample (or an identification letter which could be given to the patient) so that the laboratory is able to connect a sample (or patient) to an electronic order. This would still require the transfer of some paper-based information, and could introduce a new kind of problems.

Paper ordering forms are still used by several internal departments

Several internal departments, like the Intensive Care Unit (ICU) and the Coronary Care Unit (CCU) do not use the AMC Zorgdesktop in their primary work, but instead use their own system, PDMS. This PDMS system is accessible through every bedside terminal. If a nurse, or a physician, wants to order some laboratory tests while standing at a patient's bed, he would

have to “leave” the PDMS system, and start the AMC Zorgdesktop in which Electronic Ordering is included. This would require the user to use two different applications which both require (different) authentication. This is an unwanted situation, and therefore these departments order laboratory tests through paper-based forms, which can cause various problems, like the ones mentioned above.

This is an interesting problem, which is not easily solved by giving these departments an electronic application with which they can order their tests. This application already exists (in the form of Elord), but the departments do not want to use it. The only way to solve this problem is to modify the PDMS system to allow for the electronic ordering of laboratory tests, which would require a bi-directional interface between PDMS and LABZIS.

Every solution that would eliminate the use of paper-based forms would eliminate two of the laboratory’s application components, and four physical data processing units (at the Logical Tool Layer, the Paper-based Request Form and the EasyArchive software, and at the Physical Tool Layer the Temporary Paper Form Storage, the Paper Based Request Form, the Form Scanner, and the EasyScan Server), possibly leading to a reduction of operational and maintaining costs.

DIO

This problem is not limited to the Clinical Chemical Laboratory, but it is affecting the whole AMC. We mentioned the problems that (can) occur when DIO is fully operational. The main advantage is that data is now available and accessible within seconds and a couple of mouse clicks instead of searching all databases manually and collect the data manually to perform a research. This would take much more time. This must be kept in mind when discussing the problems of DIO.

DIO is an AMC wide data warehouse and researchers can access all linked databases (linked by DIO) with a single login. One of the questions is how is it possible to protect the data that

it will only be used for research what the researcher intended to do when he/she logged in to DIO? What research is allowed does the researcher needs the patient permission to access the data? If that is the case how does the researcher receive the patient's permission? At least there have to be clear guidelines and protocols.

There is no clear solution for this problem. Nowadays researchers can login via the LDAP server and will be authorized by the Authentication application component, but these two cannot protect the data for non-allowable research (other research than the researcher intentionally would like to do when he/she accessed the data). Therefore everything will be logged so when a researcher accessed DIO it will be logged by DIO. Every action is monitored and can be recalled if necessary (in case of the misuse of the data).

DIO is implemented in a University Medical Center (the AMC). A University Medical Center has three main functions; patient care, education and research. DIO supports research so when a patient is treated at the AMC the patient has to be informed about the fact that his/her data can be used for research. The patient must have the possibility to deny any access to his/her data for research.

Another problem is who will receive the credit when innovative research has been done? Imagine that a researcher uses DIO to perform a query and with the results of the query he/she finds a cure for breast cancer, he/she receive a massive amount of credit, but what about the people who collected and stored the data in the database (which is accessible via DIO)? This is a major problem, because physicians fear that they collect and store the data (this cost a lot of time) and someone else receive the credit with 'their' data.

All these problems are not easy to solve and at the moment we cannot do other recommendations than that there have to be clear guidelines and protocols. Our timeframe was limited to do a complete analysis and a quality assessment of the problems that can be caused by DIO.

5. CONCLUSION

The Clinical Laboratory is a highly computerized department at the Amsterdam Medical Center. Many of its core enterprise functions, which deal with the analysis of bodily fluids and other materials, are supported by dedicated application components, which are intimately linked to their physical data processing tools. A close inspection of the Logical and Physical Tool Layers of the laboratory identifies a few vulnerable components in the architecture, but these vulnerabilities are recognized and dealt with appropriately.

The DIO Project neatly integrates information from several important clinical databases, and will prove a valuable tool for clinical and scientific research in the future. Because of the central role the LABZIS component plays in the processes at the clinical laboratory, the analyses performed at the laboratory can be linked directly to important patient data from other databases, enabling, for example, simplified research in in-house drug trials.

6. DISCUSSION

During our internship, we studied the Clinical Laboratory and the DIO Project, both complicated installations closely linked to an already complicated university medical center. Because of limited time we had to make decisions about the level of detail at which we would construct our model and about what we would model at all. We focused on what we considered the main activity of the laboratory, the analysis of samples, and the application components and physical components supporting this process. Other processes at the laboratory, of which communication with general practitioners outside of the hospital is just one example, have not been given the amount of attention they would also deserve if there had been more time.

The main method we used to model and analyze the information we obtained during our internship, 3LGM, can be used to deduct much information about the workings of the laboratory (and the DIO Project), but the models we presented are abstractions of reality, also much information and detail has been lost. Therefore, the 3LGM models were not always suitable as an input for the Quality Assessment, because for such an assessment, much more detailed information is needed.

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DIO – Achtergrond informatie

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