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Enterprise Architecture Design for a

Multi-Center Anesthesia Liver Transplant

Clinical Decision Support System

Degree to be awarded: MPH

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Enterprise Architecture Design for a

Multi-Center Anesthesia Liver Transplant Clinical Decision Support System

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EXECUTIVE SUMMARY

Due to the low number of liver transplants per center, clinicians are limited in their ability to analyze and trend outcomes in their population. A solution to this problem could be a system that aggregates data among centers. This could create a significant sample size for proposing clinical practice modifications, and create an opportunity for real-time alerting and predictive analyses to support clinical decision making during intraoperative care. Currently, this functionality does not exist for this population, creating a void in clinical care and an opportunity for clinical improvement using informatics.

The idea of this system raised many questions and concerns about sharing protected health information (PHI), and whether a centralized versus decentralized approach was best, considering the need to maintain commitment from collaborating centers. Therefore, the creation of this system was studied and a preliminary enterprise architecture (EA) design was created for an Anesthesia Liver Transplant Clinical Decision System (ALTCDSS) that collects, shares, and analyzes information across multiple transplant institutions. By overlapping an Architectural Development Method (ADM) from The Open Group Architecture Framework (TOGAF) with the main components of EA: Business, Information, Application and Technology Architecture, we identified the key processes, risks, IT models, constraints, and complexities that the system would work within.

PROJECT AIMS

- **Aim 1:** Determine a high-level technological approach of managing a collaborative ALTCDSS both internally and externally.
- **Aim 2:** Determine the business rules of a collaborative ALTCDSS.
- **Aim 3:** Design a model that could support, promote, and foster the sharing of information among healthcare centers.

CONCLUSION

The EA analysis created a balance between determining and meeting the needs of the organization and formulating an IT approach. We concluded that the combination of a centralized model, and iterative development (starting with a pilot, to a registry, then to a matured system) would be the best way to circumvent wasted time, effort and resources. This iterative development will set the stage for a matured system by allowing us to evaluate methods and measure success quickly in small phases.

A comprehensive strategy for sharing PHI between centers and data governance was developed to support sustainability. These attributes address data accuracy and security while creating a process to manage modifications and development over-time. Well-defined principles were outlined for the system to follow from a business and technical standpoint.

The project team can now move forward with the EA design and the key processes we identified to obtain consensus in the proposed models with collaborating centers, create work-breakdown structures and secure funding to initiate the pilot.

PUBLIC HEALTH IMPACT

The development of any large-scale solution needs to be built with sustainability and future-use in mind. By using population-based statistics, a matured ALTCDSS could provide predictive measures to healthcare organizations to improve public health. The system can be purposed beyond liver transplant and serve the full range of organ transplantation (e.g. Kidney, Heart, Lung, Pancreas, etc.). In the future, this solution could help guide public health action at the federal, state, and local levels in producing guidelines for care, while serving as a model in sharing granular intraoperative data for other surgical specialties.

1. CHAPTER 1: INTRODUCTION

1.1 BACKGROUND

A major hurdle in researching and advancing transplantation with information technology is cultivating population-based statistics on such a low number of patients when stratifying by one organ. There has been a total of 151,826 organ transplants since 2013. To compare, there have been 154,541 ***liver*** transplants across all states since 1988. Furthermore, Georgia's three transplant centers have performed 3,918 liver transplants since 1988, making statistically valid inferences about patient care difficult. (OPTN, 2004)

A solution that targets population-based measures based on granular perioperative information could advance outcome-based research and promote predictive analytics to improve care. To identify the optimal intraoperative and surgical care, an ideal solution would identify the most effective approaches for patients based on a variety of environmental and lifestyle factors. Capturing detailed case information and collecting enough data from multiple transplant centers to generate a significant sample size are two concerns to be addressed. Identifying the best approach for collaborating and sharing information between centers is the first hurdle in developing such a solution.

In this paper, we investigate the EA that would be required for healthcare organizations to collaborate and support an Anesthesia Liver Transplant Clinical Decision Support System (ALTCDSS).

1.2 THE OPEN GROUP ARCHITECTURE FRAMEWORK

The Open Group Architecture Framework (TOGAF) is a detailed framework providing a set of supporting tools- for developing an EA. The original development of TOGAF Version 1 in 1995 was based on the Technical Architecture Framework for Information Management (TAFIM), developed by the US Department of Defense (DoD). The DoD gave The Open Group

explicit permission and encouragement to create TOGAF by building on the TAFIM, which itself was the result of many years of development effort and many millions of dollars of US Government investment. It was developed through the collaborative efforts of over 300 Architecture Forum member companies. Over the years, TOGAF has been updated and refined for the intended audience of enterprise architects, business architects, IT architects, data architects, systems architects, solutions architects, and anyone responsible for the architecture function within an organization. Version 9.1 (the most recent version) was published in 2011. (TOGAF 9.1, Ch7)

The goal in employing TOGAF is that it results in an EA that is consistent, reflects the needs of stakeholders, employs best practice, and gives due consideration both to current requirements and the perceived future needs of the business. (TOGAF 9.1, Ch7)

1.3 THE IMPORTANCE OF ENTERPRISE ARCHITECTURE

TOGAF states that the purpose of EA is to optimize, across the enterprise, the often fragmented legacy of processes (both manual and automated) into an integrated environment that is responsive to change and supportive of the delivery of the business strategy. (TOGAF 9.1, Ch7)

There are four architecture domains that are commonly accepted as subsets of an overall EA, all which TOGAF is designed to support:

- **Business Architecture:** defines the business strategy, governance, organization, and key business processes.
- **Data/Information Architecture:** describes the structure of an organization's logical and physical data assets and data management resources.
- **Application Architecture:** provides a blueprint for the individual applications to be deployed, their interactions, and their relationships to the core business processes of the organization.

- **Technology Architecture:** describes the logical software and hardware capabilities that are required to support the deployment of business, data, and application services. This includes IT infrastructure, middleware, networks, communications, processing, standards, etc. (TOGAF 9.1)

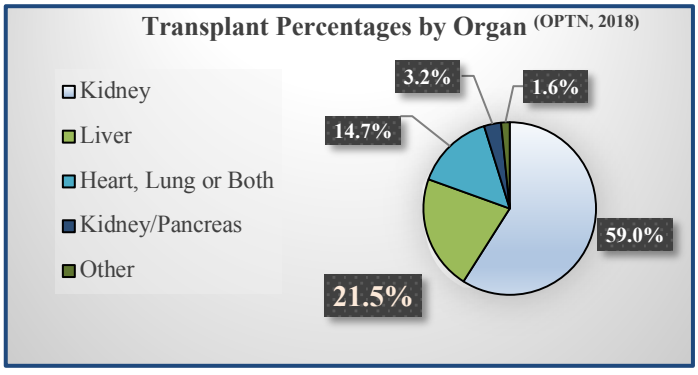
Requirements from each layer adds a foundational component to the overall EA. As we work through the four layers we identify the critical requirements and consider accompanying factors (e.g. roadmap planning, governance, change management) that provide an overarching EA.

TOGAF depicts two domains: ***1) business users***: "want a fast response from Information Technology (IT); aligned to its business strategy, dependable, stable environment, to improve business performance"; ***2) IT practitioners***: "want to make their own job easier and faster, and more reliable. This means reducing complexity and cost" (Townson, 2008). The importance of EA falls within the need to balance these domains.

EA is about more than IT -- it is about how an entire organization (or enterprise) identifies and understands all the components and interrelationships that make the organization work. The goal is a more efficient organization through better planning, earlier visibility, and more effective technical decisions.

1.4 THE LIVER TRANSPLANT POPULATION

The liver is the second-most transplanted organ accounting for 21.5% of all organ transplants (the kidney being the most transplanted with 59% of transplants) to-date. (OPTN, 2018)



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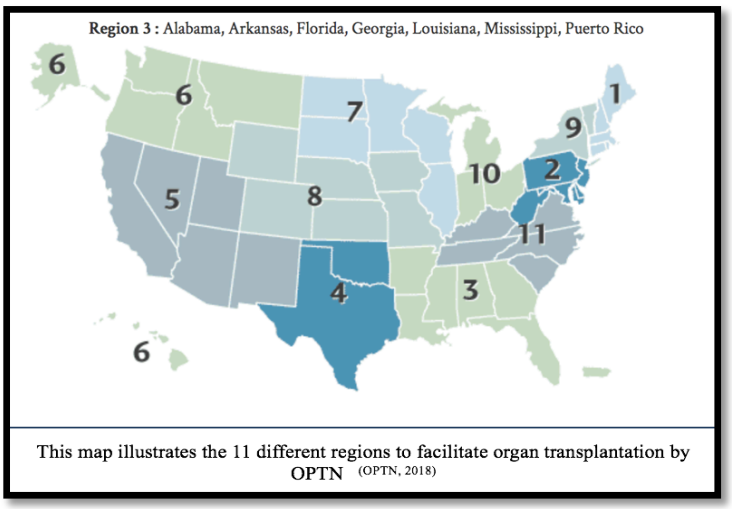
There is a critical shortage of organs. As of March 2018, there are 125,739 candidates waitlisted for organ transplantation; 14,177 of those candidates (11%) are those in need of a liver transplant. (OPTN, 2018)

The United States is divided into eleven different regions to facilitate organ transplantation by the Organ Procurement and Transplant Network. Georgia is in Region 3. Region 3 has 31 transplant centers that performed 4,557 transplants in 2017– 1,251 being liver transplants. Since 2005 to 2017, this region has averaged 1,103 liver transplants per year. (OPTN, 2018). The United Network of Organ Sharing (UNOS) is the only organ procurement organization (OPO) for the state of Georgia and it provides organs for three transplant centers. The three centers performed 264 liver transplants in 2017 surpassing the state average of 200 liver transplants per year from 2005 to the present. (OPTN, 2018)



This map illustrates the 11 different regions to facilitate organ transplantation by OPTN (OPTN, 2018)

1.5 MPOG - THE COMPARABLE EFFORT

The most comparable attempt to study granular perioperative elements is a collaborative effort started by the University of Michigan in 2008. The Multicenter Perioperative Outcomes Group (MPOG) is made up of more than three dozen academic anesthesia departments. "MPOG, is a non-profit academic consortium that represents >50 hospitals. MPOG uses electronic health

record and administrative data to analyze the interplay between patient comorbidities, surgical procedure, perioperative care, interventions, and postoperative outcomes." (MPOG, 2018)

MPOG captures clinical information from organizations utilizing a common format, Anesthesia Information Management Systems (AIMS), then transforms AIMS data to the MPOG registry, called "MPOG Central." MPOG collects data for all cases from a dozen of the participating departments. Data in MPOG are highly granular for the anesthetic encounter, capturing information on anesthesia procedures, medications, fluids, monitors and vital signs for every patient. (Dutton, 2014)

MPOG attempts to create an environment of performance improvement and research using priorities driven by its members with collaboration through informatics. However, in looking at published clinical research, presentations, and awards associated with their efforts, there has not been widespread impact. Despite having a Data Use Committee, data governance seems to rely on the AIMS specifications. This raises concerns about the structure of a decentralized model and, in turn, data accuracy and usability of the system. The lack of data governance often leads to a lack in overall data strategy. When aggregating and/or integrating data from various sources, it is imperative to work with stakeholders to understand how their processes and workflows impact the meaning of the data to derive actual value from data driven solutions.

Additionally, their model requires a sizable up-front financial investment from prospective centers. There can be a yearly fee that spans from $10,000 to $25,000 depending on the site's level of participation with MPOG (MPOG, 2018). Also, each prospective center is expected to acquire their own computer hardware and software that is estimated to cost approximately

$21,000 [MPOG, 2018]. Therefore, costs are estimated to be at least $31,000 to engage with this system as an MPOG participant.

Although this system parallels the ALTCDSS, MPOG does not collect most of the desired data elements for liver transplants. Furthermore, MPOG requires significant up-front costs for each participating hospital, while lacking data governance. The goals of MPOG (referenced below), are practically the same to those of the ALTCDSS; but the ALTCDSS would hone in on a subset of the population, accruing necessary and relevant data elements. In its most matured state, the ALTCDSS could provide quality improvement feedback to the local electronic health records (EHRs) for liver-transplant patients in a real-time basis.

Goals of MPOG: *(MPOG, 2018)*

- *Measure variation in perioperative clinical practice*
- *Benchmark ourselves to identify and implement Best Practice*
- *Inform the practice of Evidence-based medicine*
- *Improve Health Resource Utilization*
- *Guide Health Policy development*
- *Build collaborative relationships across specialties, professions and hospitals*

There is much to learn from the MPOG experience on how we can approach the ALTCDSS. Through their effort, we can anticipate a certain level of interaction from other centers, assess issues with data accuracy and integrity, and weigh the advantages versus the disadvantages of certain IT models, data mapping, and formation of policies and protocols.

1.6 OTHER REGISTRIES AND REPORTING

The United Network of Organ Sharing collects and manages all data pertinent to the patient waiting list, organ donation and matching, and transplantation occurring in the Organ Procurement Transplantation Network (OPTN), the nation's organ transplant network [OPTN, 2017] Registries, such as the Scientific Registry of Transplant Recipients (SRTR), the Global Database

on Donation and Transplantation, and the Collaborative Transplant Study (CTS), support the transplant community with data used to improve patient outcomes. These three sources provide a wealth of aggregated data that can be stratified by transplanted organ, regarding a variety of outcome-based measures (e.g. graft survival and patient survival post-transplant).

Currently, these registries (and others, such as the National Anesthesia Clinical Outcomes Registry [NACOR]), are perceived as research tools for retrospective outcome analysis and are not used prospectively by care providers in providing real-time, routine care (Niazkhani et al, 2017). Furthermore, the data are limited; the data are aggregates and do not provide the level of granularity needed for clinical teams to analyze, or make inferences to, the causes of poor outcomes. These sources of data may serve as an indicator, but they cannot drive improvement single-handedly without case-level abstraction.

1.7 PUBLIC HEALTH AND BUSINESS IMPACT

Transplant serves as the only curative treatment for end-stage liver disease and has been a standard surgical technique since the 1980s (Schuppan et.al, 2008). National registries report low mortality rates; however, there has been a shift to improve overall patient outcomes beyond patient mortality alone. The logistics surrounding the perioperative period (the events before during and after surgery) introduce complex factors that contribute to the success of the procedure. Examples of this include: infrastructural conditions in the transplant centers, experience of the surgeons involved, and anesthetic and medical management strategies (Bruns et. al, 2014). The combination of these variables affects postoperative outcomes to varying degrees. The structure of systems embedded in each organization and the lack of data exchange between organizations make it nearly impossible to create samples large enough to identify and act on clinical markers for improvement.

A matured ALTCDSS would collect, analyze, and share limited identifiable information from multiple sources, and return meaningful information on triggers, determinants, alerts, and contextual information leading to an immediate influence on patient care. This functionality supported by clinical decision support systems (CDSS) provide clinicians, staff, patients, and other individuals with knowledge and person-specific information that is intelligently filtered and/or presented at appropriate times to enhance health and health care. The typical CDSS encompasses a variety of tools to enhance decision-making in the clinical workflow. In its most basic function, these tools can include computerized alerts to providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information. (HealthIT, 2017)

These data collection activities will assist with monitoring the incidence and prevalence of intraoperative-related infection and other intraoperative-related causes of morbidity and mortality in the population. Using the ALTCDSS, we could identify changes in outcomes based on methods of care and assist in recognizing populations at risk for future operations.

1.8 RELATED USE OF HEALTH INFORMATION TECHNOLOGY

The impact in care coordination interventions using automated health information exchange (HIE)-based clinical event notifications (CEN) has been studied. One study illustrates the benefit in HIE, and CEN interventions in a health care system where patients often have numerous providers and multiple chronic medical conditions. Therefore, the interoperability of health information technology (HIT) was of special importance. Despite their study limitations, their investigation demonstrated the potential of CEN systems to improve care coordination by alerting providers to the occurrence of specific events (Gutteridge, David L., et al, 2014). The hope is that an

alert functionality of the ALTCDSS could mirror the benefit of improving care by giving notification of specific events during the surgical period of transplantation.

One of the most notable studies related to the proposed solution is a systematic review that was published in early 2017. Investigators researched the impact of CDSS utilization in organ transplant care. From 12,440 studies that were identified, ten publications were chosen based on a thorough list of inclusion criteria. (Niazkhani et al, 2017)

They found that routine use of HIT systems covering ***all*** phases and aspects of transplant care, is greatly lacking. Gaps in practice emphasize the need for orchestrated, evidence-based, cooperation of multiple distributed stakeholders including patients and providers. Furthermore, the review showed that HIT systems have a positive impact on the timeliness of transplant care as well as on laboratory and medication management practices. These systems produce a beneficial impact in patient outcomes by improving the percentage of post-transplant patients with normal lab values, a reduction in mortality and readmission rate. Use of HIT systems have a mixed impact on rejection episodes. Having HIT systems also result in decreasing deviation from the predefined immunosuppressive therapeutic window, immunosuppressive toxicity and antiviral resistance inpatients. Lastly, the study states that the systems were associated with monetary savings regarding the costs of immunosuppressive management practices as well as decreased resource utilization, particularly concerning laboratory tests. (Niazkhani et al, 2017)

1.9 **PROBLEM STATEMENT**

Due to the low number of liver transplants per center, a system is needed to aggregate data among centers to create a statistically significant sample for proposing clinical practice modifications based on empirical data. Currently, this functionality does not exist for this

population, creating a void in clinical care and an opportunity for clinical improvement using informatics.

1.10 RESEARCH QUESTION

In defining an EA for an ALTCDSS system, we could identify the best approach to foster collaboration between transplant centers, leading to improved practices through substantiated population-based analytics.

- **Aim 1:** Determine a high-level technological approach of managing a collaborative ALTCDSS both internally and externally.
- **Aim 2:** Determine the business rules of a collaborative ALTCDSS.
- **Aim 3:** Design a model that could support, promote, and foster the sharing of information among healthcare centers.

1.11 PURPOSE

Aside from surface-level statistics surrounding transplants, there is room for major growth in the collection of granular-level data of perioperative care in liver transplant. Emory's Liver Transplant Center performs approximately 150 surgeries per year. Given the low overall number of surgeries, it is difficult to improve upon clinical practice based on empirical data. By developing a system that allows other transplant centers to access and share perioperative information, the data related to care could be aggregated to identify clinical practices contributing to patient outcomes (both positive and negative). This would lead to the improvement of clinical practice and encourage advancement in the healthcare community through collaboration and informatics.

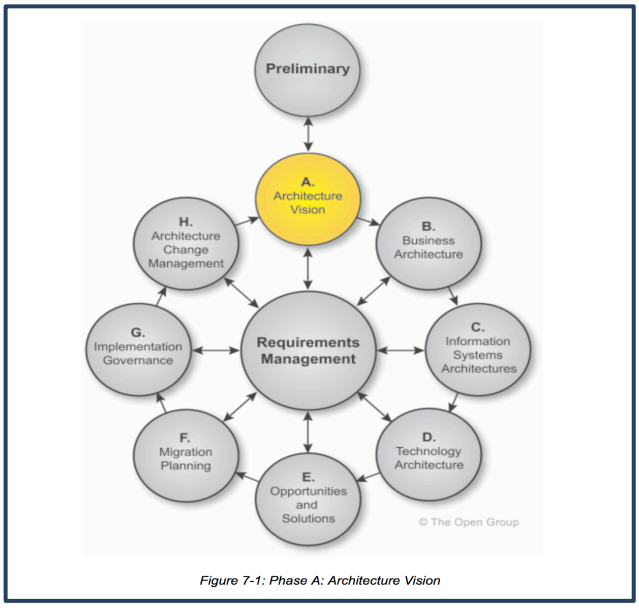
2 CHAPTER 2: METHODOLOGY

2.1 INTRODUCTION

The routine use of HIT systems covering ***all*** phases and aspects of transplant care is greatly lacking. However, according to interviews and research there is substantial interest in aggregating and analyzing this data; collectively. The perceived barrier is the "how". With an ability to isolate data elements, clinicians could provide specifications to temporal aspects to form customized algorithms and determine predictive biomarkers. Nonetheless, designing a system that meets the structural needs, fosters collaboration, and allows sharing of personal identifiable information (PHI) between two healthcare centers all the while adheres to the regulations of Health Insurance Portability Accountability Act (HIPAA) can be overwhelming for a low-resourced team.

The formation of an EA was approached by focusing on the four main layers: Business, Information, Application and Technology Architecture, and integrating the components of TOGAF's ADM.

The additional components of the ADM were then grouped into areas of focus: Roadmap Planning (E&F), and Governance (G&H). Comparing the project's current state to TOGAF's ADM, we could broaden our considerations and determine the level of granularity needed for our preliminary EA design to move us forward with development.



TOGAF's Architectural Development Method (ADM)

Given the scope of this proposed system, building an EA in this methodical way allowed us to consider the solution from a true system's perspective. Ideally, utilizing a clear method from the system's inception would accurately set expectations and circumvent wasted time, effort and resources throughout development.

2.2 PROJECT DESIGN

This project is designed as a proof of concept study to explore the feasibility of collecting, sharing, and analyzing data between two healthcare centers and to identify a potential pathway forward to designing an ALTCDSS. Beyond the system design, fostering and maintaining a level of collaboration was of great importance, due to its role for continued success.

To narrow the scope, the project was controlled to theorizing the sharing of information between two healthcare centers. Both utilize the same data sources: SurgiNet and SurgiNet-Anesthesia. However, it is worth noting that each module at each organization does allow for customization.

2.3 DATA TYPE(S) AND DESCRIPTION

Much of the data was constructed from interviews with subject matter experts (SMEs), from clinical care to informatics. To determine the need, gather requirements and evaluate the current state, there was a combination of interviews with Anesthesia-Transplant clinicians and a literature review. Through this analysis, we also defined a few key attributes of a successful system (discussed later in the results). Further interviews were needed from clinical staff to determine the level of data integrity and customizations between the data sources. Through these various interviews, matters regarding workflow, design, data frequency, user-access, data management, HIPAA, notifications, business associate agreements, and security were discussed.

Over the course of study, a literature review was performed to examine existing systems, and the business need. The Multicenter Perioperative Outcomes Group (MPOG) is a system in close correlation, therefore, many aspects about their system were studied and compared to our needs. In PubMed, searched terms were related to clinical decision systems. Exact searches were built on terms including "Clinical Decision Systems," "Precision Medicine," "Transplant and Clinical Decision Systems," and "Clinical Notification Systems." Other areas of research (but not limited to PubMed) included data governance, HIPAA privacy, data sharing, and decentralized and centralized information systems. The current process of sharing information externally was evaluated along with identifying templates for data use, data transfer, and business associate agreement forms. TOGAF's ADM was studied to evaluate the current state and lifecycle of the development.

Finally, due to the similarity of sharing information across healthcare systems, there was substantial effort in studying the Information Architecture models (Centralized, Decentralized, and Hybrid IA models) of Health Information Exchange systems (HIE's), through the Health Information Management Systems Society (HIMSS). A brief description, and definition of each model is outlined below:

- **Centralized**
  - In a centralized model or warehouse, patient health or medical-related data is collected from local sources, but stored in a central repository. If an entity requests patient data, the transaction is routed through the central repository. Such architecture permits local entities to maintain autonomy while cooperating to provide data at a local, or regional level.
  - The centralized model requires the most planning, coordination and development to be successful. From a technology perspective, the centralized model requires a heavy investment in a single vendor and system integrator to build a logical central repository that makes it functional for all stakeholder organizations.

- **Decentralized or Federated Model**
  - In a decentralized environment, there is no overall data management office managing the process.

- The decentralized or federated model provides organizational control of the healthcare record and provides the framework for data-sharing capability to enterprises, perhaps widely distributed across regions or even nationally. The local entity owns their data and the Record Locator Services manages the pointers to the information.
- The setup of decentralized or federated model systems is complex, expensive and costly to maintain. The consumer may also have concerns with data distributed far and wide in an interconnected set of frameworks. There are also many potential points of failure both in data maintenance, confidentiality and security.

- **Hybrid**
  - The hybrid model is a cross between centralized and decentralized architecture. Data is maintained partly centrally and partly within other organizational departments. But, the complete data maintenance process end-to-end is managed centrally.
  - A hybrid model provides the interface engine for which organizational entities in the HIE communicate.

Definitions of Model-Types: HIMSS HIE Guide, 2009

2.4 ELECTRONIC MEDICAL RECORD SYSTEMS

SurgiNet and SurgiNet-Anesthesia are the two systems that contain the data of interest.

2.5 IRB APPROVAL

The Emory Institutional Review Board (IRB) determined that this project was a non-human subject study, therefore, it did not require review.

2.6 ANALYSIS

A blend of business, data/system(s), and risk analysis was used throughout the project.

2.6.1 BUSINESS ANALYSIS

Business analysis was performed to identify requirements, including the specific data elements of interest along with the functionality and access requirements between the two centers. Major consideration was given to determining the level of identification needed in the initial pilot versus the fully implemented system (i.e. whether the data set needed to contain personal health information or if it could be de-identified). The answer to this question

determined the pathway that we would need to pursue to adhere with the regulations that support HIPAA throughout each stage of the project.

2.6.2 DATA/SYSTEM(S) ANALYSIS

Data and systems analyses were conducted to determine the current structure of SurgiNet and SurgiNet-Anesthesia, and to determine the availability of the specified data. Further analysis was conducted on the integrity, completeness, and location of metadata within the source.

Collectively, these requirements were weighed against the various approaches to system design. HIMSS outlined three clinical data exchange models: centralized, decentralized/federated and hybrid. Each model presents issues of interoperability; development and sustainability; and privacy and security concerns for health environments, clinical providers and patients. (HIMSS, 2009) The pros and cons of each model were analyzed alongside the goals and objectives of the organizations.

2.6.3 RISK ANALYSIS

Many of the driving components of a system (e.g. organization structure, business process, stakeholders, etc.) can be very fluid; therefore, any change without mitigation could directly impact our design and success of such a multidimensional system. At a high-level, we cataloged risks and identified methods of mitigation, and contingencies.

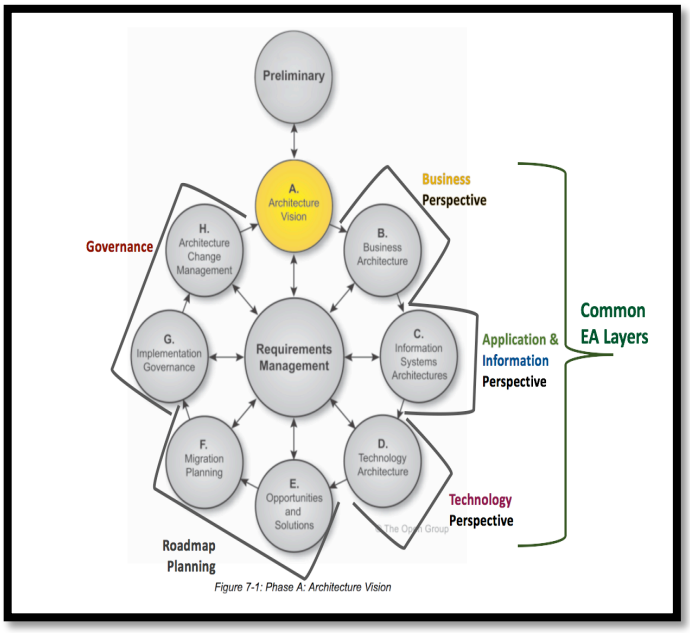
3 CHAPTER 3: RESULTS

3.1 INTRODUCTION

As introduced in the first chapter, there are four main perspectives of EA: Business, Application, Information, and, Technology perspective. Requirements gained from each layer added a foundational component to the overall EA.

Integrating TOGAF's ADM model (illustrated below) forced the assessment in a broader direction. These were grouped to include Roadmap Planning (E&F) and Governance (G&H). System attributes of this kind are critical to the data integrity and future use of the system. Through this EA analysis we identified critical requirements in each common layer and considered TOGAF's broadened factors to assemble a strategic plan and craft an overarching EA for a multi-centered ALTCDSS.

Continued are the results from the following areas:



TOGAF's ADM grouped into the areas of focus for the ALTCDSS

3.2 Business Architecture

3.3 Information-Systems Architecture

3.3.1 Information Architecture

3.3.2 Application Architecture

3.4 Technology Architecture

3.5 Roadmap Planning

3.6 Governance

3.2 BUSINESS ARCHITECTURE

Business architecture is the business strategy, governance, organization, and key processes (TOGAF, 2009). Through this phase, we identified the reason for the system and our analysis contributed to the list of facts, requirements, and assumptions that the system must work within. Specifically, we defined key attributes and business processes of a successful system, determined major barriers and created business strategies to mitigate while developing a business strategy and template for key system processes (e.g. utilization of BAA's to share PHI across entities).

3.2.1 GUIDING PRINCIPLES

During requirement gathering, we determined that a successful system would meet the demand for strong data accuracy, result in high productivity (i.e. could produce results and be used for research), provide meaningful feedback to users, and maintain engagement from the various collaborating centers. A set of guiding principles were defined, through SME interviews and literature review, to help steer an overall architecture for the ALTCDSS:

- ***Adopt Industry Proven Approaches for Secure Exchange of Information***

  I. To handle PHI and adhere to regulations of HIPAA.

- ***Platform Neutral, Standards Based, and Specification Driven***

  II. To ensure data accuracy for high productivity

- ***Moderately Distributed Architecture with a high degree of local autonomy***

  III. To promote self-sufficiency within the collaborating centers, but limit collective resources working to build the same system per the specifications needed. To also provide a high-level of data management that ensures data accuracy.

3.2.2 FACTS, ASSUMPTIONS, AND REQUIREMENTS

There were several considerations around data sensitivity, infrastructure, design, data governance, and ownership to determine the best design for efficiency and long-term success. We considered the following facts, assumptions and requirements that the system must work within while cycling through the various subsets of EA.

#	Facts
1.	The actions and decisions made during the intraoperative period of surgery can directly impact the quality of care and lasting health outcomes for a patient.
2.	Due to the size of the liver transplant population per organization, recruiting and maintaining engagement from external centers is essential for valuable analytics. *(e.g. GA state average is 208 transplants per year* [OPTN,2018]*)*
3.	A combination of resources (people, time, and money) will be needed to initiate and maintain the solution, regardless of design.
4.	Considering the granularity of data and long-term goal of tracking patients across centers, sharing and utilizing PHI will be necessary at some point.

#	Assumptions
1	This effort is in alignment with the strategic goals of each participating transplant center and each participating transplant center has the desire to receive more information about their patient population.
2.	Transplant centers are interested in measuring population-based outcomes.
3.	A substantial level of data discovery will be needed to truly capture the data of interest that support the algorithms that will in turn create the biomarkers.

#	Requirements
1.	Must collect high velocity, granular intraoperative data to determine clinically relevant algorithms and meet business needs.
2.	Must have ability to share information and be accessible to external transplant centers beyond canned reports.
3.	Must have a feedback mechanism to provide meaningful information back to the collaborating centers on their performance with benchmarks.
4.	Must have a process in place to recruit and maintain engagement from collaborating centers.
5.	Must sustain data accuracy and completeness.
6.	Must maintain strong data governance (standardization of data definitions) to maintain data integrity.

3.2.3 BUSINESS GOALS

The business-related goals are bulleted below:

- **Who:** Clinicians and analysts within the two healthcare organizations primarily in the fields of transplant surgery and anesthesia.
- **What**: Sharing granular data associated to the transplant population. This will include donor and recipient information in areas of surgery and anesthesia from the intraoperative record along with preoperative labs, orders, and postoperative outcomes. This will include PHI due to the frequency and variety of data elements needed for analysis.
- **When:** Reports will need to be monthly to identify trends and determine biomarkers.
- **Where:** The data would be shared between healthcare organizations
- **Why:** To create a statistically significant sample size for proposing clinical practice modifications based on empirical data.

3.2.4 KEY BUSINESS PROCESSES OF THE SYSTEM

1. Receive data from external sources	The ALTCDSS will need to be able to receive data from participating external centers.
2. Send information to outside source	The ALTCDSS will need to aggregate, analyze data to generate reports/dashboards for individual centers to use.
3. Perform data analysis	The ALTCDSS will identify trends, use clinically defined algorithms to analyze patient outcomes and, overtime, will serve as a predictive model by triggered events.
4. Handle PHI	The system at full maturity will host, maintain, and share PHI across centers.
5. Employ Data Governance	The lead healthcare organization will establish data governance to help manage, define, and expand on system standards, uses, constraints, and objectives.
6. Manage Access	Govern the access and engagement of centers, vendors, and external users

3.2.5 ACCESS AND ENGAGEMENT

Given the business processes and sensitivity of information, there is a need to manage the access and engagement of centers, vendors, and external users. This is a key process that is not only recommended but required for the sharing of PHI. Therefore, the following business process can be applied. Appendix A provides a Business Associate Agreement (BAA) and Data Use agreement form from MPOG that may serve as a template and be considered for use as external users engage with the system. We identified, and outlined the various events of this business process. To document each step, we used CMS's Medicaid Information Technology Architecture (MITA) business process template (referenced below).

MITA Business Process Template

Establish User Agreement/Business Associate Agreement	
Description	Create and sign agreement with business associate (e.g. collaborating centers, and any contributing vendors) to share data and protect PHI.
Trigger Event	Contact made with collaborating centers or vendor regarding the hosting and sharing of information.
Result	• Vendor agrees to relationship and hosting the service • Collaborating centers agree to participate • Establish agreement between business associates
Business Process Steps	1. Send request to establish business agreement. 2. Conduct collection of agreement materials with other party. 3. Validate information. 4. Establish terms of agreement. 5. Establish data exchange requirements. 6. Establish authentication protocol. 7. Establish security protocol. 8. Establish privacy requirements. 9. Sign agreement. 10. Send notification of agreement to business partner.
Shared Data	Data transferred and stored within ALTCDSS
Predecessor	Receive inbound transaction
Successor	Send Report Outbound
Constraints	Federal, state, and local policies and regulations
Failures	Parties cannot agree on terms of agreement
Performance Measures	Availability of meaningful data, feedback reports, and engagement with colleagues.

3.3 INFORMATION SYSTEMS ARCHITECTURE (INFORMATION & APPLICATION ARCHITECTURE)

The Information Systems Architecture serves as the bridge between the Business Architecture (BA) and the Technical Architecture (TA) by providing the framework to go from the BA's information requirements to the TA's message requirements. Sometimes, this layer is split into two areas of focus: Information (or Data) Architecture and Application Architecture. However, TOGAF combines the two based on their relativity. Information Systems Architecture is comprised of:

1) **Information Architecture**: describes the structure of an organization's logical and physical data assets and data management resources. (TOGAF 9.1)
2) **Application Architecture:** provides a blueprint for the individual applications to be deployed, their interactions, and their relationships to the core business processes of the organization. (TOGAF 9.1)

In this segment, we identified the data and integration component of the ALTCDSS, studied several types of information architecture models, and conducted analysis to weigh the pros and cons of each as they applied to the ALTCDSS. Then, we considered the application architecture as it relates to each model to determine who and/or what would interface with the system and their complexities within.

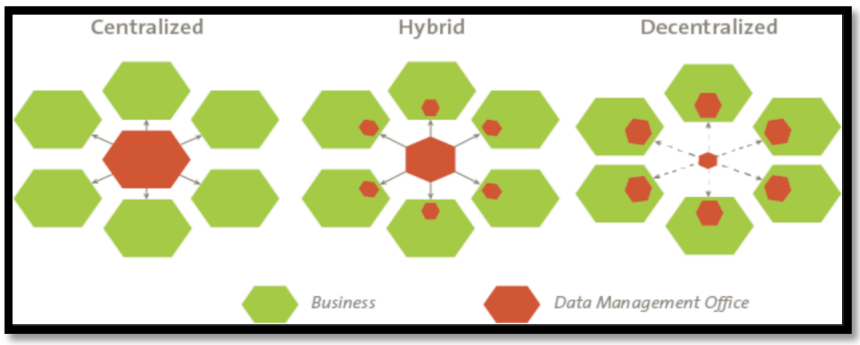
3.3.1 INFORMATION ARCHITECTURE

When studying information architecture (IA) models, there was no clear choice. A company, *Compact*, explained that "the choice of the best data management model is dependent on multiple influencing factors: data dimension, the level of automation and available expertise." In choosing a model, we identified the data dimensions that need to be maintained. We thought about which level of automation was required and for what processes. Lastly, we considered

what level of expertise existed within the business related to data management and if they could maintain the quality of data at a decentral level.

3.3.1.1 Information Architecture Model Analysis

We evaluated the pros and cons of architectural models as they applied to the ALTCDSS. This assessment had a major role in determining the best fit for our project objectives. The image below illustrates the inverse dynamic between the business and the data management component in each IA model. *Image Source: Compact*



Below are the pros, and cons of each model, from a system perspective. Those starred (*) contain the considerations of most concern for the ALTCDSS.

Centralized- Recommended	
Pros	**Cons**
Highest-level of control	High upfront investment in central resources
Single Data Source- one stop shop*	Strong central coordination is required. The central database cluster needs to be carefully managed and maintained for this system to work.
Offers the best level of data management; well defined data fields through governance, to include the addition or change in existing fields.	More risk on the central location, if other centers do not participate. *
Economies of scale can be introduced by using large-scale central resources, if appropriate investments are made.	Timeliness. Data submissions from participating systems may lag, resulting in inaccurate consolidated records at query time.
Typically, the querying system's response to a data request is quicker than other models because the data is centrally maintained and consolidated	Likely expensive option to implement, not only technically, but organizationally
No need for local experts to receive customized reporting; or information *	Less flexibility for other centers *
Better expertise in managing central resources due to their scale and class of products used	All data must be abstracted into the UI for the central system ie. no possibility for sourcing data from distributed systems.
More structured solution *	
Easier to enforce data governance *	
Less costs to external centers: could promote their buy-in *	
Successful use by subject-related registries (i.e. NSQIP, SRTR) *	

Hybrid- Not Recommended	
Pros	**Cons**
Gives the collaborating centers their own autonomy	Difficult to initiate without investment, and considerable IT resources, at each location *
Shares the responsibility of the system, across centers *	Shares the responsibility of the system, across centers; less control *
Data is always current.	Models, standards and profiles are still being defined. Not a widely-used model, to compare or evaluate against *
Any EHR system can be connected to any other, but assumes common interface standards.	Harder to employ, and enforce aspects of data governance than centralized *
Creates, and maintains stakeholder buy-in; less likely to disregard system *	

Decentralized- Not Recommended	
Pros	**Cons**
Allows the most flexibility within each organization	Need to ensure authorized and legitimate access to third-party systems.
Data is stored locally at the point of service and accessed only when needed for exchange. *	Need to capture consumer consent to opt in and opt out of the decentralized network thus ensuring legitimacy for data usage.
There is no conflict of who owns the data except for the ownership rights of the consumer.	Data control and availability is not guaranteed, thereby limiting the value that can be achieved by providers. *
Data is always current.	Standards and profiles are still being defined. *
Failure of a single system doesn't cripple the whole model or others in the exchange, but it may make some patient data unavailable at the time of a query. *	Most difficult to enforce data governance *
Any EHR system can be connected to any other, but assumes common interface standards.	
More repositories or compartmentalization means a smaller amount of data is available to potential hackers with single-system penetration, though this is arguable as penetration of an RLS could provide access to the same quantity of patient data. The data would just have to be retrieved to collect it in a central file–the function of an RLS.	

(HIMSS, 2009)

3.3.1.2 Data and Integration

When considering these IA models, we considered the current state of information and the integration that may be needed. Currently, there is not a system that collects and aggregates this data with the level of granularity needed to perform population-based analysis for this population. This type of information is typically stored within each healthcare organization and contained within their custom electronic medical record system and/or data warehouse. If analysis is needed, data is usually generated in a report and limited to the accessible information generated from that specific organization.

Enterprise Architecture Design for a

Multi-Center Anesthesia Liver Transplant Clinical Decision Support System

In the future, we want to leverage the work of existing centers by a collective interaction that allows the compilation, comparison, standardization and aggregation of granular intraoperative transplant information across multiple transplant institutions. Below is a brief description of the information's location, and expected integration of sources.

- **Location of Data**: The data of interest already exists in the local EMR at each facility. However, through the development of this system, it could be requested that other elements be added to the system and/or each local EMR respectively. Each module allows customization, so formats and locations of data elements will likely vary. There will be a need to provide data mappings between applications as definitions are identified.

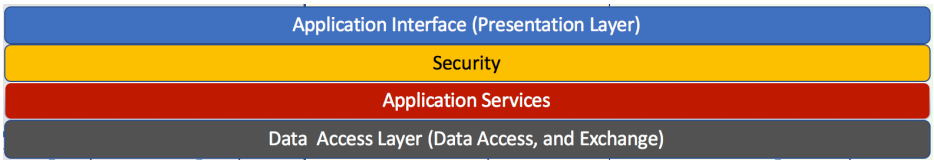
- **Integration**: PHI data from various sources at each center will be integrated into a shared system. As mentioned above, there will be a need to identify specifications and map elements from each source location to the ALTCDSS.

For purposes of the information itself, here is a sample of relevant data elements that will span the various data types of: character, varchar, integer, numeric, date, time, and timestamp.

Pre-Op	Intra-Op	Post-Op/Outcomes
Center	Cardiac Arrest (1=yes, 0=no)	cardiac arrest (1=yes, 0=no)
Year of Transplant	Total Operative Time	Intra-op death
Cardiac Arrest (1=y, 0=n)	Operation>8hr (1=yes, 0=no)	30-day graft failure (1=y, 0=no)
Donor Type (1=D, 2=L)	Case Timestamps	30-day mortality (1=y, 0=n)
MELD Calculated	Post Reperfusion Syndrome (1=yes, 0=no)	Hospital-death (1=y, 0=no)
MELD>20 (1=yes, 0=No)	Severe Hypotension (<60mmHg) (1=yes, 0=no)	1-year graft failure (1=y 0=n)
Redo (1=yes, 0=no)	FFP units	1-year-mortality (1=y, 0=n)
Age	RBC units	Post-op-Dialysis
Gender (1=M, 0=F)	PLT units	Post-venti
Weight (kg)	Cryo units	Reoperation (1=yes, 0=no)
Height (cm)	Fibrinolysis (1=yes, 0=no)	# Re-Operations (Take-Backs)
BMI	Flat TEG (1=yes, 0=no)	Mechanical Ventilation>72hr (1=yes, 0=no)
HCV (1=yes, 0=no)	Anti-Fibrinolitics given (1=yes, 0=no)	ICU LOS>7d (1=yes, 0=no)
HBV (1=yes, 0=no)	if V-V bypass (1=routine, 0=no)	Hospital LOS
Cholestatic (1=yes, 0=no)	Technique (Total Caval Isolation=1, Piggyback=2, VVB=3)	AKI at 72 h (1=yes, 0=no)
Alcohol (1=yes, 0=no)	Personnel	Mortality 1d (1=yes, 0=no)
AIH (1=yes, 0=no)	Actions: TOF, Anesthesia Ready, ABX	
Cryptogenic (1=yes, 0=no)	Arterial Line #	
NASH (1=yes, 0=no)	Art Line Location (1radial, 2 axillary, 3 femoral, 4 other)	
HCC (1=yes, 0=no)	Art Line #2 location (0 none, 1 radial, 2 axillary, 3 femoral, 4 other)	
Status 1/FHF (1=yes, 0=no)	Dialysis Line (1=yes, 0=no)	
CAD (1=yes, 0=no)	TEE (1=yes, 0=no)	
DM (1=yes, 0=no)	If yes TEE, 1=routine, 2=rescue, 3=selected patient	
HTN (1=yes, 0=no)	PAC (1=yes, 0=no)	
PPH (1=yes, 0=no)	Transfusion Protocol Used (1=yes, 0=no)	
HRS (1=yes, 0=no)	RRT intra-op (1=yes, 0=no)	
HPS (1=yes, 0=no)	Calcium Gluconate (mg)	
On RRT (1=yes, 0=no)	Induction Agent	
CHF (1=yes, 0=no)	Specified Medications, Dosages, and Timestamps	
Arrhythmia (1=yes, 0=no)	Fentanyl (mg)	
Asthma/COPD (1=yes, 0=no)	Epinephrine total (mg)	
Karnofsky score	Norepinephrine total (mg)	
	Vasopressin (u)	
	Ephedrine mg	

3.3.2 APPLICATION ARCHITECTURE

As we continued, we considered the architecture of the application that surrounds the IA model. Doing so allowed us to compare how each IA model interfaces with the users and the database. Each IA model has a unique interface when considering the interactions of the individual centers and the ALTCDSS. The application architecture that surrounds each model can require more emphasis in data services on the individual healthcare centers or on the lead center depending on model. Furthermore, when concerned about data integrity, we could pinpoint weaknesses and strengths in the data conversion processes through this comparison. An application would need to be created to interact with the ALTCDSS. There are four main application layers that would exist, regardless of IA model:



- **Presentation Interface**- this is the layer that customers most often interact with. In this case, it would be the front-end of the ALTCDSS.
- **Security Layer**: Because the database will contain PHI, security will need to ensure that all data is encrypted at rest and in motion. Minimally, the system will need authentication, identification and, authorization. In addition, it will need system entry control, auditing of report generation, security management, trusted recovery, encryption, and trusted communication.
- **Application Services:** This layer hosts a wide variety of services. It would include the business logic, workflows and intelligence services.
- **Data Access Layer:** This layer is responsible for driving the data and pulling the data to the appropriate location.

Each IA model has some level of interaction though a Data Services layer (indicated by the green icon). This process handles the data conversion and exchange of each data element. In this process, we risk losing some of the relational concepts and, therefore, a little bit of meaning each time. It jeopardizes the semantics of each data element every time a conversion takes place.

In the Decentralized model, the individual centers must establish, and manage their own data services layers that direct the collection, aggregation, exchange and conversion of their information from their local EMR to their own hosted Anesthesia Liver Transplant database. This information can then be pulled from the ALTCDSS application. This is drastically different when comparing the centralized location which sees these processes occur all in one place. One of the prime weaknesses of the decentralized model is governing and maintaining the meaning of data through this conversion process. The hybrid model may try to balance data management services with autonomy of each center; however, as indicated in the diagram below the amount of data services (e.g. data transformation) that must take place puts the meaning of such data at risk. Regardless of the model, each time this process takes place it creates the potential for data integrity and semantic mismatch issues, as the semantics from the data in each source system become jumbled.

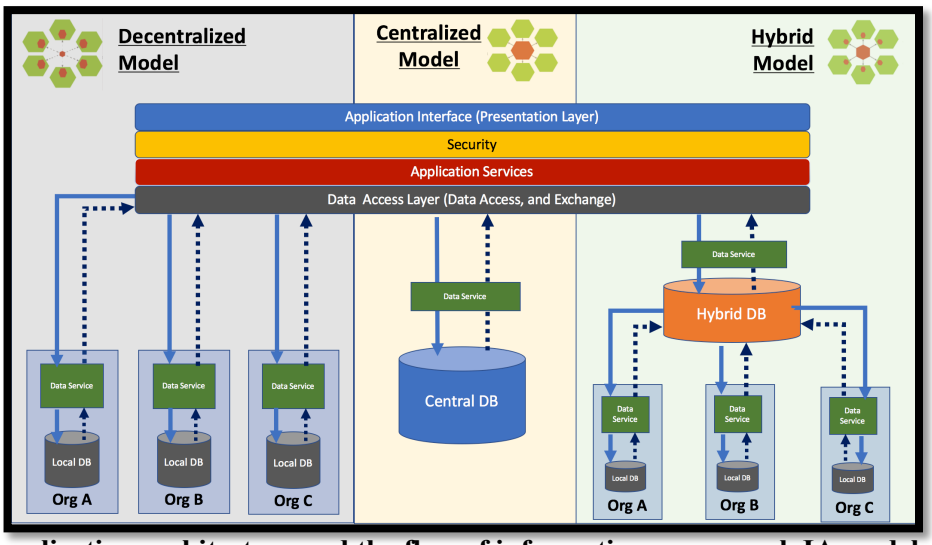


Illustration of application architecture and the flow of information across each IA model

3.4 TECHNOLOGY ARCHITECTURE

The Technical Architecture (TA) describes the logical software and hardware capabilities that are required to support the deployment of business, data, and application services. This includes IT infrastructure, middleware, networks, communications, processing, messaging standards, etc. (TOGAF 9.1, Ch7)

Examining the TA, typically identifies the new IT capabilities that are needed for the new system. In most cases, choosing the best technological solution and designing the technical architecture for the problem can only be determined through a thorough analysis of the other components. For this endeavor, the TA component remained high-level to complete an initial preliminary EA design. Therefore, to steer the future technical plan, we identified technical principles formed through the artifacts of the business, information and application architecture.

3.4.1 TECHNICAL PRINCIPLES OF ALTCDSS

- **Business driven** – ALTCDSS will employ technology that supports the business goal or objective; i.e. technology should not exist for technology's sake alone. Technical solutions will map to specific business needs.
- **Platform neutral** – Project team will evaluate the various methods of development, and choose the one best suited to meet the objective, in the most efficient manner.
- **Adaptable, extensible, and scalable** – The project team will use service oriented architecture (SOA)-based applications, so that they can develop it in a modular fashion to accommodate future expanding business requirements.
- **Open technology and standards based** – Stakeholders will leverage the advantages of standardization by requiring data sharing and interoperability.
- **Integrated security and privacy** – The system will maintain security and privacy of information throughout the solution.
- **Interoperability standards** – The system will establish and follow the SOA design principles to insure seamless functionality between services and other entities.
- **Quality data** – Participating centers will design systems, and workflows to establish the ability to provide the most current data, so that they can make business decisions in a timely and accurate manner.
- **Current and proven technology** – Stakeholders will select currently established technology, and infrastructure to support current business needs.

3.5 ROADMAP PLANNING

As mentioned in the executive summary, the development of any large-scale solution needs to be built with sustainability and future-use in mind. The opportunities for this system expand beyond liver transplant. The system can be purposed to serve the full range of organ transplantation (e.g. Kidney, Heart, Lung, Pancreas, etc.) and could serve as a model in sharing granular intraoperative data for other surgical specialties.

To prepare our design for future use we set system evaluation criteria to score the system against, and strategized high-level risks and implementation factors (e.g. data governance). Typically, this sector would include migration planning but, it was bypassed for our purposes since this system did not exist and there was nothing to transfer.

3.5.1 KEY PERFORMANCE INDICATORS/ EVALUATION CRITERIA

The system can be continuously evaluated as it progresses. A few key performance indicators of the ALTCDSS are:

- Strategic Alignment with Stakeholder Organizations
- Engagement and collaboration among Academic Medical Centers
- Increase in Surgery & Hospital Productivity
- Increase in Surgery & Hospital Efficiency
- Decrease in Overall Costs
- Improvement in Health Outcomes

3.5.2 RISK MANAGEMENT

The following table presents the risks with applicable mitigation and contingency strategies that the ALTCDSS may experience.

1. Lack of Participation

Description: The additional prospective centers may choose to drop out, or may not want to participate with the ALTCDSS.	**Probability**: Low	**Impact**: High
	Mitigation Strategy: Early in the project, discuss the benefit that may be offered to the organizations to incentivize cooperation. Get stakeholder buy-in from centers, and provide meaningful feedback with benchmarking measures.	
	Contingency Plan: Identify stakeholders at prospective centers, and identify the reasons for the lack of interest. Then try to accommodate, if possible.	

2. Vendor Limitations

Description: Vendors (SurgiNet or SurgiNet Anesthesia) may have or acquire certain limitations that could impact the output of the system.	**Probability**: Low	**Impact**: Medium
	Mitigation Strategy: Have full transparency between the project team and vendor liaison about the downstream impacts from application changes; to circumvent unknown issues and avoid unnecessary ones.	
	Contingency Plan: Adjust, if possible. Otherwise, identify the issue, pause the system (if necessary), assess the impact and plan accordingly.	

3. Security

Description: Those hosting the data are responsible for all security, and physical machines used to host the application.	**Probability**: Low	**Impact**: High
	Mitigation Strategy: Ensure security protocols are defined, and established. Security will be enabled at each layer of the application.	
	Contingency Plan: Having the ability to lock down, and/or shut off access.	

4. Data Integrity

Description: Inaccurate, and/or incomplete data could be uploaded into the system.	**Probability**: High	**Impact**: Medium
	Mitigation Strategy: Ensure data governance, and data standards are established. Employ techniques to verify the accuracy of data within the application.	
	Contingency Plan: If errors are identified, the data should be refused from uploading, and manual review can take place to validate reasonable results.	

5. Funding Issues

Description: The funding for the project may be diverted or retracted	**Probability**: Medium	**Impact**: High
	Mitigation Strategy: Express importance of project and return on investment. Obtain stakeholder support internally, and externally among participating centers.	
	Contingency Plan: Partner or seek out support from other organizations that share interests and can offer financial support; seek-out grants and awards	

7. Stakeholder/People Turnover

Description: The funding for the project may be diverted or retracted	**Probability**: Medium	**Impact**: Medium
	Mitigation Strategy: Express importance of project and return on investment. Obtain stakeholder support internally, and externally among participating centers.	
	Contingency Plan: Partner or seek out support from other organizations that share interests and can offer financial support; seek-out grants and awards	

3.6 GOVERNANCE

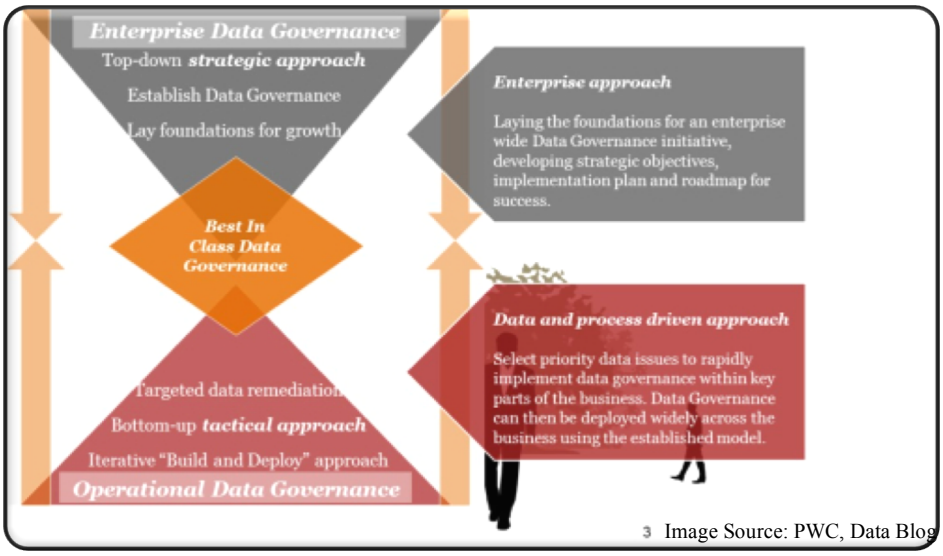
3.6.1 DATA GOVERNANCE STRATEGY

Data governance ensures that the right people are involved in determining standards, usage, and integration of data across projects, subject areas, and lines of business. Having a comprehensive data governance plan will be critical to the success of this system.

Given the strategy of piloting this system and working through the data requirements for algorithms, it is important to structure data governance in a way that can still allow iterative

development. For this reason, PWC's operational data governance approach is one to model after. They explain, "although, laying the foundations and establishing the program at an enterprise level is critical to get the buy in, it is not something that can remain an isolated set of events. This is where many programs fail. The enterprise effort needs to be supported by a tactical effort." (PWC, Data Blog).

Their model of 'Operational Data Governance' is an approach that embeds governance in an iterative way that can promote the technical team to build, test, deploy, and evaluate. Throughout the development of this system, this methodology will be keen to achieve the desired results of such a data-driven system. The strategic vision will be led by the business, mostly made of clinicians; while, the technical team evaluates and decides on tactical resolutions. As illustrated below, this visionary and operational approach provides "governance" on both sides of the spectrum.



3 Image Source: PWC, Data Blog

This methodology aims to focus on development of strategic objectives, policies, models and roadmaps with an understanding to resolve the priority data issues, defined workflows, roles and responsibilities, data management tools, processes, and enablement, and to ensure successful

deployment and adoption. It allows the business to take a concept and test it through well-planned pilot implementations in prioritized areas. (PWC, Data Blog)

3.6.2 IMPLEMENTATION OF DATA GOVERNANCE

To maintain engagement from collaborating centers, we can require participation with our strategic enterprise data governance through business associates agreements, and data use agreements. Through this implementation, the business associates become stakeholders to engage in the visionary discussions, partake in project-related matters, and ultimately, drive the existence of the system. Meanwhile, this structure of data governance will allow the tactical data governance (employed by the lead healthcare organization) to provide support, elevate concerns or limitations, and engage with the stakeholder committee throughout each deployment evaluation.

Applying data governance will promote data integrity, accuracy, and completeness from the beginning of development through maturity; which, are imperative for strong, accurate data analysis and research. Furthermore, it creates a strategy for long-term sustainability and protects each level of the EA; while, fostering engagement from collaborating centers. Through this strategic and operational implementation, we can promote and protect critical system attributes to withstand system development and modifications over time.

3.6.3 CHANGE MANAGEMENT

Change management is a process that focuses on supporting system modifications, enhancements, and affected areas that may fluctuate throughout development, and maintenance of a system. Having a process and/or protocol in place to identify, assess, and plan for these "changes" is key in meeting project objectives without negatively affecting the current state of the system.

This process can be incorporated into data governance and controlled by the two teams. The steering enterprise data governance will likely drive initiatives and create new objectives for the system to meet. Meanwhile the operational team will assess, plan and reach consensus on best approach to meet the demand. Often the value of a proposed "change" is weighed against the potential negative impact to the system. This balancing act requires a strong relationship between both governance groups, as indicated above. These teams must work together to reach project milestones, and to do so in the most efficient and effective manner.

3.7 SUMMARY

EA is a comprehensive framework used to manage and align an organization's Information Technology (IT) strategies, plans, and systems to support the organization's mission, goals, and structure [(NIH)]. Each aspect of EA: Business Architecture, Information Systems Architecture (encompassing both Information and Application Architecture) and Technology Architecture address a different aspect of the system. Working through these components and overlapping TOGAF's ADM allowed us to design a preliminary EA design for a multi-centered ALTCDSS.

Building off the existing body of knowledge (HIMSS, TOGAF, CMS, and NIH), we aligned our methods with major entities of informatics; providing standardization in our approach. Working through this process allowed us to accomplish each aim of our project:

1. *Determine a high-level technological approach of managing an ALTCDSS both internally and externally*
2. *Determine the business rules of such system*
3. *Design a recommended model that could support, promote and foster the sharing of information among healthcare centers*

A major accomplishment to highlight for the ALTCDSS project was establishing a process of sharing PHI between two centers. We conquered this hurdle by identifying a process to establish business associates through BAA agreements. The BAA will serve as a gateway to utilize the system but also as a method to engage and maintain commitment from collaborating centers, while controlling modifications for the betterment of the system.

Both the decentralized and hybrid model require each organization to create, maintain and ensure the success of their own system. This creates duplicate work and directly contradicts our third guiding principle: "*To promote self-sufficiency within the collaborating centers, but limit collective resources working to build the same system …and to also provide a high-level of data management that ensures data accuracy.".*

Furthermore, the main weaknesses of these two models are governing and maintaining the meaning of data through the transformation process. The centralized model offers more control over the data transformation process and is a more structured solution that has shown success in other greatly adopted systems (e.g. NACOR, NSIQP, etc.).

All projects are carried out under certain constraints. Typically, these constraints are cost, time and scope (often referred to as the triple constraint). Distributing the responsibility of creating these systems across multiple centers guarantees that each center will need to work within these constraints. This will delay projects, and may turn away prospective centers that do not have the time, money or resources to commit on an ongoing basis. If they can initiate the design, they may not achieve the full scope. Distributed development creates a major risk in variation between source systems and can lead to issues with completeness, and integrity of data.

Using a centralized model, there is no need for local experts to pull reports, or make slight modifications. It creates a one-stop shop and shifts the risks and effort from the external

centers to the lead organization. These risks faced by the central location can be offset by examining the other aforementioned-centralized systems in the medical field. Furthermore, we can assume that the low barriers to entry will increase the interests and adoption from external centers which will solidify the system as an institution, overtime.

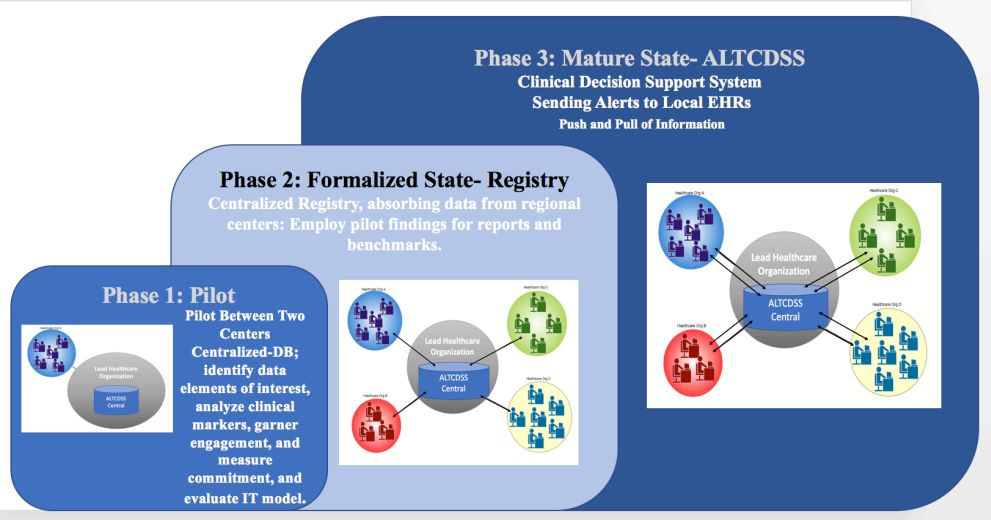
For these reasons, we determined that an iterative approach utilizing a centralized model would be the best way to circumvent wasted time, effort and resources. Breaking down the development into iterations from a pilot, to a registry, then to a matured system gives us the means to measure success, and later set the stage for a matured system. The most resourceful organization should take lead due to the required level of commitment needed upfront.

Following this iterative approach, a pilot will allow us to work through the logistics of resources, costs, time, and legal agreements. In this stage, the project team will create a central database, evaluate IT models, and measure external engagement. Again, this will require a high-level of commitment from the lead organization to drive this effort into existence but the up-front focus and planning has proven to be advantageous. Furthermore, showcasing the success from a piloted version can broaden engagement, and monetary resources from additional stakeholders.

In a formalized state the system could become a registry. It could collect, analyze, and share perioperative (identifiable) information and assist with identifying changes in outcomes based on methods of care. In this state, the system can be shared across several institutions with an established enterprise data governance committee leading the strategic vision. The system can stay in this phase for years. This stage provides the system with a chance to formalize the algorithms that could later turn into real-time triggers and/or indicators.

And lastly, in the most matured state the ALTCDSS system could become a system that returns meaningful information on triggers, determinants, alerts and contextual information on a real-time basis leading to an immediate influence on patient care.

Starting with the two centers, the illustration shows the progress of each iteration.



Iterative development phases of the ALTCDSS

Overall our EA analysis resulted in clear choices about principles that the system should follow from a business and technical standpoint. In addition, it resulted in a comprehensive strategy for sharing PHI between centers, and data governance. Through this strategic and tactical implementation, we can promote and protect critical system attributes to withstand system development and modifications over time.

4 CHAPTER 4: DISCUSSION

4.1 SUMMARY OF PROJECT

Due to the low number of liver transplants per center, clinicians are limited in their ability to analyze and trend outcomes in their population. A solution to this problem could be a system that aggregates data among centers. This could create a significant sample size for proposing clinical practice modifications, and create an opportunity for real-time alerting and predictive analyses to support clinical decision making during intraoperative care. Currently, this functionality does not exist for this population, creating a void in clinical care and an opportunity for clinical improvement using informatics.

The idea of this system raised many questions and concerns about sharing PHI, and whether a centralized versus decentralized approach was best, considering the need to maintain commitment from collaborating centers. Therefore, the creation of this system was studied and a preliminary EA design was created for an ALTCDSS that collects, shares, and analyzes information across multiple transplant institutions. By overlapping the ADM from TOGAF with the main components of EA: Business, Information, Application and Technology Architecture, we identified the key processes, risks, IT models, constraints, and complexities that the system would work within.

To address the concerns of sharing PHI, a strategy was developed for sharing PHI between centers and to implement data governance using BAAs, and DUAs and a robust cross-center data standards governance process. Having these protocols in place helps address security and data accuracy. Furthermore, it creates a process to manage modifications and development throughout the lifecycle of the system.

Overall, the EA analysis created a balance between determining and meeting the needs of the organization and formulating an IT approach. We concluded that the combination of a centralized model, and iterative development (starting with a pilot, to a registry, then to a matured system) would be the best way to circumvent wasted time, effort and resources. This iterative development will set the stage for a matured system by allowing us to evaluate methods and measure success quickly in small phases.

The project team will need likely consist of clinical SME's, legal advisors, IT project managers, software developers, data scientists/biostaticians, database administrators, IT architects for each layer of EA. At this point, the project team can now move forward with the EA design and the key processes we identified to obtain consensus in the proposed models with collaborating centers, create work-breakdown structures and secure funding to initiate the pilot.

4.2 LIMITATIONS

The application of EA can be used in a limited fashion based on the depth of the analysis required for one's project. In other words, EA is only as good as the effort put into it.

For our purposes, this was a preliminary design. A comprehensive technical plan with a work-break down structure, and cost analysis is still needed to secure funding for the concept. However, through the examination of each EA layer and the comparison of other systems, we now have a high-level architecture with enough detail so that it can be proposed to other centers. This will allow us to precisely measure the interests and manage the interworking processes of sharing PHI, governing access, and development; which, has served as the major barrier to starting this endeavor.

For our project, requirements were only gathered from one transplant center, that hopes to serve as the lead organization in this effort. Gathering requirements in this limited fashion

impacted our ability to study the needs and requirements from an external center's perspective. For example, we made assumptions related to an external center's desire to manage their own system when considering the resources needed for the endeavor. We assumed that it's easier for a lead center to carry the technological burden rather than each individual center having to initiate a separate system, and isolate resources (time, money and people) to do so.

We are also limited due to the small number of similar systems. For those that do exist, there is minimal research conducted on the success of those solutions. Informatics is a growing field, but it's relatively new and there are major gaps in the evaluation of current systems.

Lastly, this EA design remained high-level. It was designed to be flexible but during each stage of the project, the development process will breakdown each EA layer in a more granular manner. It could be expected that elements may be identified that could cause changes in design, implementation, and/or governance of the system.

4.3 FUTURE USE

With successful adoption of an ALTCDSS (over time), predictive measures can be provided to the healthcare organizations to improve public health and the specialty of organ transplantation. The system can be purposed beyond liver transplant and serve the full range of organ transplantation (e.g. Kidney, Heart, Lung, Pancreas, etc.). In the future, this solution could help guide public health action at the federal, state, and local levels in producing guidelines for care, while serving as a model in sharing granular intraoperative data for other surgical specialties.

4.4 IN SUMMARY

EA is a fundamental aspect in the field of informatics. The development of any large-scale solution needs to be planned and built with sustainability in mind. Creating a EA, identifies the key aspects that are easily overlooked in a brainstorming session. Using EA as a guide to break down the various components of a system, allowed us to identify and deliberate on aspects from strategic alignment to technical implementation and maintenance of the system overtime.

We found that the EA analysis drove us to balance the needs of an organization and the IT approach, simultaneously. Overwhelmingly, this project started as an idea to develop a major system that shares granular PHI data between healthcare institutions, and sends real-time alerts for a specified population. However, developing an EA led us to break down the business needs into iterations that parallels with the development of such system; thus, providing a systematic approach that aims to be comprehensive and efficient. With this initial design, the project team can now move forward to obtain consensus in the proposed models, and secure funding to initiate the pilot.

5 APPENDIX A

5.1 SAMPLE BUSINESS ASSOCIATE AGREEMENT- (*MPOG, 2018*)

HIPAA BUSINESS ASSOCIATE AGREEMENT

STUDENT EXAMPLE- DO NOT USE

THIS HIPAA BUSINESS ASSOCIATE AGREEMENT ("BAA") is entered into effective the ____ day of _____, 20__ ("Effective Date"), by and between _____, on its behalf and on behalf of its subsidiaries and affiliates ("Covered Entity"), and the Regents of the University of Michigan, a Michigan constitutional corporation on behalf of its affiliates ("Business Associate" "BA" or "UM").

Business Associate may perform functions or activities on behalf of Covered Entity involving the creation, receipt, maintenance, access, transmission, use and/or disclosure of protected health information ("PHI") received from or on behalf of Covered Entity. Therefore, Business Associate agrees to the following terms and conditions set forth in this BAA.

1.0 **Definitions**. For purposes of this BAA, any terms used herein, unless otherwise defined, shall have the same meanings as used in the HIPAA Privacy and Security Standards, as amended by the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009) and its implementing regulations ("HITECH") including modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules under HITECH.

2.0 **Scope and Interpretation**. This BAA shall apply only if and to the extent UM is considered a BA to Covered Entity. Subject to this limitation, the terms and conditions of this BAA shall provide for Business Associate's creation, receipt, maintenance, transmission, use and/or disclosure of PHI, in any form or medium, including electronic PHI ("ePHI"), in Business Associate's capacity as "Business Associate" to Covered Entity. Any ambiguity in this BAA shall be resolved to permit Covered Entity to comply with HIPAA.

3.0 **Compliance with Applicable Law**. Beginning with the relevant effective date, to the extent Business Associate meets the definition of a "business associate" of Covered Entity as such term is defined under HIPAA, Business Associate shall comply with its obligations under this BAA and with all obligations of a business associate under HIPAA, HITECH, as modified, and other related laws, for so long as Business Associate creates, receives, maintains, accesses, or transmits PHI.

4.0 OBLIGATIONS OF BUSINESS ASSOCIATE

4.1 Permissible Use and Disclosure of PHI. In addition to the uses and disclosures permitted by any base agreement(s) or this BAA, Business Associate may use and disclose PHI:

a. For its own proper management and administration,

b. To carry out its legal responsibilities,

c. To aggregate PHI in its possession to provide data aggregation services to Covered Entity as described in 42 C.F.R. § 164.504(e)(2)(i)(B),

d. To create De-Identified Data Sets and/or Limited Data Sets in compliance with the Privacy Rule; and to use or disclose information in such De-Identified Data Sets without further restriction; and to use or disclose information in such Limited Data Sets pursuant to a Data Use Agreement as permitted by the Privacy Rule; and

e. To report violations of law to appropriate Federal and State authorities, consistent with 45 C.F.R. § 164.502(j)(1).

4.2 Limitations on Use and Disclosure of PHI. Business Associate shall not, and shall ensure that its directors, officers, employees, agents, and subcontractors do not, use or disclose PHI in any manner that is not permitted or required by any Base Agreement(s) or this BAA, or as Required By Law. All uses and disclosures of, and requests by Business Associate for, PHI are subject to the Privacy Standards' Minimum Necessary Rule and shall be limited to the information contained in a Limited Data Set, to the extent practical, unless additional information is needed to accomplish the intended purpose, or as otherwise permitted in accordance with Section 13405(b) of HITECH, and any other subsequently adopted guidance. Additionally, Business Associate shall ensure that neither it nor its directors, officers, employees, agents, or subcontractors, access, store, share, maintain, use or disclose PHI beyond the borders of the United States of America without agreement of Covered Entity.

4.3 Security. To the extent that Business Associate creates, receives, maintains, or transmits ePHI on behalf of Covered Entity, Business Associate shall:

a. Comply with the security provisions found at 45 C.F.R. §§ 164.308, .310, .312, and .316 in the same manner as such provisions apply to Covered Entity, pursuant to Section 13401(a) of HITECH, and otherwise implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of ePHI;

b. Ensure that any agent to whom Business Associate provides ePHI agrees in writing to implement reasonable and appropriate safeguards to protect such ePHI; and

c. Report to Covered Entity promptly after its discovery any Security Incident of which Business Associate becomes aware and which results in a use or disclosure of ePHI in violation of any Base Agreement(s) or this BAA. Notwithstanding the foregoing, the parties acknowledge and agree that this Section 4.3.c constitutes notice by Business Associate to Covered Entity of the ongoing existence and occurrence or attempts of Unsuccessful Security Incidents for which no additional notice to Covered Entity shall be required. "Unsuccessful Security Incidents" means, without limitation, pings and other broadcast attacks on Business Associate's firewall, port scans, unsuccessful log-on attempts, denial of service attacks, and any combination of the above, so long as no such incident results in unauthorized access, use, or disclosure of Covered Entity's ePHI. In this context, the term "Security Incident" shall have the same meaning as such term is defined at 45 C.F.R. § 164.304.

4.4 Privacy. To the extent that Business Associate is to carry out one or more of Covered Entity's obligations under Subpart E of 45 C.F.R. Part 164, Business Associate shall comply with the requirements of Subpart E that apply to Covered Entity in the performance of its obligation(s) under this BAA. Business Associate shall also otherwise implement appropriate safeguards in accordance with the Privacy Standards to prevent the use or disclosure of PHI other than pursuant to the terms and conditions of this BAA.

4.5 Mitigation of Harmful Effects. Business Associate agrees to mitigate, to the extent practicable, any harmful effect of a use or disclosure of PHI by Business Associate in violation of the requirements of this BAA, including, but not limited to, compliance with any state law or contractual data breach requirements.

4.6 Breach of Security or Privacy Obligations.

a. Business Associate shall report to Covered Entity, within ten (10) business days of discovery, a use or disclosure of PHI not provided for in this BAA by Business Associate, its officers, directors, employees, agents, or subcontractors or by a third party to whom Business Associate disclosed PHI.

b. Business Associate shall report to Covered Entity, within ten (10) business days of discovery, a breach of unsecured PHI in accordance with the requirements set forth in 45 C.F.R. §§ 164.400-.414. Business Associate shall fully cooperate with Covered Entity's breach notification and mitigation activities, and shall be responsible for all costs incurred by Covered Entity for those activities.

4.7 Agreements by Third Parties. Business Associate shall enter into an agreement with any agent or subcontractor of Business Associate that will have access to PHI hereunder. Pursuant to such agreement, the agent or subcontractor shall agree to be bound by the same restrictions, terms, and conditions that apply to Business Associate under this BAA with respect to such PHI. Business Associate agrees to provide Covered Entity a list of all its agents or subcontractors upon request.

4.8 Access to Information. Covered Entity acknowledges and agrees that Business Associate does not, within the scope of its services, collect, retain or maintain Designated Record Set information. Accordingly, Business Associate has no obligation to comply with the access provisions of 45 C.F.R. § 164.524.

4.9 Availability of PHI for Amendment. Covered Entity acknowledges and agrees that Business Associate does not, within the scope of its services, collect, retain or maintain Designated Record Set information. Accordingly, Business Associate has no obligation to comply with the amendment provisions of 45 C.F.R. § 164.526.

4.10 Documentation of Disclosures. Business Associate agrees to document uses and disclosures of PHI and information related to such uses and disclosures as required for Covered Entity to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528.

4.11 Accounting of Disclosures. Within ten (10) business days of notice by Covered Entity to Business Associate that Covered Entity has received a request for an accounting of disclosures of PHI regarding an individual during the six (6) year period prior to the date on which the accounting was requested, Business Associate shall make available to Covered Entity information to permit Covered Entity to respond to the request for an accounting of disclosures of PHI, as required by 45 C.F.R. § 164.528. In the case of an electronic health record maintained or hosted by Business Associate on behalf of Covered Entity, the accounting period shall be three (3) years and the accounting shall include disclosures for treatment, payment, and health care operations, in accordance with the applicable effective date of Section 13402(a) of HITECH. In the event the request for an accounting is delivered

directly to Business Associate, Business Associate shall forward such request to Covered Entity within five (5) business days of receipt.

4.12 Restrictions. Business Associate shall comply with any restrictions on disclosure of PHI requested by an individual and agreed to by Covered Entity in accordance with 45 C.F.R. §164.522.

4.13 Judicial and Administrative Proceedings. In the event Business Associate receives a subpoena, court or administrative order or other discovery request or mandate for release of PHI, Business Associate shall notify Covered Entity in writing prior to responding to such request to enable Covered Entity to object. Business Associate shall notify Covered Entity of the request as soon as reasonably practicable, but in any event within two (2) business days of receipt of such request.

4.14 Availability of Books and Records. Business Associate agrees to make its internal practices, books, and records relating to the use and disclosure of PHI available to the Secretary of the Department of Health and Human Services for purposes of determining Covered Entity's compliance with the Privacy Standards.

4.15 Breach of Contract by Business Associate. In addition to any other rights Covered Entity may have in the Base Agreement(s), this BAA, or by operation of law or in equity, Covered Entity may, upon a breach or violation of this BAA, provide a reasonable opportunity for Business Associate to cure or end any such violation within the time specified by Covered Entity. If cure is not possible or if Business Associate does not cure such breach or violation, Covered Entity may immediately terminate the Base Agreement(s). Covered Entity's option to have a breach cured shall not be construed as a waiver of any other rights Covered Entity has in the Base Agreement(s), this BAA, or by operation of law or in equity.

4.16 Effect of Termination of Agreement(s). Upon the termination of the Base Agreement(s) or this BAA for any reason, Business Associate shall return all PHI created by Business Associate or received from Covered Entity to Covered Entity or, at Covered Entity's direction, destroy all PHI received from Covered Entity that Business Associate maintains in any form, recorded on any medium, or stored in any storage system. This provision shall apply to PHI that is in the possession of Business Associate, its agents and subcontractors. If it is not feasible for the Business Associate to return or destroy PHI, Business Associate further agrees to extend any and all protections, limitations, and restrictions contained herein to Business Associate's use and disclosure of any PHI retained after termination of this BAA, and to limit any further uses and/or disclosures to the purposes that make the return or destruction of PHI infeasible. Business Associate shall retain no copies of the PHI. Business Associate shall remain bound by the provisions of this BAA, even after termination of the Base Agreement(s) or this BAA, until all PHI has been returned or otherwise destroyed as provided in this Section.

4.17 Indemnification. Business Associate shall indemnify and hold harmless Covered Entity and its officers, trustees, employees, agents, and subcontractors from any and all claims, penalties, fines, costs, liabilities, or damages, including but not limited to reasonable attorney fees, incurred by Covered Entity arising from a violation by Business Associate of its obligations under this BAA.

5.0 OBLIGATIONS OF COVERED ENTITY

5.1 Notice of Privacy Practices. Covered Entity shall notify Business Associate of any limitation(s) in Covered Entity's Notice of Privacy Practices in accordance with 45 C.F.R. § 164.520, to the extent such limitations affect Business Associate's use or disclosure of PHI.

5.2 Revocation of Authorization of Individual. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose PHI, if and to the extent such changes affect Business Associate's use and disclosure of PHI.

5.3 Restrictions on Use and Disclosure. Covered Entity shall notify Business Associate of any restriction on the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 C.F.R. § 164.522, to the extent such restriction may affect Business Associate's use or disclosure of PHI.

6.0 MISCELLANEOUS

6.1 Third Party Rights. The terms of this BAA do not grant any rights to any third parties.

6.2 Independent Contractor Status. For the purposes of this BAA, Business Associate is an independent contractor of Covered Entity, and shall not be considered an agent of Covered Entity.

6.3 Changes in the Law. The parties shall amend this BAA to conform to any new or revised legislation, rules, or regulations to which Covered Entity is subject now or in the future including, without limitation, HIPAA, HITECH, the Privacy Standards, Security Standards or Transactions Standards.

6.4 Owner of PHI. Under no circumstances shall Business Associate be deemed in any respect to be the owner of any PHI of Covered Entity.

This BAA becomes binding when signed by authorized representatives of both parties.

COVERED ENTITY:

By: _____
Printed Name:
Title:
Date of Signature: _____

FOR THE REGENTS OF THE LEAD HEALTHCARE ORGANIZATION
By: _____
Printed Name:
Title:
Date of Signature: _____

5.2 SAMPLE DATA USE AGREEMENT TEMPLATE-- (*MPOG, 2018*)

MULTICENTER PERIOPERATIVE OUTCOMES GROUP
STUDENT EXAMPLE- DO NOT USE
DATA USE AGREEMENT

This Data Use Agreement ("Agreement") is by and between _____ ("Participant") and the Regents of the University of Michigan, a nonprofit educational institution of the State of Michigan ("Michigan"). Throughout this Agreement, Participant and Michigan are individually referred to as "party" and collectively as "parties." This Agreement will become effective upon execution by both parties to this Agreement as of the date of the first signature affixed below (the "Effective Date").

A. DEFINITIONS

1. *ASPIRE:* The Anesthesiology Performance Improvement and Reporting Exchange (ASPIRE) which is a sub-group of MPOG focused on using MPOG data to assess variation in practice, identify best practices, and measure process adherence and patient outcomes, and create programs for quality improvement.

2. *ASPIRE Project:* The quality improvement initiative submitted by Participant over time and approved by the ASPIRE Quality Improvement Committee and for which Michigan is providing MPOG Data to Participant under this Agreement.

3. *Covered Entity:* Per 45 CFR 160.103 ("Definitions"), is a health plan, health care clearinghouse, or health care provider that is subject to the standards, requirements, and implementation specifications of the HIPAA Privacy Rule.

4. *Individual:* Per 45 CFR 160.103 ("Definitions"), is the person who is the subject of protected health information and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

5. *Limited Data Set:* Per 45 CFR 164.514(e)(2) ("Implementation Specification: Limited Data Set"), is protected health information that excludes the 16 direct identifiers specified in that section. A Limited Data Set may contain postal address information, in the form of a town or city, State, or zip code only; age; specific dates, including birth date, admission date, discharge date, and date of death; and any other information, not amongst the listed 16 direct identifiers, that could be used, alone or in combination with other reasonably available information to identify an individual who is a subject of the information.

6. *MPOG:* The Multicenter Perioperative Outcomes Group (MPOG), which has been established to pool data submitted by anesthesiology departments of institutions with perioperative information systems into a common research and quality improvement database with the hope of accelerating outcomes research by investigating perioperative events to advance knowledge and improve patient care.

7. *MPOG Data:* The Limited Data Set provided by the Michigan data coordinating center to Participant for use a MPOG Project or ASPIRE Project.

8. *MPOG Participant:* An organization participating in MPOG that has signed a Multicenter Perioperative Outcomes Group Data Use Agreement.

9. MPOG *Project:* The research study or studies submitted by Participant over time and approved by the Perioperative Clinical Research Committee ("PCRC") and for which Michigan is providing MPOG Data to Participant under this Agreement.

10. *Participant Data:* The Limited Data Set provided by Participant to Michigan for inclusion in the MPOG centralized research dataset.

11. *Privacy Rule* shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

12. *Protected Health Information or PHI:* Per 45 CFR 160.103 ("Definitions"), means information, maintained or transmitted in any form or medium, that: (i) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual, and (ii) identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

13. *Required by Law:* Per 45 CFR 164.103 ("Definitions") means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law.

14. *Secretary* shall mean the Secretary of the Department of Health and Human Services or his designee.

B. SCOPE OF AGREEMENT

This Agreement sets forth the terms and conditions pursuant to which Participant may transfer Participant Data to Michigan for inclusion in the MPOG centralized research and quality improvement repository; Michigan's obligations and rights to receive, process, use, and distribute Participant Data, as part of MPOG Data, to MPOG Participants for use in Projects; and the Participant's rights and obligations to receive and use any MPOG Data in Projects.

C. COLLECTION OF MATERIALS

Participant represents and certifies that:

1. Any Participant Data provided to Michigan by Participant were collected pursuant to and in accordance with any applicable Institutional Review Board ("IRB") approval and in compliance with all applicable laws, regulations and policies for the protection of human subjects, including, in the case where Participant is a covered entity, 45 CFR Part 46, "Protection of Human Subjects" (the "Common Rule"), and the HIPAA Privacy Rule

2. Any relevant informed consents and authorizations permit use, processing, and redistribution of the Participant Data in the manner described in this Agreement.

3. In addition, Blue Cross Blue Shield of Michigan MPOG Participants agree to have data shared with the Michigan Surgical Quality Collaborative Patient Safety Organization for purposes of quality improvement and research and approved by the ASPIRE Quality Improvement Committee or MPOG PCRC, respectively.

D. PARTICIPANT OBLIGATIONS

Participant agrees:

1. To provide Participant Data, as applicable, to Michigan, in accordance with frequency, data, and upload specification to be provided by the coordinating center, for the sole and limited purpose of enabling Michigan to receive, process, use, and distribute the Participant Data to MPOG Participants for use in MPOG or ASPIRE Projects. Participant is responsible for ensuring the removal of all prohibited direct identifiers from the Participant Data, such that the Participant Data will be in the form of a Limited Data Set, before transfer to Michigan.

2. That Participant has the authority and hereby grants Michigan, as the coordinating center, explicit permission to:

   a. Process and use Participant Data for MPOG activities; and

b. Distribute the Participant Data, as part of MPOG Data, to MPOG Participants upon submission by such MPOG Participants of a MPOG Project or ASPIRE Project.

3. To not use or disclose MPOG Data other than as permitted or required by the Agreement or as Required by Law, and shall not use or disclose the MPOG Data in a manner inconsistent with the Privacy Rule.

4. To not use MPOG Data in any research or quality improvement initiative that is not approved as part of the Project, and for a period not to exceed the period of time identified in the Project. Modification of an approved Project requires submission of a Project amendment to, and approval by, the Perioperative Clinical Research Committee (PCRC).

5. To establish appropriate administrative, technical, procedural, and physical safeguards to protect the confidentiality of the MPOG Data and to prevent loss, unauthorized access or use, modification or disclosure, and any misuse of the MPOG Data.

6. To ensure that any agents, including subcontractors, or other third parties to whom it provides MPOG Data which is received from, or created or received by Participant agrees in writing to be bound by the same restrictions and conditions that apply through this Agreement to Participant with respect to such MPOG Data.

7. To report to Michigan any use or disclosure of MPOG Data not provided for by this Agreement of which the Participant, its officers, employees, or agents become aware, including without limitation, any disclosure of MPOG Data to an unauthorized subcontractor, within five (5) working days of its discovery, and agrees to mitigate to the extent practicable any harmful effect that is known to Participant of any such use or disclosure.

8. To not identify, attempt to identify, or contact any Individual, or living relative of an Individual, from which the MPOG Data was derived, including through the use of other outside databases or the performance of mathematical or statistical techniques to identify Individuals.

9. To submit a proposed manuscript to the PCRC prior to submission to academic journals for approval. PCRC submission is to ensure that the previously approved PCRC research hypothesis is addressed and answered and the MPOG Data was used as initially approved. Participant will submit the proposed manuscript within nine (9) months of the Participant receiving the MPOG Data.

10. To acknowledge that other researchers may have access to MPOG data sets and that overlap of research is a distinct possibility.

11. To review the most current version of the MPOG Bylaws and evidence Participant's understanding by signing the MPOG Bylaws.

E. MICHIGAN OBLIGATIONS

Michigan agrees to:

1. Use or disclose Participant Data only as permitted or required by this Agreement, or for the proper management and administration of Michigan, or as Required by Law, and shall not use or disclose the Participant Data in a manner inconsistent with the Privacy Rule.

2. Use appropriate administrative, technical, and physical safeguards to prevent use or disclosure of the Participant Data other than as provided for by this Agreement.

3. To report to the Participant any use or disclosure of Participant Data not provided for by this Agreement of which Michigan, its officers, employees, or agents become aware, including without limitation, any disclosure of PHI to an unauthorized subcontractor, within five (5) working days of its discovery.

4. Ensure that any third party to whom it provides the Participant Data agrees to the same restrictions and conditions that apply through this Agreement to Michigan with respect to protection of the Participant Data.

5. To not identify, attempt to identify, or contact any Individual, or living relative of an Individual, from which the Participant Data was derived, including through the use of other outside databases or the performance of mathematical or statistical techniques to identify Individuals.

6. Transmit MPOG Data to MPOG Participants, including Participant, for use in Projects.

F. TERM AND TERMINATION

1. *Term*: The Term of this Agreement shall commence as of the Effective Date.

2. *Termination for Cause*: Upon a Party's knowledge of a breach of this Agreement by the other Party,

the non-breaching Party shall either:

a. Provide an opportunity for the breaching Party to cure the breach or end the violation, and terminate this Agreement if the breaching Party does not cure the breach or end the violation within the time specified by the non-breaching Party; or

b. If cure and termination are not feasible, the non-breaching Party will discontinue disclosure of Materials to the breaching Party and report the breach or violation to the Secretary.

3. *Termination without Cause*. Either Party may terminate this Agreement in whole or in part for its sole convenience upon thirty (30) days prior notice.

4. *Effect of Termination*:

a. Except as provided in paragraph (3)(b) of this Article F, upon termination of this Agreement, for any reason, Michigan shall return or destroy all Participant Data received from Participant, or created or received by Michigan on behalf of Participant, and Participant shall return or destroy all MPOG Data received from Michigan, or created or received by Participant on behalf of Michigan. This provision shall apply to Participant Data and MPOG Data that are in the possession of subcontractors, agents, or other third parties.

b. In the event that returning or destroying Participant Data or MPOG Data is deemed infeasible, a Party shall provide to the other notification of the conditions and reasons that make return or destruction infeasible. If the other Party agrees that return or destruction is infeasible, such agreement shall be evidenced in writing and the protections of this Agreement shall be extended to such Participant Data or MPOG Data and further uses and disclosures shall be limited to only those purposes that make the return or destruction infeasible, for so long as the Participant Data or MPOG Data are retained.

G. MISCELLANEOUS

1. *Breach or Violation*: Neither Party is responsible for the other's violations of the Privacy Rule unless a pattern of activity or practice that constitutes a material breach or violation of the Privacy Rule is known, in which case the further delivery of Participant Data or MPOG Data will be withheld. If this is not possible, the breach will be reported to the Secretary.

2. *Amendment*: The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary to comply with the requirements of the Privacy Rule and HIPAA.

3. *Survival*: The respective rights and obligations of Recipient under Article F and G(4) shall survive the termination of this Agreement.

4. *Compliance with Laws*: In performing their respective obligations under this Agreement, Parties shall at all times comply with all applicable provisions of HIPAA, the Privacy Rule, and all other applicable state and federal laws and regulations.

5. *Interpretation:* Any ambiguity in this Agreement shall be interpreted in a manner consistent with the Privacy Rule.

6. *Disclaimer*: NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIALS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

7. *Intellectual Property*: Parties acknowledge and agree that they do not by virtue of this Agreement acquire any intellectual property rights in the Participant Data or MPOG Data or future inventions or discoveries made by MPOG Participants using MPOG Data distributed by Michigan.

8. *Relationship of the Parties*: Each Party to this Agreement is an independently contracting party. Nothing in this Agreement shall constitute, be construed, or create an employment relationship, a partnership, or a joint venture among any of the Parties.

7. *Assignment; Successors and Assigns*: Neither Party may assign its rights or cause to be assumed its obligations hereunder without the prior written consent of the other Party, which consent shall not be unreasonably

withheld or delayed. Subject to the foregoing, this Agreement shall apply to, be binding in all respects upon and inure to the benefit of the Parties hereto and their respective successors and assigns.

8. *Mutual Indemnity*: Parties shall, to the extent allowed by law, each defend, indemnify and hold harmless the other from and against any and all claims, losses, causes of action, judgments, damages and expenses to the extent caused by any breach of this Agreement or failure to perform its obligations hereunder, by the indemnifying party, its employees, officers, or agents.

10. *Execution of Agreement*: This Agreement may be executed in two or more counterparts, each of which will be deemed to be an original copy and all of which, when taken together, will be deemed to constitute one and the same agreement. The exchange of copies of the Agreement and of signature pages by facsimile transmission will constitute effective execution and delivery of this Agreement as to the Parties hereto and may be used in lieu of the original Agreement for all purposes. Signatures of the Parties transmitted by facsimile will be deemed to be their original signatures for all purposes.

11. *Entire Agreement*: This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes and replaces all prior agreement, understanding, commitments, communications, and representation made between the Parties, whether written or oral, with respect to the subject matter hereof.

12. *Severability:* If any provision of this Agreement is declared invalid or unenforceable, such provision shall be limited and construed so as to make it enforceable or, if such limitation or construction is not possible, such provisions shall be stricken from the Agreement. In such event, all other provisions shall remain in full force and effect, unless such enforcement would be inconsistent with the purposes of this Agreement.

13. *Notices:* Legal notices or matters of a contractual nature arising out of the terms and conditions of this Agreement may be directed to:

PARTICIPANT:

_____
_____
_____

PARTICIPANT		**THE REGENTS OF THE UNIVERSITY OF MICHIGAN**	
Authorized Official:		Authorized Official:	
Title:		Title:	
_____		_____	
Signature	Date	Signature	Date

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