PROBLEM

Challenge. Westlake Research Hospital is conducting a double-blinded trial or study in order to test a new depression medication. The study will consist of 400 patients and 20 doctors. In order to be able to run a study like this, effective documentation and tracking of resources is extremely essential. A database management system (DBMS) solution would be extremely beneficial for this study, but first, the database must be designed effectively and efficiently in order to comply with the needs of the two researchers that are conducting the study. Westlake Research Hospital does not currently have a database system designed to conduct such studies. The hospital is in fact using a paper-based system where all patients' records are kept in physical charts. There are several challenges that must be overcome in order to design the database needed for this study.

Some of the challenges presented in working with this type of study and in designing its database are pertinent to its restrictions. According to the Encyclopedia of Psychopharmacology (2010), "Double-blinded study is a term used to describe a study in which both the investigator or the participant are blinded to (unaware of) the nature of the treatment the participant is receiving" (p. 418). Therefore, the doctors and the patients of this trial must not know what type of drugs they are giving to the patients. "Only two test supervisors will know who is getting what" (Conger, 2014, p. 18). The database must be designed so that only those who are authorized to access certain information (e.g., the type of drug that is given to patients) are able to do so. What makes this database even more significant is the fact that some patients may elect to drop from this trial, in which case it may be necessary to completely remove their information from the database and update the database accordingly so that doctors continue to see a fair amount of patients.

Business Requirements. There are several requirements and expectations for this project. Requirements currently include: (1) providing patients with the ability to view their medical records and doctor's notes, (2) providing the doctors with the ability to view their patients' records, (3) allowing doctors to enter information regarding their patients, and (4) providing full access to the two supervisors only. Some expectations may include: (1) automatically updating the information in the database upon the withdrawal of a patient from the trial and (2) creating a secure database so that patients' data is not being accessed by unauthorized individuals, possibly from a different institution. Table 1 below illustrates a list of requirements that are more specifically related to the database design.

Stakeholder	Requirements
Doctors	Access their own patients' information Enter blood test results Enter depression indicators Enter own notes Enter explanation for dropping patients out of study
Patients	Access their own medical profile Access the doctor's notes
Supervisors	Access all patient information Access all doctors' notes Access information about the drug each patient is taking Add and remove patients from the database
Secretary	Access to the patients' schedule
Nurses	Enter vital signs including blood pressure, heart rate, and weight

Table 1. Database Requirements. This table illustrates the business requirements related to the database design.

Westlake Research Hospital is in need of this database so that the management of patients' data is more effective, and an extreme significance fall into the administration of medication to patients. It is quite important to make sure that patients are receiving the intended medication. For example, if a patient is assigned to receive the new drug, the database would help the supervisors maintain a record of what medication this patient is to receive each time the patient visits the facility. Moreover, if for some reason, the supervisors decide to change the medication and assign a different physician to that patient, then the database needs to be updated accordingly based on being a relational database. The database is needed so that supervisors can easily link between doctors, patients, and drug type. Certain business rules must be met while doing so, which include the following:

- The drug given is to only be known by the supervisors (double-blinded study)
- Doctors can only see their own patients
- Doctors must see their patients each month
- Doctors must see their patients 2 times each 1 month
- Patients can be removed entirely from the database
- Supervisors have the highest level of access to the database

Additional business requirements may be addressed in this study that pertain to the secretary for the doctors involved in this study as well as the nurses that will meet with the patients during their visits. These are currently considered additional requirements because the new system may be able to provide doctors and researchers with an alternative that may better fit their needs. Considering the current paper-based system, the secretary and the nurses provide a vital role of printing the visits schedule and taking the patients' vital signs, respectively. The database will soon offer the doctors that ability to review their patients' schedules electronically, which may be a convenient alternative to the paper-based schedule printed by the secretary. On the other hand, it may be fair to say that nurses may be able to utilize the new system to enter the results of their visits with the patients (i.e., documenting blood pressure, heart rate, and weight).

Limitations of Current System. As stated earlier, and as Dr. Lewis mentioned in describing the current process (Conger, 2014), the current system used by the hospital to conduct this type of study does not seem to contain a database structure, but instead it is based on hard-copy paper charts. Information is collected using paper forms (e.g., Patient Medical History), which are then simply kept in physical charts. Doctors review those charts prior to meeting with patients and after the patients meet with the nurses for their vital signs. Undoubtedly, this could be extremely time-consuming which may ultimately result in decreasing the amount of patients that can be seen by the doctors on a daily basis. Those limitations pose other challenges once the database design is completed.

Having used a paper-based system for its patients, Westlake Research Hospital does not have the necessary tools or resources to enter patients' information in an electronic database. This suggests that the database design should be simplified to house information about patients that may have already provided their information such as their medical history. The current system makes it more difficult to collect information from the patients and possible increase the level of error when entering patients' information provided on paper into the computer. For example, if patients had the opportunity to enter their information electronically, then the level of error may be decreased as their information would be automatically added to the database. The new database will be designed with this fact in mind, which would most likely affect other departments and operations in the hospital.

Departments and Operations

The aforementioned issues and challenges will impact departments and operations within Westlake Research Hospital. Considering the paper-based current system, departments must determine which operations need to stay in effect. For example, departments will have to determine whether gathering patient information using the existing forms should continue or be converted to a new system that would the database design. Furthermore, other departments in the hospital may require to update their systems in order to comply with the new database.

The current system is based on obtaining information from patients and keeping the forms used to obtain the information in charts. Other departments in the hospital can be based on retrieving information from these forms that are essential for the study results. Once the paper-based system is converted to the electronic-database system, other departments would have to make the necessary changes to be able to obtain information as their physical charts would no longer exist. Therefore, these departments would have to implement new software that would allow them to obtain information and generate reports that they may need. This would undoubtedly change the operations of those departments affected by the change.

There are other departments that may not be directly involved with the trial, but they may be impacted by the challenges of this study. These departments may be restricted to the type of information that they may retrieve. For example, a finance departments may not be able to retrieve sufficient information for its administrative work because the double-blinded study is limited to the amount of information that can be released from the trial and the database will restrict such a department from retrieving any information. Similarly, a supervisor may want to see the progress of the trial; however, he or she will be unable to do so to the database restrictions. The reason why this may impact operations is because restrictions can be set to the database, whereas for physical charts, anyone can simply pull the chart off the shelf and read through them.

Once the database design is complete, departments will need to ensure that they have the available resources to maintain the database. For example, a system administrator may have to maintain the security of the database by frequently performing updates. According to Oracle (2002), "Each database requires at least one database administrator (DBA) to administer it". This may cause one of the largest impact on the organization as a result of the challenges associated with the database design merely because the hospital does not currently have the staff needed (e.g., database administrators). This is due to the fact that the hospital currently uses a paper-based system and staff such as DBA was not required to maintain the current system's database.

Lastly, the organization may have to equip the departments with the necessary staff to make sure that the database is not jeopardized. Aside from database administrators, these departments may require security officers and network administrators. These personnel will ensure that each user who has access to the database is authorized to do so and are accessing the database with the level of access that they are authorized with. They will also work towards preventing any outside intrusion, which is extremely critical in the double-blinded study. Table 2 includes some of those personnel that may be required once the hospital begins to use the new electronic database.

Administrators	Duties
Database administrators	Updating database servers Modifying database structure Managing users Monitoring user access
Security officers	Maintain system security Monitor users access Control users access
Network administrators	Administers networking products

Table 2. Maintaining the Database. This table presents some of the personnel that Westlake Research Hospital may need to recruit once the database is in place. Data retrieved from *(Oracle, 2002).*

Database Analysis and Design

Conceptual Model

Figure 1 below illustrates the conceptual model for Westlake Research Hospital. The model includes the entities, their attributes, and their relationships.

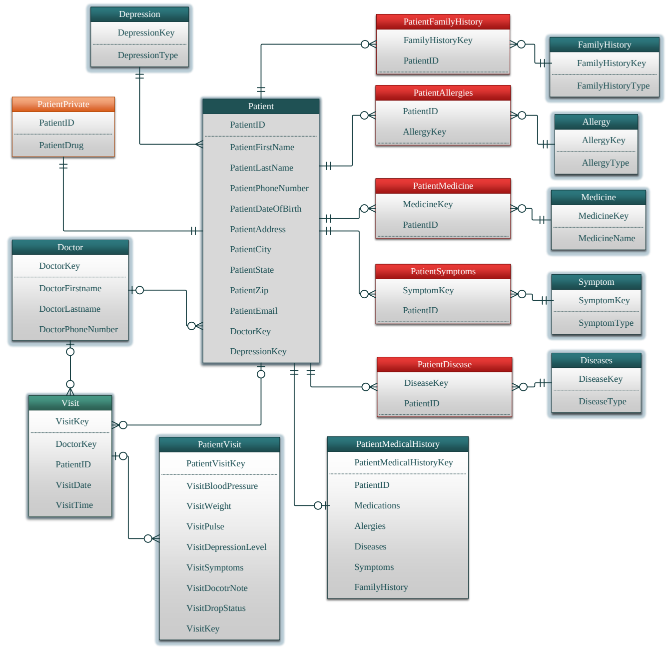


Figure 1. Conceptual Model. This diagram illustrates the conceptual model of Westlake Research Hospital database.

This conceptual model could be presented without the linking tables (highlighted in red); however, including them in the design clarifies the business rules. According to Halpin (n.d.), “Conceptual modeling makes it easier to capture and validate the business rules at a high level.” The model provides a snapshot of the general relationships between the entities. Primary keys or foreign keys are not addressed in this model, instead they are presented in the logical model below. The business rules are further discussed in the **Physical Model** section later in this paper.

Logical Model

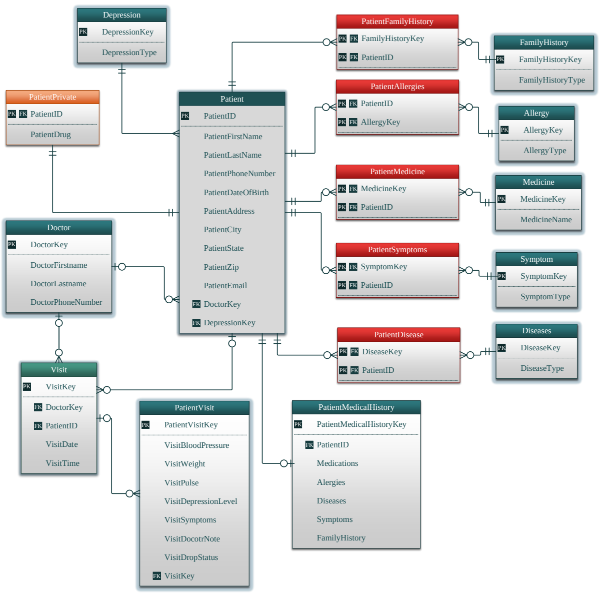


Figure 2. Logical Model. This diagram illustrates the logical model of Westlake Research Hospital database.

The logic design of Westlake Research Hospital database illustrated in Figure 2 includes its entities, attributes, relationships, primary keys, and foreign keys. According to Conger (2014), “Logic design is concerned only with defining the entities, their attributes, and their relations to other entities.” Despite which DBMS (Database Management System) Westlake uses to create the physical design of its data, this logical design will not change. However, the model does represent the necessary aspects of the DBMS such as the assignment of primary keys.

Physical Model

The physical model of Westlake Research Hospital Database is built on the nonphysical models mentioned above. The first step was to create a new database for Westlake Research Hospital as illustrated in Figure 3.

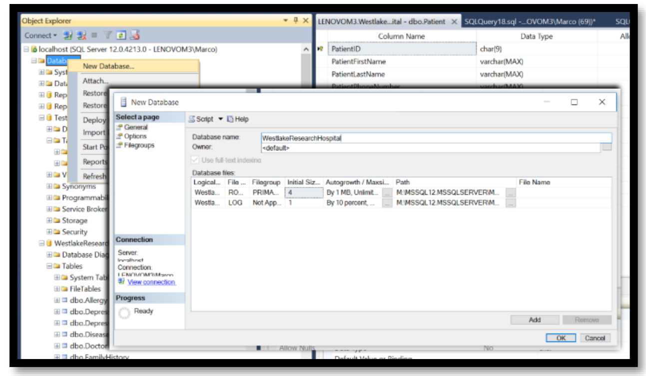


Figure 3. Creating Westlake Research Hospital Database.

Then, to create the physical database model, I created seventeen tables to reflect the entities mentioned above, each with its own columns and data types. In order to reduce drive space, I included separate tables for diseases, symptoms, medications, allergies, and family history. Furthermore, I decided to create a separate table for the patients’ medical history. This table is used to indicate whether a patient has any diseases, symptoms, allergies, medications, or relevant family history in a Boolean form. A Boolean indicates the existence of only two possibilities, either true or false (Fry & Reas, 2015). This would resolve a lot of space issues. For example, instead of including all the diseases names in the patients’ medical history table, I included only the attribute *Diseases*, and if its value is true, then the system would look for the type of disease that a patient has. The true/false values will be associated with *Diseases*, *Symptoms*, *Allergies*, *Medications*, and *FamilyHistory* in ***PatientMedicalHistory***. As another example, some patients may not have any diseases - other than depression – at the time of the clinical trial; therefore, it wouldn’t be ideal to include all the diseases names in their record indicating “false” for having the disease.

As required by the study, each patient is to have one doctor, and each doctor is to have 20 patients. Therefore, in designing the physical database, it is vital to limit each doctor’s patients list to only 20 patients. In order to satisfy Westlake’s requirements, these facts were considered in designing the physical database. For example, in order to prevent researchers from assigning more than 20 patients to the same doctor, I created a trigger on the ***Patient*** table to check the number of existing patients for the inserted physician prior to inserting a new patient. The code for the trigger is illustrated in Figure 4. Figure 5, on the other hand, illustrates the trigger for preventing the user from inserting more than 400 patients in the database. It is one of the business requirements that the clinical trial only has 400 patients; therefore, if the researchers try to insert more than the intended number, they should be alerted. Like the patient limit trigger, the doctor limit trigger aids in preventing the user from inserting more than the allowed number of – in this case – doctors. Only 20 doctors can be inserted in the database as illustrated in Figure 6 below.

```
CREATE TRIGGER DoctorPatientLimit ON Patient
INSTEAD OF INSERT
AS
DECLARE @DoctorKey CHAR (6)
DECLARE @Doctor INT
DECLARE @PatientMax INT
DECLARE @PatientInTable INT
SET @PatientMax = 20
SELECT @Doctor = DoctorKey FROM inserted
SELECT @PatientInTable = COUNT (*) FROM Patient WHERE
DoctorKey = @Doctor
IF @PatientInTable < @PatientMax
BEGIN
INSERT INTO Patient
(PatientID,PatientFirstName,PatientLastName,PatientPh
oneNumber,PatientDateOfBirth,PatientAddress,PatientCi
ty,PatientState,PatientZip,PatientEmail, DoctorKey,
DepressionKey)

(SELECT
PatientID,PatientFirstName,PatientLastName,PatientPho
neNumber,PatientDateOfBirth,PatientAddress,PatientCit
y,PatientState,PatientZip,PatientEmail, DoctorKey,
DepressionKey FROM inserted)
END
ELSE
BEGIN
Print 'Doctor assignments cannot exceed 20 patients'
END
```

Figure 4. Doctor to Patient Trigger. This code illustrates the trigger code to prevent the user from inserting more than 20 patients for the same doctor.

```
CREATE TRIGGER PatientLimit ON Patient
INSTEAD OF INSERT
AS
DECLARE @TotalPatients INT
DECLARE @PatientMax INT
SET @PatientMax = 400
SELECT @TotalPatients = COUNT (*) FROM Patient
IF @TotalPatients < @PatientMax
BEGIN
INSERT INTO Patient
(PatientID,PatientFirstName,PatientLastName,PatientPh
oneNumber,PatientDateOfBirth,PatientAddress,PatientCi
ty,PatientState,PatientZip,PatientEmail, DoctorKey,
DepressionKey)
(SELECT
PatientID,PatientFirstName,PatientLastName,PatientPho
neNumber,PatientDateOfBirth,PatientAddress,PatientCit
y,PatientState,PatientZip,PatientEmail, DoctorKey,
DepressionKey FROM inserted)
END
ELSE
BEGIN
Print 'Only 400 Patients can be added!'
END
```

Figure 5. Patient Count Limit Trigger. This code illustrates the trigger code to prevent the user from inserting more than 400 patients in the database.

```
CREATE TRIGGER DoctorLimit ON Doctor
INSTEAD OF INSERT
AS
DECLARE @TotalDoctors INT
DECLARE @DoctorMax INT
SET @DoctorMax = 20
SELECT @TotalDoctors = COUNT (*) FROM Doctor
IF @TotalDoctors < @DoctorMax
BEGIN
INSERT INTO Doctor (DoctorKey, DoctorFirstName,
DoctorLastName, DoctorPhoneNumber)
(SELECT DoctorKey, DoctorFirstName, DoctorLastName,
DoctorPhoneNumber FROM inserted)
END
ELSE
BEGIN
Print 'Only 20 Doctors can be added!'
END
```

Figure 6. Doctor Count Limit Trigger. This code illustrates the trigger code to prevent the user from inserting more than 20 doctors in the database.

The following tables demonstrate the database tables that were used in the physical design, presented in alphabetical order. Each illustration table includes the query statement that was executed to create the physical database tables. All aspects of the database were considered, including business rules and requirements, in creating the tables. For example, each doctor had to be assigned a patient, and as illustrated in Table 9, patients could not be added to the database unless a doctor is assigned to him or her. Furthermore, in order to actively and effectively retrieve data from the database, I included a variety of data types. For example, I included date and time (0) data types in the ***Visit*** table so that the secretary would be able to retrieve information from the database based on time. For instance, the secretary may want to retrieve a patients list for those who are visiting in a certain month.

Table 3. Allergy Table Components.

Keys	Column Name	Data Type	Null	Query
PK	AllergyKey	char(3)		`CREATE TABLE [dbo].[Allergy]( [AllergyKey][char](3) NOT NULL, [AllergyType] [varchar](max) NULL, CONSTRAINT [PK_Allergy] PRIMARY KEY CLUSTERED ( [AllergyKey] ASC ));`
	AllergyType	vchar(max)	✓	

Table 4. Depression Table Components.

Keys	Column Name	Data Type	Null	Query
PK	DepressionKey	char(1)		CREATE TABLE [dbo].[Depression]([DepressionKey] [char](1) NOT NULL, [DepressionType] [varchar](max) NULL, CONSTRAINT [PK_Depression] PRIMARY KEY CLUSTERED ([DepressionKey] ASC));
	DepressionType	vchar(max)	✓	

Table 5. Disease Table Components.

Keys	Column Name	Data Type	Null	Query
PK	Disease Key	char(2)		CREATE TABLE [dbo].[Disease]([DiseaseKey] [char](2) NOT NULL, [DiseaseType] [varchar](50) NULL, CONSTRAINT [PK_Disease] PRIMARY KEY CLUSTERED ([DiseaseKey] ASC));
	Disease Type	vchar (50)	✓	

Table 6. Doctor Table Components.

Keys	Column Name	Data Type	Null	Query
PK	DoctorKey	char(6)		CREATE TABLE [dbo].[Doctor]([DoctorKey] [char](6) NOT NULL, [DoctorFirstName] [varchar](max) NULL, [DoctorLastName] [varchar](max) NULL, [DoctorPhoneNumber] [char](10) NULL, CONSTRAINT [PK_Doctor] PRIMARY KEY CLUSTERED ([DoctorKey] ASC));
	DoctorFirstName	vchar (max)	✓	
	DoctorLastName	vchar (max)	✓	
	DoctorPhoneNumber	char(10)	✓	

Table 7. FamilyHistory Table Components.

Keys	Column Name	Data Type	Null	Query
PK	FamilyHistoryKey	char(5)		CREATE TABLE [dbo].[FamilyHistory]([FamilyHistoryKey] [char](5) NOT NULL, [FamilyHistoryType] [varchar](max) NULL,CONSTRAINT [PK_FamilyHistory] PRIMARY KEY CLUSTERED ([FamilyHistoryKey] ASC));
	FamilyHistoryType	vchar (max)	✓	

Table 8. Medicine Table Components.

Keys	Column Name	Data Type	Null	Query
PK	MedicineKey	char(4)		CREATE TABLE [dbo].[Medicine]([MedicineKey] [char](4) NOT NULL, [MedicineName] [varchar](max) NULL, CONSTRAINT [PK_Medicine] PRIMARY KEY CLUSTERED ([MedicineKey] ASC));
	MedicineName	vchar (max)	✓	

Table 9. Patient Table Components.

Keys	Column Name	Data Type	Null	Query
PK	PatientID	char(9)		CREATE TABLE [dbo].[Patient]([PatientID] [char](9) NOT NULL, [PatientFirstName] [varchar](max) NULL, [PatientLastName] [varchar](max) NULL, [PatientPhoneNumber] [varchar](max) NULL, [PatientDateOfBirth] [date] NULL, [PatientAddress] [varchar](max) NULL, [PatientCity] [varchar](max) NULL, [PatientState] [char](2) NULL, [PatientZip] [char](5) NULL, [PatientEmail] [varchar](max) NULL, [DoctorKey] [char](6) NOT NULL, [DepressionKey] [char](1) NULL, CONSTRAINT [PK_Patient] PRIMARY KEY CLUSTERED ([PatientID] ASC));
	PatientFirstName	vchar (max)	✓	
	PatientLastName	vchar (max)	✓	
	PatientPhoneNumber	vchar (max)	✓	
	PatientDateOfBirth	date	✓	
	PatientAddress	vchar (max)	✓	
	PatientCity	vchar (max)	✓	
	PatientState	char(2)	✓	
	PatientZip	char(5)	✓	
	PatientEmail	vchar (max)	✓	
FK	DoctorKey	char(6)		
FK	DepressionKey	char(1)	✓	

Table 10. PatientAllergies Table Components.

Keys	Column Name	Data Type	Null	Query
PK, FK	PatientID	char(9)		CREATE TABLE [dbo].[PatientAllergies]([PatientID] [char](9) NOT NULL, [AllergyKey] [char](3) NOT NULL, CONSTRAINT [PK_PatientAllergies] PRIMARY KEY CLUSTERED ([PatientID] ASC, [AllergyKey] ASC));
PK, FK	Allergy Key	char(3)		

Table 11. PatientDisease Table Components.

Keys	Column Name	Data Type	Null	Query
PK, FK	PatientID	char(9)		CREATE TABLE [dbo].[PatientDisease]([PatientID] [char](9) NOT NULL, [DiseaseKey] [char](2) NOT NULL, CONSTRAINT [PK_PatientDisease] PRIMARY KEY CLUSTERED ([PatientID] ASC, [DiseaseKey] ASC));
PK, FK	Disease Key	char(2)		

Table 12. PatientFamilyHistory Table Components.

Keys	Column Name	Data Type		Query
PK, FK	FamilyHistoryKey	char(5)		CREATE TABLE [dbo].[PatientFamilyHistory]([FamilyHistoryKey] [char](5) NOT NULL, [PatientID] [char](9) NOT NULL, CONSTRAINT [PK_PatientFamilyHistory] PRIMARY KEY CLUSTERED ([FamilyHistoryKey] ASC, [PatientID] ASC));
PK, FK	PatientID	char(9)		

Table 13. PatientMedicalHistory Table Components.

Keys	Column Name	Data Type	Null	Query
PK	PatientMedicalHistoryKey	char(10)		CREATE TABLE [dbo].[PatientMedicalHistory] ([PatientMedicalHistoryKey] [char](10) NOT NULL, [PatientID] [char](9) NULL, [Medications] [bit] NULL, [Alergies] [bit] NULL, [Diseases] [bit] NULL, [Symptoms] [bit] NULL, [FamilyHistory] [bit] NULL, CONSTRAINT [PK_PatientMedicalHistory] PRIMARY KEY CLUSTERED ([PatientMedicalHistoryKey] ASC));
FK	PatientID	char(9)	✓	
	Medications	bit	✓	
	Alergies	bit	✓	
	Diseases	bit	✓	
	Symptoms	bit	✓	
	FamilyHistory	bit	✓	

Table 14. PatientMedicine Table Components.

Keys	Column Name	Data Type	Null	Query
PK, FK	Medicine Key	char(4)		CREATE TABLE [dbo].[PatientMedicine]([MedicineKey] [char](4) NOT NULL, [PatientID] [char](9) NOT NULL, CONSTRAINT [PK_PatientMedicine] PRIMARY KEY CLUSTERED ([MedicineKey] ASC, [PatientID] ASC));
PK, FK	PatientID	char(9)		

Table 15. PatientPrivate Table Components.

Keys	Column Name	Data Type	Null	Query
PK, FK	PatientID	char(9)		CREATE TABLE [dbo].[PatientPrivate]([PatientID] [char](9) NOT NULL, [PatientDrug] [varchar](max) NULL, CONSTRAINT [PK_PatientPrivate] PRIMARY KEY CLUSTERED ([PatientID] ASC));
	PatientDrug	vchar(max)	✓	

Table 16. PatientSymptoms Table Components.

Keys	Column Name	Data Type	Null	Query
PK, FK	SymptomKey	char(2)		CREATE TABLE [dbo].[PatientSymptoms]([SymptomKey] [char](2) NOT NULL, [PatientID] [char](9) NOT NULL, CONSTRAINT [PK_PatientSymptoms] PRIMARY KEY CLUSTERED ([SymptomKey] ASC, [PatientID] ASC));
PK, FK	PatientID	char(9)		

Table 17. PatientVisit Table Components.

Keys	Column Name	Data Type	Null	Query
PK	PatientVisitKey	char(5)		CREATE TABLE [dbo].[PatientVisit]([PatientVisitKey] [char](5) NOT NULL, [VisitBloodPressure] [char](7) NULL, [VisitWeight] [char](6) NULL, [VisitPulse] [int] NULL, [VisitDepressionLevel] [char](1) NULL, [VisitSymptoms] [varchar](max) NULL, [VisitDoctorNote] [varchar](max) NULL, [VisitDropStatus] [varchar](50) NOT NULL, [VisitKey] [char](10) NULL, CONSTRAINT [PK_PatientVisits] PRIMARY KEY CLUSTERED ([PatientVisitKey] ASC));
	VisitBloodPressure	char(7)	✓	
	VisitWeight	char(6)	✓	
	VisitPulse	int	✓	
	VisitDepressionLevel	char(1)	✓	
	VisitSymptoms	vchar(max)	✓	
	VisitDoctorNote	vchar(max)	✓	
	VisitDropStatus	vchar(50)		
FK	VisitKey	char(10)	✓	

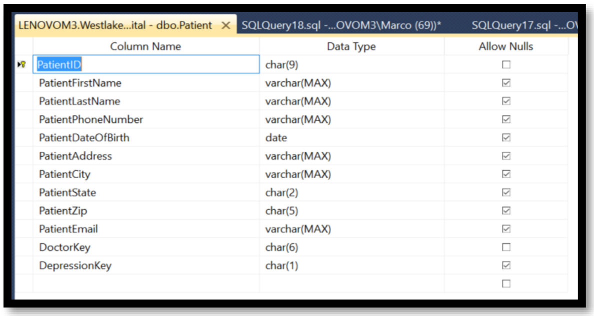
Table 18. Symptom Table Components.

Keys	Column Name	Data Type	Null	Query
PK	SymptomKey	char(2)		CREATE TABLE [dbo].[Symptom]([SymptomKey] [char](2) NOT NULL, [SymptomName] [varchar](max) NULL, CONSTRAINT [PK_Symptom] PRIMARY KEY CLUSTERED ([SymptomKey] ASC));
	SymptomName	vchar(max)	✓	

Table 19. Visit Table Components.

Keys	Column Name	Data Type	Null	Query
PK	VisitKey	char(10)		CREATE TABLE [dbo].[Visit]([VisitKey] [char](10) NOT NULL, [DoctorKey] [char](6) NULL, [PatientID] [char](9) NULL, [VisitDate] [date] NULL, [VisitTime] [time](0) NULL, CONSTRAINT [PK_Visit] PRIMARY KEY CLUSTERED ([VisitKey] ASC));
FK	DoctorKey	char(6)	✓	
FK	PatientID	char(9)	✓	
	VisitDate	date	✓	
	VisitTime	time(0)	✓	

I also elected to create some of the tables without using a query, but instead by using the "New Table" function in SSMS. Figure 7 illustrates creating the ***Patient*** table using the "New Table" function.



Column Name	Data Type	Allow Nulls
PatientID	char(9)	☐
PatientFirstName	varchar(MAX)	☑
PatientLastName	varchar(MAX)	☑
PatientPhoneNumber	varchar(MAX)	☑
PatientDateOfBirth	date	☑
PatientAddress	varchar(MAX)	☑
PatientCity	varchar(MAX)	☑
PatientState	char(2)	☑
PatientZip	char(5)	☑
PatientEmail	varchar(MAX)	☑
DoctorKey	char(6)	☐
DepressionKey	char(1)	☑

Figure 7. Patient Table Components Using SSMS's "New Table" Function.

The next step was to create the relationship between the tables. For example, Figure 8 illustrates the relationships between ***Patient*** table and ***Depression***, ***Doctor***, ***PatientAllergies***, ***PatientDisease***, ***PatientFamilyHistory***, ***PatientMedicalHistory***, ***PatientMedicine***, ***PatientPrivate***, ***PatientSymptoms***, and ***Visit*** tables.

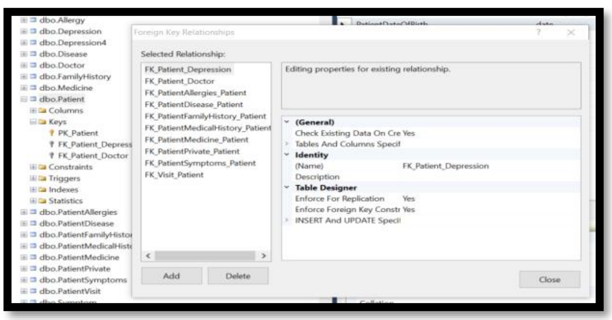


Figure 8. Relationships between Patient Table and Other Tables.

Figure 9 below shows the relationships between the database tables in an SSMS database diagram.

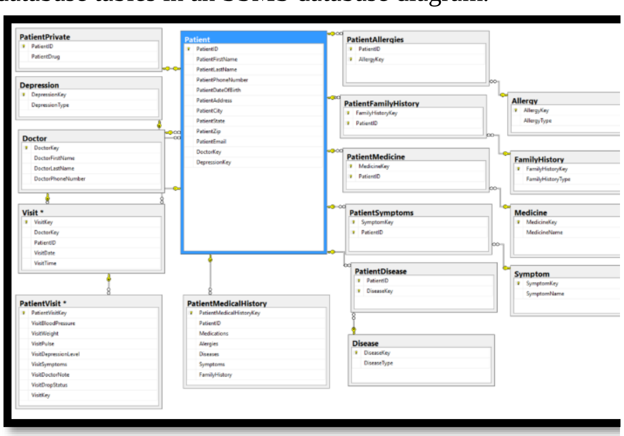


Figure 9. SSMS Database Diagram. This figure illustrates the relationship between the database tables.

Once the tables were created, I used INSERT INTO statements to insert values in all the tables. For example, in order to insert a patient's information into the ***Patient*** table, I executed the statement INSERT INTO Patient (PatientID, PatientFirstName, PatientLastName, PatientPhoneNumber, PatientDateOfBirth, PatientAddress, PatientCity, PatientState, PatientZip, PatientEmail, DoctorKey, DepressionKey) VALUES ('PAT103430', 'Carolyn', 'Moore', '3526080574', '1956-12-20', '140 Highland Street', 'Gainesville', 'FL', '32601', 'Carolyn.Moore@University.edu', 'PHYCAG', 'A'); Once I inserted all the values in the patient table, I was able to SELECT * FROM Patient and retrieve that patients information as illustrated in Figure 10. Constraints seemed to work as intended. For example, once I inserted 20 doctors in the database, I wasn't able to add any more doctors, which satisfies the business rules. This was due to the DoctorLimit trigger that was illustrated previously in Figure 6. The results of executing the query to exceed 20 doctors is illustrated in Figure 11 below.

Figure 10. Retrieving All Patients' Data. This figure illustrates the retrieval of all the patients' information from the database.

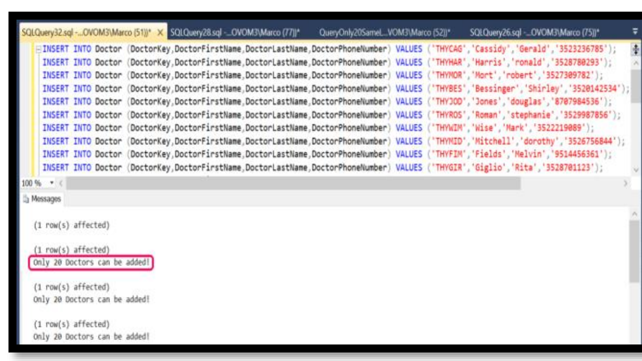


Figure 11. Inserting Doctors in Doctor Table. This illustrates the inability to enter more than 20 doctors in the database due to the DoctorLimit trigger.

DBMS Research and Recommendation

The increase of data over the years has required many businesses to begin to utilize database managements systems (DBMS). The exponential growth of data can no longer be managed by a simple spreadsheet and the need of a DBMS is becoming a requirement. However, do database analysts consider multiple DBMSes when designing their database structure? How much do they rely on the existing DBMSes when designing their database? According to Hernandez (2013), database analysts frequently and unwillingly depend on the DBMSes of their business when developing their database structure instead of seeking a new DBMS as necessary. Not seeking the right DBMS is not recommended because it distances the database structure from the business requirements because database analysts become restricted by the DBMS and are no longer merely designing a database structure to fit the business needs. For example, if a database analyst designs the database with certain entity relationships but is restricted to using a DBMS that does not support those relationships that must exist between entities, then he or she is ultimately designing a database that does not fit the business needs.

Therefore, database analysts must disregard any existing DBMSes that their business may have and construct their database strictly based on the business needs. Database analysts should then look for the DBMS that would fit their database structure. The entity-relationship diagram for Westlake Research Hospital has been designed and several DBMSes are now under consideration. These DBMSes include Oracle, IBM DB2, MySQL, MS Access, and Microsoft SQL Server.

Research

A database management system (DBMS) is simply a software application that interacts with where the database is housed while maintaining its integrity. According to Bare (2014), “database management systems provide powerful tools to organize and manage data”. Unlike old-fashioned spreadsheets, access to this data can be controlled by the DBMS so that only authorized personnel can access particular data that is to be determined by the database administrator (DBA). Although DBMSes ultimately serve a similar purpose, they all have some similarities and differences.

Oracle. Oracle is a relational database management system (RDBMS) developed by Oracle, hence the name (Bassil, 2012). One of the main Oracle database versions today is the Oracle 9i (Arif, n.d.). Several Oracle DBMSes have been published up to this day. Oracle RDBMS “moves data into a database, stores the data, and retrieves it so that it can be manipulated by applications” (Oracle, 2015). Oracle provides many features along with the DBMS, and that includes administration tools, development tools, and the tools to recover and backup the database (Dell, 2016). The development tools would aid in improving the quality of the code which would dramatically assist developers. The administration tools would allow the DBA to better manage the database. The backup and recovery tools, on the other hand, would assure that data is not lost and is restored under harsh circumstances (Dell, 2016).

One of the new introduced systems by Oracle is the 12c, where "c" stands for cloud services (Oracle, 2016). Although, this raises some security questions when it comes to patient confidentiality that we are trying to accomplish and would most likely be safer to avoid the 12c system despite the level of security that Oracle may provide. Considering that Westlake Research Hospital patients may need to access the system from home to review their medical records may imply that using a cloud-based database could benefit this process; however, many security concerns arise with the use of cloud computing. These concerns are further discussed in latter sections. The basic Oracle license is about $37,000 (Komo, 2007). Table 20 provides more features of Oracle.

IBM DB2. IBM has produced many DBMS over the past many years and the IBM DB2 is another database management system that made it to the market for “robust, enterprise-wide solutions handling high-volume workloads” (IBM, 2012). There are multiple versions including the Enterprise Server, Workgroup Unlimited, and Workgroup (Arif, n.d.). According to Mullins (2016), DB2 competes for operating systems such as UNIX and Linux; however, it is also available for Windows. The challenge with DB2 is having the skills needed to manage the database on several levels. Developers seem to be more skilled in Oracle, for example, than IBM DB2 (Mullins, 2016). This of course raises a question about Westlake Research Hospital developers who will be utilizing this software. Will they have the skills necessary in order to maintain this system in the case that we do consider it? It is also important to mention that due to the level of complexity, IBM DB2 would be constantly updated to meet the needs of the larger consumer (i.e., big companies), and DBA administrators may have to constantly follow up on these updates, which may be challenging. The cost of IBM DB2 is around $40,000 (Komo, 2007). Table 20 provides more features of IBM DB2.

MySQL. MySQL is an open source database management system (Bassil, 2012). Some of its features include working on multiple platforms, using multi-layered server design with independent modules, executing very fast, and supporting many data types (Amlanjyoti Saiki, 2015). It is able to provide multiple instances of the same database server, and automatically update and delete data in the nested tables (Microsoft, 2012). However, MySQL lacks big data support, data mining, and high speed drivers (Microsoft, 2012). MySQL is available to the public and businesses as a free software (open source). Table 20 provides more features of MySQL.

MS Access. Microsoft Access is another RDBMS that is produced by Microsoft, hence the name, which is interchangeably known as Microsoft Office Access, Microsoft Access, or MS Access (Microsoft, 2016). This RDBMS "combines the relational Microsoft Jet Database Engine with a graphical user interface and software development tools" (Bassil, 2012). MS Access is more commonly used by individuals or small business as well as small departments within large corporations. Bassil (2012) suggested that MS Access is more effective when used to manage smaller projects. The cost of MS Access is dramatically lower than the most of the DBMSes. According to Microsoft (2016), MS Access 2016 is just around $100. Table 20 provides more features of MS Access.

SQL Server. This server is an RDBMS developed by Microsoft (Bassil, 2012). The name implies that the database in this system are queried using the Structured Query Language (SQL). According to Bassil (2012), Microsoft SQL Server supports mirroring and clustering. In the case that a lot of data is present in the database and there is a need to split the data usage between multiple servers, clustering will make it possible. If one of the strategies in designing the database included denormalization, then using SQL Server would be possible due to being equipped with mirroring. Mirroring will allow the database analyst to have copies of the database tables in efforts to increase performance. Microsoft SQL Server also allows for storing large data such as photos and videos (Swati, 2015).

Unlike the complexity found in IBM DB2, Microsoft SQL Server provides a less-complex platform that would be easier for users to utilize (Mullins, 2016). As mentioned earlier, depending on the experience of the developers and DBAs, having a complex DBMS may not be ideal for our project. Therefore, the ideal level of complexity of Microsoft SQL Server will allow Westlake Research Hospital to focus on the study instead of finding the experts that could better manage the DBMS (e.g., IBM DB2). The basic license for Microsoft SQL Server ranges between $500 and $5,000 (Komo, 2007), which is extremely less expensive that IBM DB2 and Oracle. Table 20 provides more features about Microsoft SQL Server.

IBM DB2	**MS Access**	**SQL Server**	**MySQL**	**Oracle**
ACID	ACID	ACID	ACID	ACID
Backup	Integrated Storage Manager	Backup	Backup	Referential Integrity
Compressi on of Data	Compressi on of Data	SQL Interpreter	SQL Interpreter	Unicode
Encryption of Data	Custom Functions	Import Data	Import Data	Transactio ns
High Availabilit y	Transactio ns	Real Time Access to Database	Export Data	
Highly Scalable	Unicode	Transactio ns	Integrated Storage Manager	
Java Support	Referential Integrity	Custom Functions	Java Support	
Referential Integrity		Referential Integrity	Referential Integrity	
Unicode		Unicode	Database Imports	
XML Format Support			Custom Functions	
Transactio ns			Transactio ns	

Table 20. DBMS Features. This table compares some of the major feature of the considered DBMS. Retrieved from *(Graphiq, 2016)*.

Analysis

The similarities between the aforementioned DBMSes makes it a little challenging to decide which system would best fit the needs of the Westlake Research Hospital's clinical trial. However, considering the entity-relationship diagram that has been designed for this project as shown in Figure 12, narrowing the strengths and weaknesses of these DBMSes may not be as challenging as it seems.

Before determining which DBMS to use for this project, one must understand the concept of SQL.

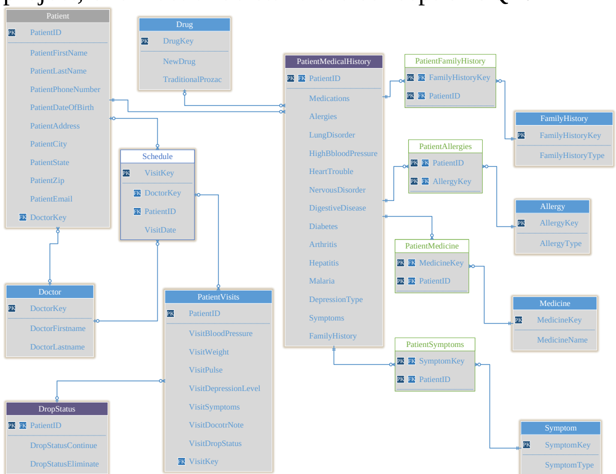


Figure 12. Normalized Westlake Research Hospital Database. This figure illustrates the final normalized database for the clinical trial.

Most DBMSes conform to the SQL standards; however, SQL dialects are occasionally caused by vendors (e.g., Oracle) implementing their own features (Darmawikarta, 2014). According to Darmawikarta (2014), there are two languages that constitute SQL: (1) data definition language (DDL), and (2) data manipulation language (DML). DDL includes commands for altering, creating, and dropping objects, while DML includes commands for manipulating and selecting database data (Conger, 2014). For example, the statement SELECT * FROM Patients has the DML command to return all columns from the ***Patients*** table. What does this mean for our DBMS? The DBMS that we choose must be able to run these types of commands as it interacts with the database. However, not all DBMSes perform at effective levels.

Strength and Weakness. According to a study in the Journal of Computer Science and Research (2012), DBMSes may execute every query statement with different performance metrics. In a database with a logical design similar to the one of Westlake Research Hospital (Figure 12), executing the query statement SELECT * FROM Patient would be handled differently by each DBMS. Depending on the size of the database, the difference between the execution time between Oracle and IBM DB2 may be between 5 and 10ms (Bassil, 2012). The difference between MS Access and SQL Server, on the other hand, was between 50 and 100ms (Bassil, 2012). CPU utilization also differs when running a query statement (e.g., SELECT * FROM Patient). For example, in the aforementioned study, the CPU utilization for SQL Server was 9%, whereas Oracle CPU utilization was 14%. The study concluded that the average execution time for MS Access was 1885.6ms (Bassil, 2012), which was pronouncedly higher than the rest of the DBMSes. SQL Server, for example, had an execution time of 1101.3ms (Bassil, 2012). Furthermore, another study in the International Journal of Advanced Research in Computer and Communication Engineering (2015) revealed that SQL Server performed exceptionally when running most queries, except for INSERT queries.

Other strengths and weaknesses exist in the relational database management systems under our consideration, some of which are directly related to querying the database. Although DDL will not be extensively utilized in the Westlake Research Hospital's clinical study, it is vital to take its commands into consideration when choosing the DBMS. This is due to the fact that future developments may require that the researchers alter, create, or drop objects of the database. According to Darmawikarta (2014), the INSERT statement in Oracle can only insert one row, but multiple rows can be inserted when using MySQL. This was one of the first indications that the Oracle may not be a fit for our clinical trial purposes. Although Oracle may have other syntax to inserting multiple row, it would be easier for a DBA to use a single statement for either a single row or multiple rows. For example, syntax INSERT INTO Patients (PatientFirstName, PatientLastName, …) VALUES (John, Adams, …) can be used to enter a single row in MySQL database.

Unfortunately, some of the simplicity and flexibility in the aforementioned MySQL syntax poses a threat on data integrity and security. Westlake Research Hospital supervisors have made it clear that security is one of the main concerns. MySQL may not be the ideal DBMS because it has one file for schema, one file for data, and one file for index (Vernon, 2003). If Westlake Research Hospital is more and only interested in speed and low cost, then MySQL might be a good option; however, for a better security, data integrity, and data recovery, we may need to consider other DBMSes.

MS Access has been known to be used for a smaller scale projects such as academic projects. Additionally, new developers or beginners may use MS Access for practice purposes so that they are familiar with and used to running queries and building databases. "One of the benefits of Access from a programmer's perspective is its relative compatibility with SQL queries" (Bassil, 2012). Essentially, projects where security and even performance are not much of a concern, MS Access maybe ideal. However, in the Westlake Research Hospital case, MS Access would not be an option because other DBMSes such as Microsoft SQL Server are better equipped to provide security and performance at a higher level.

Although most of the DBMSes share several similarities, unique differences will aid us in determining which DBMS to proceed with. For example, both IBM DB2 and Microsoft SQL Server include data scheme, secondary indexes, and SQL; however, one of the major differences between the two is that Microsoft SQL Server only works with Windows server operating systems. IBM DB2 on the other hand works with Linux, UNIX, Windows, and z/OS (IBM, 2012). How does this affect our decision? Some of the great features of IBM DB2 may actually pose some difficulties when administering the data. Although Windows SQL Server has the limitations of only running on Windows Operating Systems, it provides the simplicity that we need for our study's database that is otherwise not provided by IBM DB2.

Finally, the total cost of ownership must be considered and the cost be emphasized when making the selection among the DBMSes. A product such as Microsoft SQL Server had been researched, developed, and invested in to make sure that it completely satisfies the business needs of those who obtain it (Microsoft, 2012). Therefore, implementing SQL Server would mean that the focus would be on the project itself, and the project team will have little concern about security and support. For example, if Westlake Research Hospital were to implement the free software MySQL instead of purchasing SQL Server, then it would most likely further invest in resources to support the use of MySQL and the protection of that database, which would ultimately raise the total cost of ownership.

Recommendations

The process of recommending the most appropriate database management system starts by identifying the size of the Westlake Research Hospital project. There are several factors that we must look at when determining which DBMS to use for our project. How big is the project? What is the amount of security that we will need? What is the data integrity level that the DBMS must maintain? Who will be managing the database? What is the level of expertise of the users? The business needs that were discussed earlier address questions like these. The idea is to have a DBMS that would be financially ideal for our project, meet our business needs, and provide users with a user friendly interface to be able to interact with the database. After careful consideration of all the above market-leading DBMSes, I have decided that Microsoft SQL Server would be the ideal system for our project.

As previously indicated, the researchers will conduct the trial on 400 patients and 20 doctors will examine those patients. The big number here is the 400 patients. This may seem like a large number; however, it is relatively small compared to large business who may need thousands if not millions of rows and columns in their database. Microsoft SQL database falls within the parameters of our project.

Another key factor in determining which DBMS to use is security. Several aspects in the Westlake Research Hospital study call for extreme security. First, the type of study that the researchers are conducting, which is a double-blinded study. This means that the database must maintain a high level of security where only those who are authorized to access information from the database can do so in order for the researchers to insure the integrity of the study. Second, it was emphasized as part of the study that protection must be maintained against outside competitors. The database can only be protected if the database management system is designed to provide such protection (Muntjir, Aljahdali, Asadullah, & Haq, 2014). Microsoft SQL Server provides substantial security measures including auditing, transparent data encryption, and stored procedure security (Microsoft, 2012). One must always take into account the level of security that a DBMS has in comparison to the cost. As evidenced above, some of the DBMS under consideration are relatively expensive. In contrast, some are extremely inexpensive and can most likely satisfy most of the business needs of Westlake Research Hospital. However, how much security is provided by the inexpensive products? According to Microsoft (2012), MySQL lacks active directory support, role-based, stored procedure security, auditing, transparent data encryption, and centralized key management. This raises an obvious security concern and suggests that patients' confidentialities may be jeopardized. This further emphasizes the use of SQL Server.

Aside from security, the DBMS that we select for this study must be able to manage transactions effectively and efficiently. There is a high level of database interactions as shown in Figure 13 that include most elements of the study. Nurses will be accessing the database to enter vital signs each time their patients visit the facility. The doctors will also be entering their notes in the database as well as retrieving the patient medical history. Furthermore, the researchers will be constantly utilizing the database to make sure that the study is on the right track and to run their analyses on order to evaluate the study. Therefore, there should be no room for error during these transactions. This emphasizes the need for a recovery and backup management. If one of the database users enters information in the database and an errors occurs, then the DBMS must be able to return the database to the state prior to the data entry, which is an ability of SQL Server. Due to the type of this study, losing any kind of data is extremely vital. This study is time sensitive, and when treating the patients with a certain medication during a certain period of time, it will not be logical to restart the study in the case that the database fails and some of the information is lost.

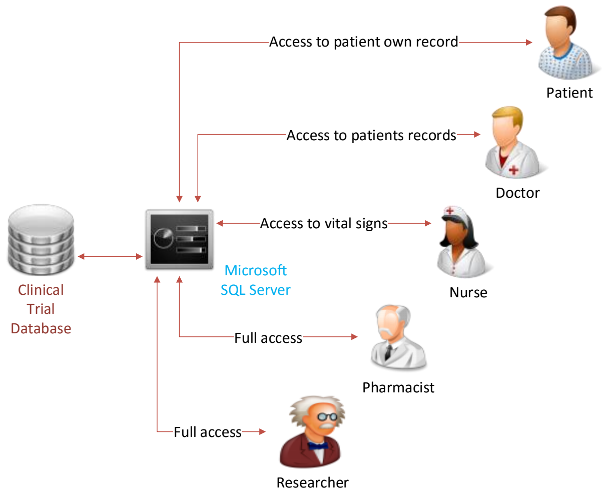


Figure 13. DBMS Controlled Access. This figure illustrates the level of access for each user.

To conclude, Microsoft SQL Server would provide Westlake Research Hospital's study with the needed access controls in order to protect the study and the database. For example, SQL server will provide password complexity rules and limit the resources by the user. This would enforce the security of the database and limit the type of access that each user has to the database (e.g., patients will only be able to view their medical history and doctor notes while researchers have access to all the data). Furthermore, SQL Server will give the patients the ability to review their patient profile and medical records from home due to its integrated web server.

Hardware and Software

In order to have the database fully functional, we need both hardware and software implemented in the appropriate departments that will be utilizing the database. Westlake Research Hospital IT department would have to decide where the physical machines should be installed that would house the database. The database needs to be housed in a computer (server) that must be kept in a locked and secure area. I will recommend that the server be installed in one of the data centers that already exist for the hospital. The IT department would most likely already have a machine that we can use for our purpose, whether physical or virtual. However, it has been evidenced that the virtual database servers have a higher response time than physical servers (Ahmed, 2013).

Aside from the hardware where the physical database would be housed, each user must have access to a computer so that he or she can interact with the database. For example, the doctor must have access to a PC so that he can review the patient medical history and enter his or her notes. The nurse, on the other hand, must have access so she can enter the vital sign for each patient electronically. Researchers will most likely have access to the database from their offices where they will have full authorization to access the database. Lastly, patients will be able to access their medical records and doctor's notes from their home computer through a browser.

The software that would be needed for our purpose of the clinical trial is the DBMS itself (i.e., Microsoft SQL Server). However, patients may also need a software application if they want to review their records. Westlake Research Hospital most likely has a patient portal already setup online. If requested, this patient portal can pull data by interacting with the DBMS. The patients will only need to retrieve data from the database, and will not be updating or changing any data. Therefore, the DBMS will act as the controller in allowing the patients to retrieve only the data that they are allowed to access. Patients are considered "naïve users" because they will not be utilizing interfaces provided by the DBMS and will not necessarily be aware of the presence of the database. "Naive users are end users of the database who work through a menu driven application program, where the type and range of response is always indicated to the user" (Thakur, n.d.). The online patient portal will provide the patients with the online terminal to access the data without necessarily understanding how the database works. They will be able to simply follow a set of instructions on the screen that will guide them to the information that they need.

Data Model

In the data modeling for Westlake Research Hospital, I am simply addressing the objectives of the researchers, which include obtaining reliable information form a secured patient database in order to examine, analyze, and produce effective results for the clinical study under consideration. In order to support these objectives, I will include several elements in the enterprise data model that would support the Clinical Research department at Westlake, including all users that would be utilizing a database to retrieve, update, or analyze data.

Enterprise Data Model

The enterprise data model (EDM) should address all cases that deal with clinical trials. Therefore, the data model will not only apply to the depression clinical trial, but also other trials that Westlake decides to undertake. The EDM will include several areas consisting of the clinical sites such as the clinical trial unit and the data sites such as the data center. According to Oita University Hospital General Clinical Research Center (2011), the general organization structure of a clinical research facility includes areas such as clinical trial support, network division, and data management. Similarly, a clinical trial at Westlake would involve the clinical trial unit, clinical trial support division, clinical trial office division, network division, data center, and data management. In this case, researchers would manage the data as they monitor the database and analyze its data. All these areas work in conjunction when there is a clinical trial to undertake. Therefore, the EDM must apply to all of them.

According to Williams (2015), a good approach in designing an EDM is to consider the statement of objectives. This would simplify the identification of "Things of Interest" that should be included in Westlake's enterprise data model. Considering the aforementioned objectives of Westlake, the EDM should include: (1) Type of clinical trial, (2) Researchers, (3) Patients, (4) Doctors, (5) Family history, (6) Allergies, (7) Medicines, (8) Symptoms, (9) Diseases, (10) Visit, (11) Patient Private, and (12) Drug as illustrated in Figure 14.

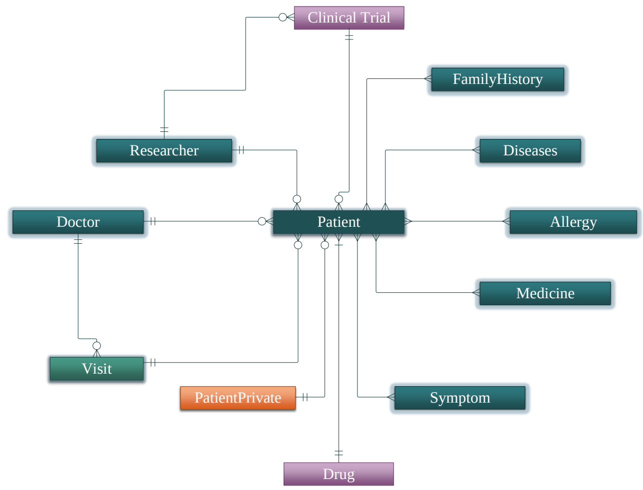


Figure 14. Enterprise Data Model. This diagram illustrates the data model at the enterprise level.

Furthermore, the EDM can be comprised of three different levels including SAM, ECDM, and ELDM (Stiglich, 2012). These acronyms refer to a subject area model, conceptual data model, and a logical data model, respectively. The levels are commonly illustrates as shown in Figure 15.

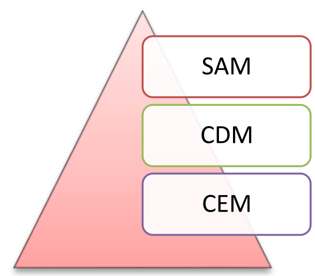


Figure 15. Enterprise Data Model Levels. This diagram illustrates the three levels of the enterprise data model. Source: *(Zhang, 2011)*

It is ideal to develop an SAM (Subject Area Model) in the Westlake Research Hospital clinical trial research because it would aid in developing the enterprise data model. According to Zhang (2011), the purpose of an SAM is to provide the structure for organizing EDMs. The SAM for Westlake's clinical trials is illustrated in Figure 16. The diagram illustrates the Westlake's high-level subjects that would be involved in a clinical trial at any given time. For example, each clinical trial conducted by the Clinical Research department at Westlake would involve doctors and patients as well as researchers that conduct the study. The SAM provides analysis and justifies including elements shown in the EDM in its design. For example, since doctors must treat patients in the Clinical Research department, then both doctors and patients are important elements of the EDM design. Both the ECDM and ELDM are illustrated in **Exhibit A** and **Exhibit B**, respectively.

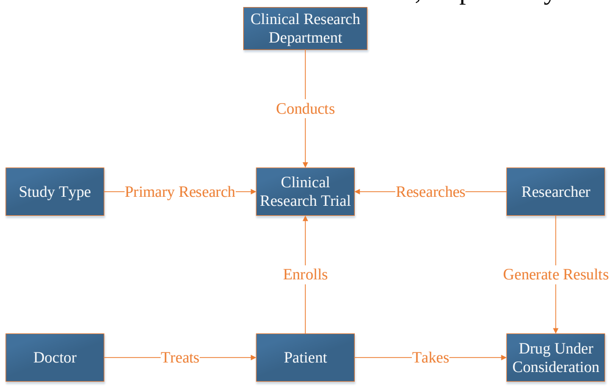


Figure 16. Subject Area Model. This diagram illustrates the relationship among these elements within the enterprise as a whole.

Operating Rules

Considering the nature of clinical research, Westlake has several operating rules when conducting research through the utilization of a patient database. According to Accord Clinical Research (2016), the two major types of clinical research trials are Comparative and open Lab. Westlake mostly conducts double-blinded trials, which are comparative clinical research trials. However, Westlake may also conduct an open lab clinical research trial. Therefore, one element within the current EDM (i.e., Patient Private) may or may not serve the business. A database designer, however, would favor having this element in the model because it would serve the double-blinded studies. Furthermore, the standards of Westlake Research Hospital would require the collection of patients' list of allergies, medications, symptoms, and family history as it was indicated on their forms that patients need to complete prior to enrolling in the study.

As indicated in the enterprise data model, researchers are key members in the clinical trials. They are the members conducting the research and coming up with meaningful statistical results. The Clinical Research department at Westlake Research Hospital employs more than one or two researchers; therefore, identifying the researcher in the data model is necessary. There are several rules that would apply to researchers and other users in the Clinical Research departments. One of the major rules re-emphasizes the type of study being conducted. In the current double-blinded clinical research trial, neither doctors nor nurses should be aware of the type of drug that is being administered to the patients. This also extends to the patients taking the drug.

The EDM shows application specific rules that must apply when conducting a clinical trial. Aside from rules imposed by the type of study, Westlake's Clinical Research department must have several doctors treating more than one patient. The rules also indicate that no one patient should be treated by more than one doctor. Furthermore, each trial must be conducted by professionals within the Clinical Research department such as the researchers. Either one researcher or more can be conducting the study. The model also indicates that rules apply to clinical trials in terms of what the trial is trying to accomplish; therefore, each trial should have one, and only one drug under consideration. However, to what extent does the model reflect the rules of the organization?

Rule Reflection

Since the type of clinical trials conducted by Westlake Research Hospital may vary, then the 'type of clinical trial' should be included in the EDM so that it is clear what clinical trial the researchers are working on. The idea is to utilize this EDM for several projects that pertain to clinical trials so that they follow the same enterprise standards. The clinical trials, as they pertain to Westlake, should always include the list of medication, allergies, and symptoms when conducting research as well as other subjects addressed in the model. However, even if the type of clinical trial is identified, there continues to be certain limitations to how the relationships between the subjects reflect the rules of Westlake and its Clinical Research Department.

The relationships shown in the EDM above are the result of the operating rules imposed by Westlake. Relationship-specific rules may or may not indicate complete constraints (Hernandez, 2013). The model simply provides the general idea behind the clinical trials as they should satisfy the business. However, it does not provide specific details about the relationships between the elements of the EDM. For example, the EDM shows that it may be possible for one of the doctors in the Clinical Research department to be treating more than one patient; however, it does not specify if each doctor has a limit in the amount of patients that he or she can see. Therefore, these areas or limitations were addressed in the physical design of the database to apply the business rules as necessary (i.e., each doctor can only have twenty patients).

Law, Ethics, and Security

Standards

Designing a database includes determining user authentication so that unauthorized users do not have access to the database. This is true in most cases; however, in a clinical trial research study like Westlake's, further considerations surface because of the type of study undertaken. The double-blinded study involves collecting patient information and keeping a patient database, which should stay confidential under HIPAA (Health Insurance Portability and Accountability Act) regulations. Since the database is designed for patient information, then HIPAA's Security Rule must be taken into consideration when designing the database. The Rule concludes that all businesses dealing with electronic protected health information (ePHI) must adhere to the national set of security standards, which was established by HIPAA (Department of Health and Human Services [HHS], 2015).

Furthermore, the clinical study would only allow for certain individuals to view the data so that the integrity of the study is maintained. In the Westlake's clinical trial, researchers are the only ones to view all the research data and it is prohibited that either doctors or patients know the type of medication that is being administered. Depending on the clinical trial that Westlake undertakes, the database design should include restraints that limit the doctor-to-patient assignments as well as the number of patients that can be involved in the trial. Once constraints are set to meet the specific clinical trial, then the data integrity must be maintained while stored, accessed, and manipulated. HIPAA provides a set of rules and regulations that is specific to the use of ePHI; therefore, in the solution design and future implementations, HIPAA regulations must be considered in order for Westlake to comply with legal and ethical standards and regulations.

Legal Compliance

Since Westlake is a research hospital, then much of the database design and use must comply with legal and even governmental standards to protect the information of patients according to HIPAA. Any time there is a transfer of information via a network, there is a chance that patients' information may be jeopardized, including storing patient information in a database. Most healthcare facilities use an electronic health record (EHR) to enter and utilize patient information (Rodriguez, 2011). However, the rules apply to all applications that deal with patient electronic health records. There are certain rules and regulations set by different Acts that enforce the integrity and security of the data. For example, according to the U.S. National Library of Medicine (2016), HIPAA "establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically."

Furthermore, in order to ensure legal compliance, Westlake's DBA must address any issues with the database in a timely fashion. For example, if a doctor realizes while using the database that there might be a bug in the system and informs the IT department, then Westlake needs to act accordingly to ensure legal compliance. Furthermore, Westlake should ensure that it is using all possible resources to provide its database with security, confidentiality and data integrity. These areas are strongly associated with HIPAA regulations that determine whether or not a business is being legally compliant. These regulations include, but are not limited to: (1) ensuring that servers are configured to use Windows Authentication, (2) establishing access management processes for individuals and entities, (3) enforcing strong password policies, and (4) limiting the use of shared administrative and service accounts (Zodrow & Rozek, 2013).

Ethical Practices

The ethical concerns surrounding the patient medical records are not limited to a single department such as the Clinical Research department at Westlake. These concerns do not only revolve around accessing the database, but also designing the database where patient data is stored. Some of the ethical concerns in the depression clinical trial deal with the integrity of information that is being revealed to individuals. For example, a doctor may be interested in discovering what medication his or her patient is taking. This would violate the code of ethics in terms of conflict of interest. The Institute of Electrical and Electronics Engineers (2106) emphasizes the importance of avoiding any conflict of interest situations, and reporting them to the affected individuals if they do occur.

Furthermore, the Association of Computing Machinery (2015) addresses certain rules and regulations that software engineers must adhere to when it comes to software development. Their code of ethics states that "Software engineers shall act in a manner that is in the best interests of their client and employer consistent with the public interest" in terms of client and employer (ACM, 2015). This is similarly true for Westlake's professionals who design and monitor the database. When designing the database, professionals should ensure the integrity of their patients' information by making sure that the information is secure to the best of their knowledge and ability. This is also true for those who can provide certain privileges (e.g., DBAs) to certain users. For example, in the depression study of Westlake, if a DBA does not ensure that sufficient limitations are enforced on doctors, then the doctors may be able to either intentionally or unintentionally discover the type of drug that is being administered to their patients and ultimately jeopardize the integrity of the entire study. Ensuring ethical practice should include: (1) verifying that the database was designed to enforce referential integrity, (2) verifying that applications are controlled as far as input and output validation, (3) verifying that database monitoring is in place, and (4) verifying that the database was designed using secure development methodologies (Zodrow & Rozek, 2013).

Security Needs of Solution

There are several security levels that must be considered at the level of the Clinical Research department and at the level of Westlake Research Hospital as a whole. Westlake will have access to general patient information through a DBMS as well as the type of trial that each patient is enrolled in. The data at the higher level may or may not be in a relational database, and the relationship between that database tables may not be as significant as it is to the several studies conducted by the Clinical Research Lab.

The DBMS solution chosen for the Clinical Research department and Westlake Research Hospital as a whole should be able to provide database designer with the tools to make the database more secure. A database designer needs to be able to develop Stored Procedures that would meet the needs of the different departments in the hospital. This would allow the DBA to assign different databases to different departments in the hospital, and then assign the Stored Procedures to the individual departments. The DBMS should also allow for creating individual logins to provide for authentication. For example, with MS SQL Server Management Studio, I was able to create a special login for the patients so that they have certain limitations when accessing tables in the database as described earlier. Furthermore, the DBA can use the DBMS to create Views for certain users. This would allow the DBA to give certain privileges to individual departments at Westlake. For example, the Clinical Research department would have their own Views from specified tables in the database (e.g., Medications and Allergies), and Administration would have their Views from tables such as Doctor and Patient.

Therefore, there is a difference when it comes to user privileges and limitations at the level of Westlake and at the level of the individual departments such as the Clinical Research department. The hospital as a whole may have certain privileges to enforce security that would only be based upon views of the database rather than manipulating the database such as adding or deleting tables. The Clinical Research department, on the other hand, would have privileges to create, update, or delete tables because they are more closely associated with the database and the clinical studies. The DBMS would allow for each department having its own privileges, and this is especially true when the DBMA allows for Triggers. "Enabling triggers can provide more specific security for delete, insert, and update operations" (SAS, 2011). Specific features of Microsoft SQL Server are presented in Table 21, which would be extremely beneficial for Westlake in order to comply with HIPAA's rules and regulations.

Microsoft SQL Server
Database auditing capabilities with SQL Server Audit
Extensible Key Management (EKM)
Granular access control
Reporting Services
Transparent Database Encryption (TDE)
Performance data collection
Policy-based Management

Table 21. Microsoft SQL Server Features. This table illustrates some of the features beneficial to Westlake in order to be compliant with HIPAA rules and regulations *(Zodrow & Rozek, 2013).*

Database Security Plan

The database security plan should take into consideration rules and regulations set by HIPAA because it sets the ground rules for dealing with patient electronic records. The business nature of Westlake mainly involves record keeping for patients and is, therefore, in strong associated with HIPAA regulations. Westlake DBAs should first ensure that each individual has the right privileges and limitations to the database. This can be accomplished by setting up usernames and passwords for authentication. Then, in order to ensure compliance with HIPAA, Westlake Research Hospital as a whole can assign one of its members to monitor the day-to-day compliance activities, whether in the Clinical Research department or other departments as well.

Certain steps must also be taken to ensure the security of the database that may not necessarily be closely related to the DBMS. For example, encrypting the data that is being transferred over the clinical study will reduce the risk of jeopardizing patient information. Furthermore, this would also ensure the integrity of the clinical research because information about the type of drug that is being administered to each patient would be more secure and therefore would further satisfy the needs of the double-blinded study and other future clinical studies. Finally, to comply with HIPAA regulations, conducting an annual risk analysis maybe ideal, especially since HIPAA requires an annual security risk analysis (Ferran, 2015). This would serve Westlake Research Hospital at a higher level in ensuring the security of its data for the current study and future studies.

Exhibit A

ECDM

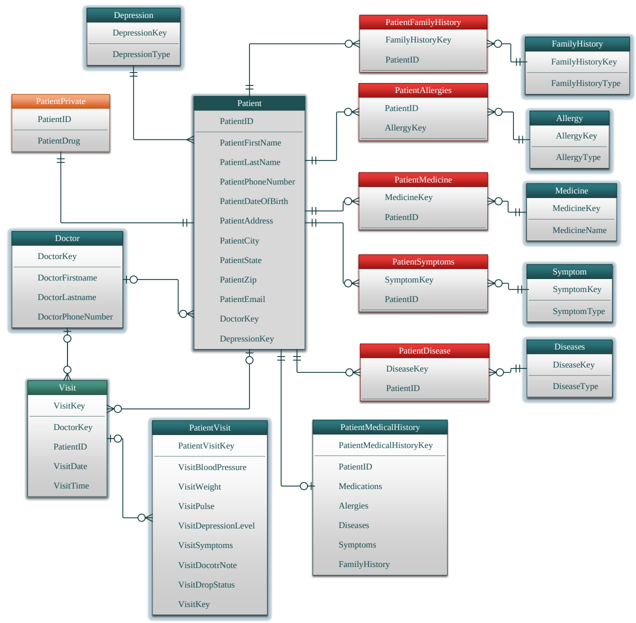


Figure 17. ECDM.

Exhibit B

ELDM

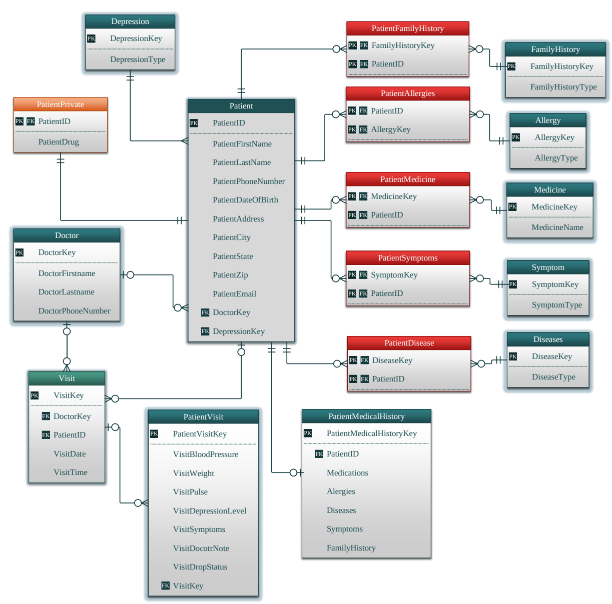


Figure 18. ELDM.

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