

Evaluation Plan

Tennessee State Regional Demonstration Project

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I. Abstract

The State of Tennessee proposes planning, implementing, and evaluating a state-based regional data sharing and interoperability service interconnecting the health care entities in the three counties surrounding Memphis in the southwest corner of Tennessee. The State has formed a consortium with Vanderbilt University to manage this Project. Completion of this project will depend on the success of governance structures that address both state-wide issues and regional control, an information management architecture that supports data sharing and interoperability, and tools to help healthcare entities incorporate standards into their local systems, thus enabling true interoperability over time. We propose identifying metrics for measurement of impact at the start as we identify desired outcomes and Core Clinical Data Elements. We propose to achieve scale through a project management office to support planning, both levels of governance, implementation of the Regional Databank, and evaluation.

II. Goals of the Project

Our goals are to improve the quality of care provided throughout the region by improving access to data at the point of care. We will demonstrate the efficacy of data exchange by assessing its impact on ED care initially, with a long term goal of determining how this technology improves community health care delivery.

The project team recognizes that a successful, sustainable, and worthwhile data exchange program will improve health care in the region. Discussions with southwest Tennessee stakeholders have disclosed the following drivers motivating their involvement:

- Incomplete information increases admission rate and ED LOS
- Poor communication impacts ED efficiency
- Less patient data at the point of care impacts the rate of test ordering
- Less patient data at the point of care impacts clinical outcomes

Furthermore, exploratory analyses of claims data in our region, coupled with demonstrated savings published in the peer-reviewed literature suggest that data exchange could result in significant overall savings from reduced inpatient hospitalizations, improved distribution of ED encounter summaries, reduced admission days for neonates due to missing Group B streptococcal tests in mothers, reductions in duplicate laboratory and radiology tests, and reductions in Emergency Department expenditures. These measures form our initial evaluation strategy.

Our project is limited in scope to the emergency department in the first phase. However, we anticipate additional drivers and therefore evaluation measures for later phases involving community practitioners, public health aggregate data, etc.

The project team recognizes that several aspects of this program may impact the value proposition as described above. Among the key variables are:

- Overall costs (personnel, training, equipment, meetings, software development, customizations)
- System usability
- System use
- System utility

We have been in production since spring, 2006. This has put us in position to understand the impact of our health information exchange program from many of the aspects above. Evaluation is based on the hypotheses that health information exchange:

1. will improve the efficiency of care in all care settings, as manifest by
 - a. lower rates of testing (expenses per encounter)
 - b. lower rates of admission
 - c. shorter time spent per encounter in the ED
2. will change the case mix of the ED, as demonstrated by
 - a. decreased repeat ED visits over 30 days
 - b. decreased poly-pharmacy and chronic pain patients
3. will alter the workflow of the environments in which it used, by
 - a. changing time spent seeking information
 - b. changing time spent using computer technology during patient care
 - c. changing who is responsible for information seeking
4. will improve the outcomes of specific clinical conditions (to be determined)

To best understand the impact, we have identified a set of key “phase 1” metrics that assess the overall functionality of our health information exchange system. Those metrics are listed in the table below, and will be explained in more detail in the following section.

Measure	Timeframe	Design	Analysis Plan	Power/Sample size
ED Demographics	T – 1 month	Site-based Survey	Values will be used as co-variates	One survey per site.
Usability	T + 1 month, 6 months, 1 year post implementation	Survey, administered to pre-defined cohort at each site. If necessary, survey results will target focus group meetings for clarification. HELP desk use logs.	Scores for each of six axes, used formatively during implementation, and later as a co-variate for use, disease-specific outcomes	30% sample with replacement until cohort is established. Expect 15 participants per site.
Use (functional,	Annually	Audit data (logins, access duration, data elements viewed, patients viewed)	Reported / month , averaged over the year.	All sites involved with data exchange
Functional utility	Continuous reporting	Feedback cards per site	Descriptive	N/A
Testing frequency	Annually starting year 3	Audit data	Reported / site/ 100 patients	N/A
Costs	Annually	Logging of costs	Annual cost calculated	N/A

			deterministically	
Time per encounter	Quarterly after implementation	internal audits of data in exchange		N/A
admission/re-admission rates	Quarterly	Claims data	Reported per site per month	
ED repeat visits	Quarterly	Audit data	Reported per site per month	
ED Casemix	Quarterly	Audit data	Reported per site per month	
Workflow efficiency	1 year post implementation (tool development underway)	Direct observation + survey	descriptive	All sites involved with data exchange

Question	Domain			
	Quality and Safety	Organizational Efficiency and Effectiveness	Financial	Formative Outcomes
What characteristics of your exchange either facilitate (or impede) the evaluation of this domain?	<ul style="list-style-type: none"> • Users are not required to use our HIE. Medication data are not available for all patients. • <i>ED physicians are motivated to use HIE</i> • <i>There are more than 1 year's worth of data now available</i> • Clinicians are accessing the system directly in many cases 	<ul style="list-style-type: none"> • <i>HIE is being integrated into the work of nurses, registrars and physicians</i> • <i>Champions are looking for ways to improve patient throughput using HIE</i> 	<ul style="list-style-type: none"> • Users are not required to use HIE 	<ul style="list-style-type: none"> • Difficulty traveling to and from Memphis • Evolving system that is used differently by different sites
What are some potential system-generated measures (e.g., for which data are routinely collected) that you could use to address this domain?	<ul style="list-style-type: none"> • Average number of prescriptions per patient* • Neonatal sepsis admission rate • HIV acuity and admission rate • Improved medication dosing, monitoring, and adherence 	<ul style="list-style-type: none"> • System use • Overall latency/downtime • Number of data elements • Number of patients with data in HIE • ED Casemix* • ED Length of stay* • Admission rates* • Re-admission rates* • Narcotic prescription rates • Change in patient sources and destinations 	<ul style="list-style-type: none"> • Lab testing rates • Other diagnostic testing rates • (variables with asterisks) 	<ul style="list-style-type: none"> • System use • Latency/downtime • Looking up data for patients seen previously
What are some potential measures (that will require primary data collection from users) in this domain?	<ul style="list-style-type: none"> • Content quality • LWBS, AWOL rates 	<ul style="list-style-type: none"> • ED Profile information(share) • Usability • System (overall and function-specific) usefulness • System utility • Workflow efficiency • Rate of case management referral • Rate of social worker referral 	<ul style="list-style-type: none"> • System development and support costs 	<ul style="list-style-type: none"> • Usability • Content quality • Overall usefulness • Opt-out rate
What is the anticipated	Will address this domain beginning in 2007	Have begun collecting pre-intervention and immediate post-	Developing models for analysis now. Collecting	All data are being collected and reviewed

* denotes variables also in the financial domain

<p>timeline in which your project can address this domain?</p>		<p>intervention data for all system-generated measures, ED profile, system usability, workflow efficiency. Other variables will be obtained later in the year. Summative data will be collected in the final year of the project.</p>	<p>information from RHIO about costs.</p>	<p>periodically since 2006</p>
<p>What are some methodological challenges that you anticipate having in evaluating this domain that will require the assistance of NRC staff?</p>	<p>IRB for on-site outcomes will be challenging. Study designs to account for site-specific workflows that may impact system we are studying.</p>	<p>Medication data not uniformly available. Will only be able to assess this for select populations</p>	<p>None apparent at this time</p>	<p>Defining and measuring use will be challenging.</p>

III. Formative Evaluation

The MSeHA evaluation plan consists of both formative and summative components. Formative components, that have been largely in place since 1 month after rollout, will be described in this section.

A. System Use

1. Overview

Health information exchange (HIE) tools are designed to provide data from disparate electronic sources within a region, with a goal of improving the care that can be delivered to patients. However, optimum delivery of care requires systems-based changes that are, at most, facilitated by HIE. Furthermore, any healthcare system change catalyzed by HIE, by definition, assumes appropriate access to and use of HIE. System use therefore represents one of the most fundamental metrics to measure as a part of an HIE evaluation.

There are varying definitions of use that range from simple login statistics to more sophisticated keystroke maps that assess both the breadth and depth of use at a functional level. Because our HIE system is evolving, we chose to concentrate first on assessing who is using the system and for which patients.

Specific Aim: to assess the use of a web-based tool for clinical data review, as defined through a series of quantitative metrics, including system uptime/24 hours, user login rates, number of patient records accessed, and number of disenrolled patients.

2. Study Design

System use is evaluated monthly and reported to the internal development team and the Board <need the right name> on a quarterly basis. Data for this report are derived from audit logs, and consists of:

- **Enrollment** (total patients disenrolling per month, provider/staff enrollment per month)
- **Access statistics** (percent total hours the HIE is available/ week; number and percent of providers accessing SPL per month; number and percent of patient records accessed)
- **Patient statistics** (number of patients with visits to another hospital within 30 days, number of patients with no data available in the system)

The table below characterizes the components of use that we review monthly.

Term	Definition
Visits	Encounters associated with a registration event. May

	represent the same patient returning multiple times.
Visits with data from other sites	The subset of visits that have data in the system from other sites (not the index site) within the past 30 days
Visits looked up	The subset of visits that was looked up in the system by the index site during this visit
Looked up visits with history from other sites	The subset of visits looked up that had history from other sites (#3)
Percent of visits with history from other sites	Calculated
Enrolled providers	Physicians and nurse practitioners with access at the site
Number of active providers	The subset of enrolled providers who have logged in at least once in the past month*
Total logins	Each login is defined as any successful sign-on event, regardless of the time since the last sign-on event.
Provider logins	The subset of logins completed by active providers
Enrolled registrars	Registrars with access at the site
Active registrars	The subset of enrolled registrars who have logged in at least once in the past month
Registrar logins	The subset of logins completed by active registrars
Enrolled clerks	clerks with access at the site
Active clerks	The subset of enrolled clerks who have logged in at least once in the past month
Clerk logins	The subset of logins completed by active clerks
Enrolled nurses	nurses with access at the site
Active nurses	The subset of enrolled nurses who have logged in at least once in the past month
Nurse logins	The subset of logins completed by active nurses
Enrolled others	QA, legal, developers, other personnel with access at the site
Active others	The subset of enrolled others who have logged in at least once in the past month
Other logins	The subset of logins completed by active others
Staff additions	The number of new non-provider and non-other enrolled users
Provider additions	The number of new provider enrolled users
Disenrolled providers	The number of providers no longer having access to the system
Recent Reg Viewed	The number of visits brought up on the recent registration screen
Automatic search via Recent Reg Screen	The number of times the recent registration screen is used to display patient detailed information
Manual Search by non health care provider	The number of times the patient search is conducted (not from recent registration screen) by non MD or RNs

Manual Search by RN or MD	The number of times the patient search is conducted (not from recent registration screen) by RN or MD
No record found search	The number of times the patient search is conducted (not from recent registration screen) by anyone, with a “ no record found” result
Total viewed by health care team	the count of visits where the record was printed for review OR manually searched for and viewed by anyone
Detail review	the number of records where detail clinical information was viewed.
Patients seen today who have visited other hospitals in <= 30 days	Total visits
Number of looked up patients who have had a recent visit TO OTHER HOSPITALS IN <= 30 DAYS	Total viewed by health care team

3. Analysis Plan

Use data are summarized in a monthly report and trended over time. IRB approval has been obtained for this aim.

B. System Usability

1. Overview

The design and rollout of our HIE has been iterative. The rollout plan allows us to evaluate aspects of how the system works in clinical settings, make changes, and re-evaluate. Toward that end, we have conducted periodic usability assessments, with a goal of providing a periodic summary of usability issues to the design team and the Board. Usability data from each site will provide an important outcome of our efforts in its own right; it also will likely be correlated with the impact that HIE will have on other outcomes in that site.

Specific Aim: The specific aim of the proposed project is to assess trends in usability of a web-based tool for clinical data review.

2. Study Design

Before beginning this study, our research team purchased a site license to use the Questionnaire for User Interface Satisfaction, developed by Norman and colleagues at the University of Maryland’s Human Computer Interaction Laboratory. Subscales from this tool that addressed usability dimensions not as relevant to this project (training, user manuals) were removed, and additional dimensions based on an initial review of the MSeHA user interface (addressing searching for patients and scrolling through results) were added, and then pilot tested for face and content validity in the Vanderbilt Emergency Department.

The study is being conducted using faculty and staff from the following clinical sites in the southwest Tennessee region:

- Methodist University Hospital

- Baptist Memorial Hospital
- The Regional Medical Center
- Methodist Hospital
- Methodist LeBonHeur Hospital
- Other sites as they are included as active participants

Each of these sites has agreed to participate in the data-exchange project and in this usability assessment.

For each site, we defined an initial cohort of users who will provide usability data. Using our access logs, we emailed a request to each of these people asking them to participate in a usability study that will involve completing a usability survey at least three times each year. Each user replied with their willingness to participate. Once this cohort was defined, each member of the usability cohort was assigned a study ID. Each study ID was linked to a mailing address, to which surveys were mailed. Each survey was distributed with a sheet of paper that identifies its recipient by study id. The sheet was removed before analysis, thereby allowing additional surveys to be sent to non-respondents but protecting the identity of the cohort member. We distribute a maximum of three surveys to each cohort member during each phase of the usability assessment.

Because usability will be related to use, and use is related to other factors, we will ask each site’s physician and nursing directors to complete two brief questionnaires designed to assess the site’s readiness for healthcare information technology and to gather site-specific demographic data important for subsequent analyses. These data will be collected at the beginning of the study only.

Sampling of the cohort has proceeded in the following manner:

Site	GO LIVE	Dec 06	Jan 07	Apr 07	June 07	Sept 07			
Memphis Regional Medical	4/06	X			X				
St. Francis	10/06		X			X			
Baptist	10/06		X			X			
Methodist	4/07					X			
Le Bonheur	6/07					X			

3. Analysis Plan

Monthly usability data are summarized for each member of the cohort and given to the development team semi-annually. We anticipate that periodic changes to the system will impact usability, and these data will be used to further stimulate changes as appropriate.

C. Impact

1. Overview

In one of our initial Board meetings, there was concern expressed about the “drunk looking for keys under a light post” model of evaluation—choosing what to measure based on how easy it will be to measure it. Rather, a suggestion was made to adopt the “Willie Sutton” model of outcomes research—going where the “money” is. Qualitative researchers have long understood this tension. Therefore, after consulting with the Board and with our evaluation team, we decided to provide a mechanism to uncover assertions about the impact of health information exchange on patient care. This campaign, that we call “What Song Are You Singing” (a title appropriate for the Memphis region) is an outgrowth of that discussion.

Specific Aim: To generate hypotheses about negative or positive areas of HIE impact in the Memphis region.

2. Study Design

The “What Song Are You Singing?” campaign uses a survey, designed as a simple check box and large area for open-ended responses. This model was chosen because we needed to minimize biases, and maximize the opportunity for answers of any type.

Each site involved in HIE was provided with response cards (shown below) and a box designed to hold the cards and allow responses to be private. Each site has a champion who was asked to promote this mechanism of providing feedback to our evaluation team.



Each month, these cards are collected from the boxes by a member of our team. The responses are transcribed and categorized. In addition, 3 respondents are selected at random to receive a small gift of thanks for entering a response. Because of the need to contact respondents who are selected, the cards provide a place for a respondent to write his or her name and contact phone number.

3. Analysis Plan

Information from each card is entered into a database anonymously. These comments are then categorized into themes as a part of that database by one reviewer (KBJ.) Themes from the cards are reviewed quarterly and summarized for the development team. We will review the themes and report what they were and how they changed over time during the life of the project.

D. System Performance

1. Overview

System performance is defined as overall productivity of the system, tied to availability, throughput, and response time. In the case of the MSeHA, high performance is defined by those attributes that are required for the system to impact patients seen daily by health care providers:

- Latency (how long does a data element take to arrive in the HIE system after that element is available in the originating system?)
- Uptime (how often is the system available to be used in an average week)
- Data coverage (which needed data are available in the system)

2. Study Design

Performance measures will be collected prospectively from system log data and reported to the user community on an annual basis. Latency, defined above, will be summarized from data stream logs. Failure of any stream of data to be uploaded into SPL for greater than 24 hours will be reported as downtime for that period. Uptime will be summarized monthly as the sum of prolonged latency periods, delayed response times greater than 1 minute, and system unresponsiveness for any period of time.

3. Analysis Plan

System performance will be evaluated at the level of each site, and reported quarterly (since high performance is expected.)

E. Content Quality

1. Overview

For HIE to be effective, data that are contained within each patient record must be accurate, complete, appropriately categorized, and in the form necessary to be relevant at the point of care. Content quality is the direct reflection of the work done by the SPL team to receive and process information from disparate information sources. As such, content quality is a critical metric to evaluate in this study. It is possible, for example, for systematic errors in processing to cause mis-categorization or rejection of data elements that might be appropriate and necessary at the point of care.

2. Study Design

Our study design will rely on the assumption that no content quality errors are acceptable. We analyzed our content during the development phase of the project using a quality assurance team to ensure accuracy and appropriate categorization. However, data will continually be updated from feeder systems and will need to be monitored to ensure high levels of content quality.

Each quarter, we will randomly sample our HIE data to look for evidence of missing data elements, categorization errors, parsing errors or inaccurate assignment of data. In addition we will assess content using our quality assurance team.

3. Analysis Plan

We will report our error rate as the percent of total messages exchanged each month that are not accurately depicted in the HIE system.

IV. Summative Evaluation

A recent review of approaches to evaluating innovations validated many of the impressions we had in developing our final summative evaluation strategy. This review was highlighted by the discovery of articles by Stead¹ and Friedman^{2,3}, which both suggest the importance of scaling an evaluation to the life-cycle phase of an innovation. In the case of HIE, where adoption and usage are likely to be in an evolving state for the next few years, it may be impractical to create generalizable results about many clinical outcomes that relate directly to patient health. For example, in the MSeHA, medication history data are not currently available for all patients, even though these data are available for a subset of patients. It is difficult to imagine busy clinicians taking time to discover the subpopulation of patients who has a medication history in the system; therefore, it may be impractical to conduct a study formally examining how the provision of a medication history has decreased the prescriptions for controlled substances.

Keeping this strategy of a “right-sized” evaluation in mind, our evaluation will focus on a series of measures driven by our key stakeholders:

- contractors (the State of Tennessee and AHRQ)
- clinician users
- Memphis healthcare organizations (Board)

Our guiding hypothesis is that HIE will result in better utilization of the emergency department and inpatient units, better utilization of test results from other institutions, better access to medical history from other institutions, a higher rate of referrals back to a “medical home” for pregnant patients, and changes in the workflow and associated information seeking tasks in the emergency departments.

To address this hypothesis, we will evaluate the following aspects of the system during the final year of the project:

- A. Usability and provider satisfaction
- B. Record grouping and locating service
- C. Site utilization
- D. Rate of test ordering
- E. Changing ED casemix
- F. Workflow change
- G. Disease-specific hypotheses, as defined during the next year
- H. Value and sustainability

A. System Usability and Provider Satisfaction

1. Overview

We will begin our summative evaluation with a final assessment of the system's usability. Because our formative data are collected from a convenience sample of clinicians from all sites, these data are not sufficient to evaluate the overall opinion about the HIE system.

One of the observations made by our Technology Advisory Panel was the extreme variety of workflows exemplified by each site involved with HIE. For this reason, it is often quite confusing to aggregate usage data. At their recommendation, one of the first activities we will complete is a series of activity diagrams to elucidate the way HIE is used in each setting.

2. Study Design

The general study design has been described above. We will use QUIS, as used for our formative analyses. The study population will consist of all users who have access to the HIE from all sites of care. Each participant will be mailed a survey using the anonymous ID methodology. Non-respondents will receive up to 3 repeat mailings, with the final mailing using a receipt method to capture any non-delivered surveys. Each participant's survey responses will be paired with data about their system use (site(s) of use, number of months using the system, patients accessed) and their role (MD, registrar, nurse)

Activity diagrams will be constructed for each site. These diagrams will be constructed from structured interviews, with sequences of steps arranged according to the actor (clerk, nurse, physician, patient, medical records department, etc.) and actions (retrieve old records, etc.) The investigators have had experience using this modeling approach in the past.⁴

We are exploring a number of possible survey instruments that have been validated, including those by Detmer and Shortliffe, the American Academy of Family Physicians, and others. None of these instruments specifically addresses health information exchange, but that may, in fact, be acceptable.

In addition to these surveys, a team of evaluators will hold separate facilitated group discussions with four groups of stakeholders across all sites:

- Nurses
- Clerical staff
- Physicians / residents
- ED Administrators

These group discussions will include 8-12 users, selected based on volume of use, work shift, gender, and age. Discussions will be audiotaped and transcribed, and will follow a semi-structured model focusing on usability, workflow integration, barriers to use, and impact on care delivered in these settings.

3. Analysis

Analysis of the satisfaction survey data will be primarily descriptive, and will be compared with participant usage data, work site, and role to assess the relationship between these parameters.

Group discussion transcripts will be analyzed qualitatively. Transcripts will be independently categorized by two investigators, who will categorize comments into specific themes within the conceptual framework used to guide the discussion.

B. Record Grouping and Locating Services

1. Overview

The MSeHA record locating approach uses a novel approach constructed by a computer science team with years of expertise in both probabilistic searching and in clinical information systems development. This process, which appears to be both robust and fast, has been evaluated iteratively during the life of the project. We will conduct a more formal evaluation of it at the conclusion of this effort.

2. Study Design

There are three components to the evaluation of the record grouping and locating services.

(1) Calculate accuracy statistics based on a gold standard built from the Memphis data.

We have (and are continuing to refine) a toolkit to provide computer assistance in building a gold standard data set. It is a rule engine into which we have fed a number of rules that we iteratively handcrafted based on extensive review of the Memphis data. The rules make use of a library of attribute comparison functions to determine which pairs can be ruled out as links. The goal of the rule engine is to pare down the number of pairs that must be reviewed by a human. We believe this process worked very well for us in our trial run based on 1,000 randomly sampled records. We should probably verify this approach on a completely handcrafted gold standard.

Our plans are to grow the data set over time and continue to update the confusion matrix from which we derived our accuracy statistics.

(2) Graph-based analysis of record grouping.

Once the records have been grouped, it is relatively straightforward to apply some graph algorithms to analyze the structure of the groups. To get the intuition behind this approach, consider all the records in our data as vertices in a graph and each link between records as an edge in the graph. Two types of subgraphs are of interest in our analysis. A *connected subgraph* is a collection of vertices (records) that are connected by edges (links). A traveler could get from any vertex in the subgraph to any other by traversing some sequence of edges. A fully connected subgraph is called a *clique*. In a clique, each vertex is directly linked to every other vertex in the subgraph. This distinction is important because we do not want to infer links based on transitivity. Cliques represent highly probable associations among records. Subgraphs that are not cliques represent uncertain associations and must be evaluated to have links removed or additional links added based on data, rather than inference. Links need to either be added or removed until we are left with only cliques.

We currently have a tool that identifies all the connected subgraphs and analyzes their clique status. It partitions those subgraphs into three groups. Group 1 contains the trivial cliques – subgraphs with only two vertices. Group 2 contains all cliques with 3 or more vertices. Group 3 contains all subgraphs that are not cliques.

In our initial analysis with this tool, there are relatively few items in Group 3, and in a sample taken from that group, all the problems identified were caused by missing links. One way in which this approach complements approach 1 is that it does not rely on sampling. It identifies all groups with a problematic structure. It can't tell us which links are right or wrong, but it identifies those groups that definitely need examination.

(3) Regrouping analysis.

Because the end user has the ability to tailor the grouping of records based on additional clinical (or cognitive) information, one measure of performance is the extent to which this approach is used. Our team has the ability to extract statistics regarding how the record regrouping features are used. We will conduct this analysis as well.

C. Emergency Department Utilization

1. Overview

Studies by Overhage and colleagues⁵ have noted cost savings associated with HIE in an emergency department. Although many factors are likely to contribute to these cost savings, the provision of timely information at the point of care may directly influence the length of stay and the admission rate for patients in this setting by speeding up the process of decision-making. It is possible that both the length of stay and admission rate could increase. For example, use of a tool that improved adherence to an asthma guideline was associated with longer and more expensive visits in one emergency department.⁶ The use of HIE could provide data about a patient's risk for immunodeficiency, thereby providing a rationale for a more conservative management approach. For this reason, it is important to consider the impact of HIE to positively or negatively affect the length of stay.

2. Study design

We will rely on data already being captured at each site, as a part of quality improvement efforts underway there. Each site will provide us with their monthly statistics about:

- number of visits per day
- admission rates
- lengths of stay
- case mix
- number of patients transferred to other facilities (and reason for transfer).
- patient insurance coverage
- triage acuity level
- number of patients who left-against-medical advice (AMA)
- number of patients who left-without-being-seen (LWBS)

Each site uses standard definitions for these terms. Other data, collected as a part of our ED Demographic Surveys, will allow us to characterize the EDs in terms of staff/patient ratio, number of beds, and access to ancillary services.

3. Analysis

Measuring the length of stay for a patient in an emergency department can be difficult, and is confounded by the workflows related to independent activities such as triage and discharge planning. However, each emergency department has a relatively consistent overall workflow, and will serve as their own control for the purposes of this analysis.

Change in length of stay, referral rate, AMA rate, LWBS, transfer and admission rate will be conducted using a time series analysis.

D. Rate of Test Ordering

1. Overview

As required by the Agency for Healthcare Research Quality contract, as noted by early results from the “What Song Are You Singing” campaign, and as reported by a variety of researchers, HIE is likely to favorably impact the rate of radiology and laboratory diagnostic/therapeutic testing. In the initial RFP, AHRQ stated, “The cost savings resultant from redundant test ordering...should be examined.” However, the definition of a redundant test remains elusive. For example, in an early case exposed through our HIE, a patient received 3 sets of ankle radiographs from two institutions within a week total. While at first glance at least two of these might appear redundant, closer inspection revealed that the results from each set were significantly different from one another! For this reason, we have reviewed the definitions used by other studies.^{5, 7-13} This literature provided minimal prior work leading to a standard definition of redundant tests.

After discussion with other SRD evaluation team members and clinicians from the MSeHA Clinical work group, the following definition appears to best articulate the area of impact.

We hypothesize that tests can be categorized as either low or high stability. Low stability tests are those whose results could change rapidly such as CBC or EKG. High stability tests (HST) are those whose results are unlikely to change rapidly (ie. if repeated within 2 weeks) such as HbA1C, HIV or most radiology tests.

Availability of HIE data will most greatly impact the duplication of high stability tests. However, if there is no suspicion of an acute process, knowledge of recent normal results may allow the clinician to avoid duplicating an unnecessary low stability test as well.

2. Study design

Our study will utilize data within the repository of the HIE system. Preliminary data demonstrate that fewer than 40% of patients who visit the ED and who have visited another ED

within 30 days have their record reviewed in detail. Although case mix data for these two populations has not yet been analyzed, we hypothesize that many patients will have repeat high and low stability tests within this population. For this analysis, we will target the following high and low stability tests:

Low Stability Tests	High Stability Tests (HST)	HST Duplication Interval
CBC	HbA1c	12 weeks
CMP	TSH	6 weeks
UDS	Hepatitis serologies	4 weeks
Chest X-ray	HIV	2 weeks
	Echocardiogram	4 weeks
	MRI Head	2 weeks
	CT Head	2 weeks
	CT Abdomen	2 weeks
	Ankle X-ray	2 weeks

By their very nature, low stability tests are less likely to be duplications. Therefore, no duplication interval can be intelligently applied that would capture/identify duplication rates.

A high stability test is defined as a duplication if a result is found within the interval defined above. The first analysis, therefore, will include all lab & radiology tests that meet this simple criterion.³

We will select a random cross section of tests, associated with patient visits from the 4th year of the project. For each of these tests, we will extract data from the HIE as follows:

Visit ID, date, time, testing site	Detail review by providers (Y/N)	Test/component (from list above)
Diagnosis	Duplicate (based on definition)	Component result (normal, abnormal)
Duplicate test result	Chief complaint	

This process has been facilitated by LOINC-encoding all tests of interests at the component level, thereby making aggregation across sites possible.

3. Analysis

A test is a duplicate if either (a) it is a high stability test that has been repeated too soon, or (b) it is a low stability test that has been normal when last checked. The proposed analysis plan will be implemented for combined low stability tests, combined high stability tests, and each of their sub-category tests listed under Study Design section as long as the sample size requirements of the proposed statistical methods are met.

For each site, Chi-Square test will be used to study if the test duplication rates are different between the tests ordered for patients whose records were accessed for those who were not. To adjust for site effect, Mantel-Haenszel test will be used treating site as strata factor, and is expected to be effective when the tendency in each site has the same sign.

To account for the possible correlation within the tests ordered for the same patient, generalized estimating equations with joint estimates of the mean and covariance parameters (GEE2) will be used treating the patients as the repeated measurements and controlling for the sites and chief complains effects. The state-of-art GEE2 method will yield valid conclusion even with misspecified covariance matrix, however, the choice of accurate covariance matrix will increase the power of finding the system implementing effect. Therefore, the choice of covariance matrix will be determined by all our team members including clinicians and statisticians to mimic the clinical knowledge of the test and increase the power of the study.

The duplication intervals for the high stability tests are determined based on our best knowledge. However, as the length of the duplication intervals might be crucial in our study, sensitivity analysis for the intervals will be implemented by increasing and decreasing the interval length for 25%.

Administrative outcomes will be derived from data already collected by these EDs for internal and external reports. We have begun discussing this with ED administrators but have not yet completed this phase of the evaluation plan. We plan to complete this phase over the next 6 months.

For each of these administrative outcomes, we will rely on data that have been collected before implementing SPL as a benchmark and study design. Each site that is able to access SPL will be included in the study, we will use a pre-post design collecting data from our vaults that have been acquired before those data were made available to clinicians at each study site. In addition to those date available from the SPL vaults we will rely on claims data to determine the inpatient admission rate at the sites of care, both pre and post implementation. We will also use claims data to determine rates of duplicate testing using definitions provided to us through NRC and the CITL. We will also record costs per visit using claims data.

E. Changing ED Case mix

1. Overview

One of the early observations from our initial rollout site was the opportunity to identify populations of patients who either used the ED in lieu of their medical home or who took advantage of the ED's lack of interconnectedness to achieve a secondary gain from their visits. The awareness about these patient populations among the ED staff may impact their prevalence in the EDs over the time of the study. In addition, the Memphis EDs have begun to address this group of patients with a shared management plan **across the EDs at different institutions**. This is the first area of collaboration that has sprung up as a result of the HIE, and the effect may be significant.

Initial data have been collected to demonstrate the relative percent of patients with different numbers of visits in a 30-day period. Our hypothesis is that there will be a shift in the number of patients who have frequent visits to the ED, and a concomitant change in the Case mix of those patients with frequent visits. <Cindy, I'm sure there is a cost analysis to do here as well. Would you give that some thought?>

2. Study Design

The analysis of ED Casemix will occur primarily through data within the HIE system vaults. For each ED, we will evaluate the monthly values for:

- Counts of patients who have more than 1 visit to an ED (regardless of location)
- Chief complaint and discharge diagnoses for patients with more than one ED visit during the month

3. Analysis

Case mix and multiple visit data will be analyzed descriptively each month and analyzed using a time-series approach. Analysis will also determine the extent to which changes in case mix are site-specific or are more generally associated with increasing exposure to HIE over time across all sites.

F. Workflow Change

1. Overview

A key, long-term expectation of HIE is that this tool will enable ED services to be rendered as efficiently as possible. Success in this endeavor is critical to avoid long waits and duplicative services and to ensure high quality and patient safety in this setting. Key determinants of ED efficiency (and ultimately, ED costs) include, but are not limited to, staff-to-patient ratios, the number and complexity of tests and procedures performed for diagnosis and treatment, and the availability of knowledge about treatment the patient has received recently at other facilities, particularly at other EDs. Traditional methods for measuring and quantifying ED costs often fail to isolate the interrelationship between efficiency of information flow during the process of care and the efficiency with which care is rendered overall, the goal of this study is to assess the impact of HIE on workflows and information-sharing within and among EDs in Memphis over time.

Activity-based costing yields more precise estimates of operational and patient care costs by examining specific tasks and procedures performed in support of patient care or unit management, then calculating the cost of the labor and material resources required to accomplish these tasks and procedures (Helmi, 1991).

Activity-based costing enjoys widespread acceptance in the US health care sector (Grandlich, 2004; Green & Metwalli, 2001; Nisenbaum, et al. 2000; Storfjell & Jessup, 1996; McKeon, 1996) and among researchers undertaking cost analyses in other parts of the world (Edbrooke, et al., 1997; Edbrooke, et al., 1999; Edbrooke and Hibbert, 1999; Edbrooke, et al. 2001; Harihan, et al. 2002; Jegers, et al., 2002; Parikh & Karnad, 1999; Ridderstolpe et al., 2002). Activity-based costing has also been applied to quantify the costs of emergency department care (Graff, et al., 1993; Hollingsworth, et al., 1998; Kyriacou, et al., 1999), but has not been applied specifically to quantify the economic impact of information flow in emergency departments. This is due in part to the labor-intensive nature of data collection when a bottom-up approach is used (i.e., total costs are determined by specifying and aggregating the costs of component activities) (Edbrooke, 2004). The goal of this project is to document information flows at Memphis EDs in preparation for assessing the impact of a Regional Health Information Organization (RHIO) founded to improve secure data sharing among EDs in southwestern Tennessee.

Specific Aim. The specific aims of the proposed project are to 1.) develop automated data collection tools and 2.) use those tools to collect activity-based data in a standardized fashion from the adult and pediatric emergency departments (EDs) of 5 hospitals in Memphis, TN (Baptist, Methodist/LeBonheur, Regional Medical Center at Memphis [The Med], St. Francis, and St. Jude Children's Hospitals, and) via direct observation of caregiving.

Hypothesis or Research Question. Although no formal hypothesis testing is planned at this time, we do plan to publish our findings (positive or negative) in order to facilitate implementation of information sharing initiatives like the RHIO.

2. Study Design

The specific scientific objective of the proposed project is to collect activity-based data in the adult and pediatric emergency departments (EDs) of 4 hospitals in Memphis, TN (Baptist, Methodist, Methodist/LeBonheur, St. Francis, and Baptist Memphis hospitals) via direct observation of caregivers. We are particularly interested in the cycle time required to obtain information regarding 1.) prior medical history, 2.) triage decisions, and 3.) plan for follow-up after discharge from the ED. Although no hypothesis testing is planned at this time, we intend to publish descriptive information about our findings (either positive or negative) in order to improve understanding of information flow in real time in emergency departments.

To access workflow efficiency, we will use an activity based costing approach with a model that was constructed at Vanderbilt Emergency Department. We will use this model to construct an activity matrix of which people in the ED are responsible for which activities and what percent of time they spend in these activities. These data will allow us to categorize activities according to agent and time spent. All data for this phase of the study will be collected electronically. Many of the data elements as specified in the table above will be derived from either secondary analyses of claims data or data extracted from mining activities from within our SPL vaults. Activity matrix data will be partially collected through direct observation and partially collected through the collection of a survey based on the model we develop after evaluating three sites (two within the Memphis area and one at Vanderbilt).

Composition of Participants. The sampling frame for the proposed study is personnel caring for patients in adult and pediatric EDs of 5 hospitals in Memphis, between 2/1/2007 and 1/31/2008. Depending on availability of data collectors and to minimize observer fatigue and improve accuracy of data collection, observations will be conducted in 240 minute intervals on varying days during the work week (Monday – Thursday, Friday – Sunday) and at varying times during the workday (6 am -- Midnight). A copy of the written consent form will be provided to each participant the first time they are asked to participate.

We have used preliminary data manually collected at VUMC's adult emergency department during Spring/Summer 2006 to design and construct automated tools for activity-based data collection. Manual data collection at Vanderbilt was necessary to generate relevant task lists for inclusion in the automated data collection system. Use of the automated system in the Memphis

EDs is required to standardize data collection across sites and facilitate evaluation of the operational and economic impacts of the HIE program.

Personnel who have indicated their willingness to be observed will be approached by the research assistant and asked to review and sign a consent form before being observed. Personnel with less than 6 months experience, or personnel actively involved with training (either as a preceptor or trainee) will be excluded. The research assistant will then observe the employee and document activities performed by tapping the corresponding button on the data collection device (computer). Date and time of the activity will be recorded simultaneously, and duration of activities will be calculated by the data collection software.

3. Analysis

At the end of each observation, the task data from each session/case is automatically saved as a text file. A custom data analysis program written in Visual Basic (Microsoft Corp., Redmond, WA) analyzes each observation log or data file by automatically calculating and collating the minutes and percentage of time spent on each activity and task group, as well as the number of times each task was observed during the study period (task occurrence) and the mean duration of each task occurrence (task duration). The task occurrence multiplied by the task duration equals the average total time spent on each individual task. The analysis program also provides basic descriptive statistics of the task data (i.e., means, standard deviations, median, standard error of the mean, min and max) and prepares preformatted data files for each metric to be imported into statistical software applications for further analysis.

G. Disease- Specific Hypothesis

1. Overview

The overall goal of HIE is to improve the care delivery in the Southwest Tennessee area. We have involved the region and a committee known as the Clinical Advisory Group (CAG) to derive from the interests of the core entities disease specific hypothesis related to HIE. In 2005, the CAG agreed to a set of clinical outcomes that were not based on the actual implementation but were related to regional priorities. In the past 2 years, there have been significant changes, both in their awareness of what HIE can facilitate and in the regional goals.

Two regional interventions have been implemented that may be improved by HIE. The first is a concerted effort to recognize and encourage the use of any medical homes by patients. Patients who present in early labor to “the nearest facility” have, according to the CAG, been transferred to the site where their prenatal care has been delivered. This transfer may have many clinical ramifications, including improved access to prenatal data that impacts the care of newborns (which was initially of interest to the region.)

Another regional intervention is the institution of care plans for patients known to frequently visit the EDs. The use of HIE enabled each ED to see data about how a subpopulation of patients was using the ED, including the fact that XX patients had more than YY visits to the ED in one year. At our last CAG meeting, a member mentioned that this initiative was underway.

A third change in the healthcare system at the EDs is a belief that patients who frequently visit the ED are being referred to the social work team in the EDs more often. This practice has the potential to impact the workflow of the social work team as well as the care of the patients, and may be a very enlightening intervention to explore.

Our plan is to evaluate a set of these regional initiatives that rely on HIE, after first learning more about each of them, and in close partnership with their champions in Memphis.

2. Study Design

Our design to access disease specific hypothesis will be further defined over the next year. However, it is likely that we will use this data in our HIE vaults as a one data source for outcomes, and data collected on site through interviews and chart reviews as other data sources. We have reconvened our CAG using a listserv as well as face-to-face meetings (the first of which had relatively poor turnout) and will be visiting each site in the next few months to uncover the clinical outcomes that are possible to evaluate. We will select candidates based on what could be learned about an intervention in a year (recognizing that at this stage of HIE, the art of the possible may make larger scale data collection infeasible) and based on the resources available in Memphis to help with this phase of the evaluation

3. Analysis Plan

Planning for disease-specific hypotheses is underway. We anticipate having IRB approval to assess baseline rates by the end of this year.

H. Value and Sustainability Analysis

1. Overview

In 2004, a *pro forma* economic impact model was developed to demonstrate the potential financial impact of the fully operational MSeHA HIE on emergency room costs among eleven participating hospitals.¹⁴ That analysis projected savings exceeding \$8 million per year due primarily to decreases in laboratory and radiographic tests, fewer admissions for observation, and lower overall emergency department costs. In 2006, the model was expanded to reflect the potential value of using the HIE to coordinate care among the EDs and ambulatory care facilities (medical homes) to support better means of providing non-urgent acute care and chronic disease management. Others have pointed out that there are multiple perspectives on financial impacts and that the immediate business case for the investors and key stakeholders differs from the full return on investment from a societal viewpoint.¹⁵ We have chosen, as appropriate for MSeHA, a model of cost recovery in the early years of the HIE, followed by a more comprehensive value and sustainability (V&S) analysis of the downstream effects on healthcare quality and efficiency to a broadening set of stakeholders. This approach to assessing value focuses on making the immediate business case for HIE by stratifying potential benefits as follows, with the expected percentage of savings that can be directly attributed from each stratum:

Realized and Measured	Benefits
100%	Monetary savings directly attributed to HIE
10%	Monetary savings indirectly attributed to HIE

0%	Monetary and nonmonetary value indirectly associated with HIE-enabled fiscally responsible, higher quality care to the community
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Table 1. The immediate business case for an HIE pilot implementation

The overall approach to evaluation of the value and sustainability of the MSeHA is:

- 1) to utilize results published from other HIEs, insights from MSeHA’s Technical Advisory Panel and Financial Workgroup, and return on investment models, such as those developed as part of the *eHI Value and Sustainability Toolkit* and the *CITL value tool*, to identify the super set of potential measures of financial value that may be directly or indirectly attributed to the HIE, as well as the appropriate strata for benefit realization;
- 2) focusing primarily on those measures that are directly attributable to the HIE, to model the beneficiaries, values, flows, and to collect and analyze the quantifiable savings data;
- 3) to efficiently synch these efforts with those supporting the evaluation as a whole; and
- 4) to accurately and comprehensively monitor (and place in appropriate context) the cost of the investment to develop and support the HIE.

The transformation potential of HIE implies a constant state of evolution during the evaluation period. The value and sustainability analysis needs to be based on a model that allows the conclusions to be recalculated as the HIE system evolves. This model also requires a level of stability so that the parameters (such as opt out rates) are at least discovered before it is finalized. Therefore, in almost all cases, initial evaluations of impact measures will be limited in their significance unless re-visited over time. We will work with NORC to harmonize our approach with those approaches being taken by other grantees.

2. Study Design

Measure identification. The original financial impact model has been vetted through consultation with the MSeHA Financial Workgroup (financial leaders of the participating organizations) and our Technical Advisory Panel in September 2007 to determine which measures should populate our V&S model and which of these are more likely to generate monetary savings that can be directly or indirectly associated with HIE.

Directly and indirectly linked measures. The measures in Table 2 have been identified as potentially promising but present challenges as we attempt to isolate direct relationships and to quantify actual savings (or cost avoided). In addition to data available through the HIE system vaults, we will access the Tennessee Hospital Association’s payer information for patients whose records were accessed through the HIE (discharge information is submitted quarterly for charges related to inpatient, emergency room, and observation discharges, as well as for CT, PET, and MRI scans). To assign monetary values to rate reductions and improved productivity, actual savings will be collected from sites whenever possible and when they are not, reasonable proxies for savings will be validated through cross-confirmation. Also, payer mix influences whether and to whom real savings accrue from avoiding redundant tests or hospital admissions (e.g., offset by lost revenue). All participating facilities have agreed to share their primary/secondary payer and plan mix by site of care.

Measure	Rationale and Comments
Imaging testing rate	Particularly MRI imaging savings due to additional staffing requirements, capital expenditures, and increased ED LOS
Laboratory testing rate	Lower savings potential (initial and incremental) unless purchased from external lab
ED-to-hospital admission rate	Applies to only patients who were referred to appropriate medical home for non-emergent care; requires confirmation of referral and avoidance of future ED visit
ED LOS	Throughput improvement may allow site to care for larger volumes of patients with existing staff levels or reduce on-call nurse expenditures; confounded by multiple initiatives to reduce ED LOS

Table 2. Directly and indirectly linked cost savings measures

Indirectly linked efficiency and quality measures that are described in previous sections. In addition to these financial measures, we anticipate that there will be cost savings associated with other outcomes we are assessing (described in previous sections) and other outcomes that may evolve as the HIE evolves, including:

Measure	Rationale and Comments
<i>Unreimbursed care rate</i>	Changing ED casemix and improved use of the medical home as a result of the HIE
<i>Workflow efficiency - providers</i>	Less time searching for information and improved provider satisfaction as a result of HIE
<i>Workflow efficiency – payers (potential)</i>	Less time verifying appropriate referrals and follow-up; would require changing access model to include payers

Table 3. Indirectly linked efficiency and quality of care measures

Costs. Data collection for many actual cost variables was initiated with the project and will continue to be assessed over the 5-year period of implementing and maintaining the HIE across all eleven hospitals (EDs and hospitalists) and the growing number of outpatient facilities. The investment for development, implementation, and ongoing support will include costs associated with:

- Project team
- Community meetings and coordination
- Infrastructure
 - Software development
 - Equipment
 - Support
- Training
- Evaluation
- Travel

- Participating organizations' contribution (primarily personnel costs but could evolve to membership or transaction models)
 - Site-specific customization, training, and support

3. Analysis Plan

Analysis of savings. Beginning in the second year of implementation, we will analyze savings data in support of the metrics in Table 2 annually. Since savings may be offset by lost revenue, depending on payer/plan, we will apply the payer/plan mixes reported by each site to our analyses to arrive at site- and organization-specific savings, as well as overall savings attributable to HIE.

Analysis of costs. We are developing cost determination models that are focused on two key questions that we would like to answer about HIE costs: 1) how much did it cost to establish the MSeHA HIE (i.e., research, development, and implementation of the pilot) and 2) how much would it cost to replicate its functionality elsewhere? Beginning in the second year of implementation, we will populate these two models with the cost data described above and collected from the development team and all of the MSeHA sites since the project's start.

Analysis of rate of return on investment:

Several return on investment models exist or are in development (e.g., *CITL value tool*, *eHI Value and Sustainability Toolkit*). These include *pro forma* analysis models that will permit comparison to estimated value model developed for MSeHA¹⁴, as well as those of other HIE grantees and/or initiatives nationally. We will continue to evaluate the application of these tools (or some subset thereof) to our financial impact analysis, with the expectation of converging on a best practices model for our anticipated annual cycle, as well as the summative assessment in the final year of the contract.

An ongoing effort will be made to standardize the data collected and harmonize the analysis methods employed for assessment of financial impacts of HIE with those approaches being taken by other grantees. We also must maintain sensitivity to the evolving HIE environment within MSeHA's HIE and nationally for the potential to assess additional financial impacts that may arise from unintended consequences (positive or negative).

Preliminary calculations indicate that the core healthcare entities can expect a NPV of approximately \$4.3 million after 5 years. This model is based on the following assumptions:

- Based on data obtained on the core healthcare entities and Memphis Managed Care
- Deployment schedule is limited initially to EDs and Labor & Delivery; years four and five will extend to all healthcare providers
- The RHIO support desk infrastructure is not established; Vanderbilt will provide this service
- The average cost for a core healthcare entity for implementation and operation activities is \$30,000 per year.

We will collect data to validate this model as a part of our overall return on investment analysis.

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