ABSTRACT

Laboratory testing is necessary when it contributes to the overall clinical management of the patient. Redundant testing, however, is often unnecessary and expensive and contributes to overall reductions in healthcare system efficiency. The purpose of this study is two-fold. First, to evaluate the frequency of ordering duplicate laboratory tests in hospitalized patients and the costs associated with this practice. Second, it was designed to determine if the use of a computerized alert or prompt will reduce the total number of unnecessarily duplicated Acute Hepatitis Profile (AHP) laboratory tests.

This two-phase study took place in an inpatient facility that was part of a large tertiary care hospital system in Florida. A retrospective descriptive design was used during Phase 1 was to evaluate six laboratory tests and the frequency of ordering duplicate laboratory tests in hospitalized patients and to determine the associated costs of this practice for a 12-month time period in 2010. A test was considered a duplicate or an unnecessarily repeated test if it followed a previous test of the same type during the patient’s length of stay in the hospital and one in which any change in their values likely would not be clinically significant.

A quasi-experimental pre- and post-test design was used during phase 2 was to determine the proportion of duplication of the AHP test before and after the implementation of a computerized alert intervention implemented as part of a system quality improvement process on January 5th, 2011. Data were compared for two 3-month time periods, pre- and post-alert implementation. The AHP test was considered redundant if it followed a previous test of the same type within 15 days of the initial test being final and present in the medical record.

In phase 1, including each of the six tests examined, there were a total amount of 53,351 test ordered, with 10,375 (19.4%) of these cancelled. Out of the total amount of result final tests
(n = 42,976), including each of the six tests examined, 4.6-8.7% were redundant. Results of the proportion of duplication of the six selected tests are as follows: AHP 196/2514 (7.8%), Antinuclear Antibody (ANA) 120/2594 (4.6%), B12/Folate level 396/5874 (6.7%), Thyroid Stimulating Hormone (TSH) 1893/21595 (8.7%), Ferritin 384/5171 (7.4%), and Iron/Total iron binding capacity (TIBC) 316/5155 (6.1%). The overall associated yearly cost of redundant testing of these six selected tests was an estimated $419,218. The largest proportion of redundant tests was the Thyroid Stimulating Hormone level, costing a yearly estimated $300,987.

In Phase 2, prior to introduction of the alert, 674 AHP tests were performed. Of these, 53 (7.9%) were redundant. During the intervention period, 692 AHP tests were performed, of these 18 (2.6%) were redundant. The implementation of the computerized alert was shown to significantly reduce the proportion of AHP tests (Chi-Square: χ² = df 1, p ≤ 0.001). The differences in the associated costs of duplicated AHP were $5238 dollars in 2010 as compared to $1746 in 2011 post-alert and these differences were significant (Mann Whitney U, Z = -4.04, p ≤ 0.001).

Although the proportions of unnecessarily repeated diagnostic tests that were observed during Phase 1 of this study were small, the associated costs could adversely affect hospital revenue and overall healthcare efficiency. The implementation of the AHP computerized alert demonstrated a drop in the proportion of redundant AHP tests and subsequent associated cost savings. It is necessary to perform further research to evaluate computerized alerts on other tests with evidence-based test-specific time intervals, and to determine if such reductions post-implementation of AHP alerts are sustained over time.
ACKNOWLEDGEMENTS

I would like to sincerely thank and acknowledge my committee members for their contributions to this thesis. First, I would like to express my genuine gratitude to my advisor and committee chair, Dr. Anne Norris. Dr. Norris was available to provide guidance, answer questions, and offer advice on how to best structure this thesis. Her input was very valuable, and despite her having numerous responsibilities, she came through in a big way in the end. Second, I would like to thank my committee member, Dr. Susan Chase who, despite her numerous responsibilities as the Associate Dean for Graduate Affairs for the College of Nursing, provided her assistance to me in the way of helping me to clarify and summarize the writing throughout the thesis. Prior to her being on my committee she also helped me with starting and shaping the proposal for this study in our Seminar class. Third, I would like to convey my deepest thanks to my committee member Dr. Linda Papa, physician and researcher for Orlando Health, Department of Emergency Medicine. Dr. Papa has provided me with assistance throughout this thesis over several semesters while attending residency with her learning more about clinical research. She has helped tremendously with the statistical analyses and organization of the results. I send a heartfelt thank you to all my committee members for their time, expertise, and support in helping me to attain my goal of completing my thesis and graduating with a Doctor of Nursing Practice degree.
This work is dedicated first and foremost God, my father, whom I live, move, and have my very being, who has allowed me to do all things through him who strengthens me and to his Son Jesus Christ who made The Way for me. I also want to dedicate this to my family who has instilled in me the value of hard work and to my husband who really came through in the end.
# TABLE OF CONTENTS

LIST OF FIGURES ........................................................................................................................................ x

LIST OF TABLES ......................................................................................................................................... xi

CHAPTER 1: THE PROBLEM ......................................................................................................................... 1

Significance of the Unnecessary Duplication of Tests ................................................................. 1

Adverse Effects of Unnecessary Duplication of Laboratory Testing .......................................... 2

Causes of Unnecessary Duplication of Laboratory Testing ...................................................... 2

Policy Initiatives ..................................................................................................................................... 4

Significance of the Study for Advance Practice Nursing .......................................................... 6

Purpose of this Study .............................................................................................................................. 7

Research Questions .............................................................................................................................. 8

   Phase 1 ........................................................................................................................................ 8

   Phase 2 ........................................................................................................................................ 8

Research Assumptions ....................................................................................................................... 10

Definitions of Terms ........................................................................................................................... 10

   Conceptual Definitions of Terms ................................................................................................. 10

   Operational Definitions of Terms ............................................................................................. 11

Summary ............................................................................................................................................... 12

CHAPTER 2: SYNTHESIS OF THE RESEARCH EVIDENCE ................................................................ 14

Cost, Quality, and Efficiency of Unnecessary Duplication of Laboratory Tests ..................... 14

Administrative Efforts to Reduce Unnecessary Laboratory Testing .......................................... 16

Test Ordering Behaviors Related to Unnecessary Duplication of Laboratory Tests .................. 21

Computerized Alert Effects on Test-Ordering and Laboratory Duplication ............................. 23
Selected Tests for Evaluation........................................................................................................27
Summary.......................................................................................................................................28

CHAPTER 3: METHODS ................................................................................................................30
Setting for the Study .......................................................................................................................30
Sample Criteria and Methods for Chart Selection ......................................................................30
Protection of Human Subjects ......................................................................................................31
Statistical Analysis .......................................................................................................................31
Phase 1 Design .............................................................................................................................31
Phase 1 Procedures .......................................................................................................................31
Phase 1 Statistical Analyses .........................................................................................................33
Phase 2 Design .............................................................................................................................33
Phase 2 Procedures for Implementation of Computerized Alert ................................................34
Phase 2 Statistical Analyses .........................................................................................................36
Summary ......................................................................................................................................38

CHAPTER 4: RESULTS AND ANALYSIS OF DATA .................................................................. 39
Phase 1 .........................................................................................................................................39
Research Questions and Results .................................................................................................39
Repeat AHP Testing and Yearly Costs of Duplication ...............................................................39
Repeat ANA Testing and Yearly Cost of Duplication .................................................................39
Repeat B12/Folate Testing and Yearly Cost of Duplication .......................................................40
Repeat TSH Testing and Yearly Cost of Duplication .................................................................40
Repeat Ferritin Testing and Yearly Costs of Duplication ..........................................................40
Repeat Iron/TIBC Testing and Yearly Costs of Duplication ...................................................... 40
Summary ..................................................................................................................................... 41
Phase 2 ...................................................................................................................................... 42
Research Questions and Results ........................................................................................... 42
CHAPTER 5: DISCUSSION ........................................................................................................... 55
Discussions of Findings and Recommendations for Future Research ........................................... 55
Limitations of Study ......................................................................................................................... 59
Implications for Future Research .................................................................................................. 60
Implications for Advanced Practice Nurses ..................................................................................... 61
Summary ..................................................................................................................................... 62
APPENDIX A: UNIVERSITY OF CENTRAL FLORIDA INSTITUTIONAL REVIEW BOARD APPROVAL ................................................................. 63
APPENDIX B: FACILITY INSTITUTIONAL REVIEW BOARD APPROVALS ........................................... 65
APPENDIX C: DEMOGRAPHIC CHARACTERISTICS FOR PATIENTS WITH APH TESTS IN FIRST QUARTER 2010 COMPARED TO Q2, Q3, AND Q4 2010 (COMBINED) TO ASSESS IF SAMPLE REPRESENTS REST OF YEAR ............................................... 68
LIST OF REFERENCES ................................................................................................................. 70
LIST OF FIGURES

Figure 1: Computerized Alert. ........................................................................................................... 35

Figure 2: Phase 2 Results. ..................................................................................................................... 44

Figure 3: Comparison of the Proportion (Percent) of Patients with Duplicate AHP Tests
Performed Before and After the Alert Protocol was Implemented (January to April 2010
versus January to April 2011) (Chi-Square; χ²=19.1; df 1; p<0.001). ........................................ 45

Figure 4: Ordering Pattern and Percentage of Duplicate AHP Tests Performed in Each Month
from January to April in the Pre- and Post-alert Periods. ............................................................. 46

Figure 5: Comparison of the Total Cost of Duplicate AHP tests Performed Before and After the
Alert Protocol Was Implemented (January to April 2010 versus January to April 2011)
(Mann Whitney U; Z = -4.04; p ≤ 0.001). ....................................................................................... 47

Figure 6: Not Duplicated Group Shows Consistent Ordering Pattern Across Months; Duplicated
Group Shows Greater Variability in Ordering Patterns Across Months (introduction of
computerized alert was the likely factor contributing to this discrepancy). ............................. 52

Figure 7: Adjusted Odds Ratios for Patient, Test, and System Factors Relative to Duplication are
Presented in the High-Low Graph with 95% CIs. ............................................................................... 53
LIST OF TABLES

Table 1: Selected Tests and Unit Costs.......................................................................................... 8
Table 2: Patient, Test, and System Factors. ................................................................................... 9
Table 3: Characteristics of Six Selected Tests............................................................................. 41
Table 4: Comparison of the Demographic Characteristics of the Study Populations of those with
      AHP Tests in Phase 1 and Phase 2 of the Study................................................................. 43
Table 5: Comparison of Characteristics of Patients who had Duplicated AHP Tests in Periods
      Before and After Implementation of Computerized Alerta.................................................. 49
Table 6: Comparison of Characteristics of Patients With and Without Duplicate AHP Tests
      During Both 2010 and 2011 Study Periods Combineda. ..................................................... 51
Table 7: Adjusted Odds Ratios with a 95% Confidence Interval for Patient, Test, and System
      Factors Relative to Duplication in 2010 and 2011 Pre- and Post-alert Study Periods
      Combined.................................................................................................................................. 54
CHAPTER 1: THE PROBLEM

Significance of the Unnecessary Duplication of Tests

Rising healthcare costs are no longer sustainable in the current healthcare system. Reducing these costs has become a major concern of the U. S. government and healthcare policy in this century (DesRoches et al., 2010). One major component of these costs is the wide range and overwhelming number of diagnostic tests available (Jackson, 2007). The Medicare expenditure on laboratory testing was $6.6 billion in 2005 alone. The U.S. healthcare system faces urgent challenges to not only improve the quality and safety of care but to also manage rising costs (Jha, Chan, Ridgway, Franz, and Bates, 2009). These laboratories related costs are only necessary if they permit accurate diagnosis to be established, proper treatment to be initiated and monitored, accurate prognosis to be made, and reductions in patients’ length of stays in the hospital (Kwok & Jones, 2004; Walraven & Naylor, 1998).

While healthcare expenditure per capita in the U.S. is greater than twice that of other industrialized countries, the U.S. ranks relatively low on important indicators of the population health status and quality of healthcare. Inefficiencies such as prevalent regional practice variations and duplicate tests plague the already burdened healthcare system (Wang et al., 2002; National Quality Forum (NQF), 2009; Wennberg, 2002).

Health care providers are pressed to make an accurate diagnosis and rely on the use of laboratory tests or imaging studies in the process of patient management. However, duplication of many of these tests is often unnecessary for the clinical management of patients (Miyakis, Karamanof, Lontos, & Mountokalakis, 2006; Nies et al., 2010). Laboratory testing of hospitalized patients can at times be redundant when multiple providers order the same or similar
tests on the same patient, contributing needlessly to the total health care system costs (Bates et al., 1998; Kwok & Jones, 2005; Walraven & Naylor, 1996).

In 2009, Jha, et al. performed a comprehensive literature review to identify the rates of unnecessary laboratory and radiology tests in U.S. hospitals and associated costs. They concluded eliminating unnecessary laboratory and radiology testing would have saved an additional 8 Billion health care dollars in 2004.

**Adverse Effects of Unnecessary Duplication of Laboratory Testing**

Performing redundant tests could have adverse effects for the patient. For example, unnecessary duplicate testing can lead to patient discomfort or sleep disturbance from repeat blood draws, risk of false positive results that could induce fear, anxiety, or further unnecessary testing in patients, and delayed treatment or length of stay if prior results were not checked and a repeat test was ordered (Bates et al., 1999; Jackson, 2007; Kwok & Jones, 2004; Miyakis et al., 2006; Walraven & Naylor, 1998).

Nearly all of the clinical and financial impact of a laboratory tests is determined by how the test result changes patient management (Jackson, 2007). Besides increasing healthcare cost, frequent unnecessary blood work could potentially reduce the patient’s hemoglobin and circulating blood volume, at the same time contributing little to the patient’s clinical management (Bates et al., 1998; Beland, D’Angelo, & Vinci, 2003, Jackson, 2007; Kumwilaisak et al, 2008).

**Causes of Unnecessary Duplication of Laboratory Testing**

There are at least five causes for unnecessary duplication of laboratory tests. First, unnecessary testing can occur as a result of false-positive test results and can trigger potentially
expensive and dangerous diagnostic evaluations and therapies. It is particularly concerning when a redundant test gives a false-positive result and leads to a lengthy succession of additional tests to clarify the result. This phenomenon has been referred to as the “Ulysses syndrome” and is similar to mythological Ulysses who fought in the Trojan War and then decided to come home. During his long trip home he experienced a series of needless and often dangerous adventures. This syndrome refers to the physical and mental changes that occur in patients who, though healthy at outset, make a long journey of repeat tests and investigations as a result of a false-positive test result. Thus, these mental and physical changes are a result of the investigations themselves and not the therapy (Jackson, 2007; Rang, 1972).

Second, computerized physician order entry (CPOE) systems lead to repetitive testing, chiefly when the flow of questions or items to be completed do not mirror the routine behavior of a clinician (i.e. viewing the results on the monitor verses a summation of laboratory tests printed in the chart). For example, clinicians may order a test for a patient and not recognize that the same test has recently been ordered, despite the results of the latest test being saved, resulting in a redundant test (Nies et al., 2010). Fortunately, embedded in the CPOE system is an opportunity to improve processes of care that would reduce unnecessary duplication of laboratory tests (Jackson, 2007).

Moreover, some CPOEs have been designed with alerts indicating a test was recently performed. However, clinicians often bypass these alerts. Clinicians can quickly become annoyed when the amount of nuisance alerts is deemed too high in relationship to the number of valuable alerts, leading to an occurrence called alert fatigue. The term nuisance alert refers to a computerized decisional support system (CDSS) alert that offers modest perceived assistance to the clinician at the time of the alert. These nuisance alerts lead to alert fatigue when clinicians
either subconsciously or consciously start bypassing CDSS alerts, with no consideration to their importance, permitting clinically significant alerts to be overlooked (Chaffee, 2010).

Third, clinician naïveté or lack of knowledge about the proper use of tests, failure to confirm earlier results, test ordering customs that are not easily changed, or fear of errors of omission and lawsuits (Bates et al, 1998; Kwok & Jones, 2004; Miyakis et al., 2006; Neilson et al., 2004) are additional reasons for unnecessary test ordering and duplication. Fourth, the use of protocols or guidelines, inadequate educational feedback, and clinician’s lack of awareness of the cost of examinations have been linked as causes for laboratory overutilization (Miyakis, et al., 2006). Fifth, patient preferences may cause redundant testing when patients actively ask for tests and attach greater significance to the test results than is warranted (Kwok & Jones, 2004; Neilson et al., 2004).

**Policy Initiatives**

Computerized systems designed for order entry and electronic medical records (EMR) represent two of the most highly recommended advances in healthcare. These systems provide opportunities to improve practice by conveying prompts to clinicians at the point of care. These prompts range from straightforward prescribing alerts to more refined support for decision-making (Shojania et al., 2010). As would be expected with any other health care innovation, CDSSs ought to be scrupulously assessed to ascertain the effects in clinical practice.

Successions of major policy initiatives, started during the George W. Bush administration, concluded in the endorsement of the Health Information Technology Economic and Clinical Health (HITECH) Act as a component of the American Recovery and Reinvestment Act (ARRA) of 2009 (DesRoches, et al. 2010). ARRA has offered a projected $20 billion in
direct grants and financial incentives to support health care clinicians’ adoption and meaningful utilization of EMRs. ARRA established a requirement that institutions are obligated to exhibit “meaningful use” of their Health Information Technology (HIT) system before they can receive federal funds to help finance it. There is regulatory language comprised of twenty-five different measures of meaningful use that has now been proposed by the federal government. Measures of meaningful use include such areas as care coordination, privacy and security, quality and efficiency, and safe practices (DesRoches, et al. 2010).

Gever (2010) reported the long-term investment in a HIT system has paid off for the Veterans Administration (VA). The major benefits seen from the use of the HIT system in the VA was the deterrence of adverse drug events, trailed by the elimination of medical errors and redundancies such as duplicate laboratory tests. Their HIT system is estimated to save more than $500 million in net annual benefits from 2001 to 2007.

Yet, while there are those who perceive that CDSSs improve effectiveness and reduce healthcare costs, the current supporting evidence is limited. A literature review performed by Garg et al. (2005) included controlled trials assessing the effects of CDSSs to identify study characteristics predicting the benefit of such systems. Their findings suggest while some of the included studies evaluated costs when outcomes were improved, the cost-effectiveness of these systems still remains unknown.

Performance measurement is critical to the transformation of the healthcare system (NQF, 2009). There is increasing concern in the area of HIT and its effect on the health care system due to technological advances, greater access to computer systems in clinical practice, and rising concerns about the process and quality of health care. These concerns have prompted
the need for the assessment and evaluation of the CPOE and CDSSs systems particularly in how they affect patient outcomes, cost, and subsequent quality of healthcare (Garg et al., 2005).

**Significance of the Study for Advance Practice Nursing**

The Institute of Medicine’s (IOM) *Crossing the Quality Chasm* describes six dimensions of quality and aims for quality improvement that can be translated into measurable outcomes and goals. One of the aims is *efficient* care and refers to cost effective care and services and reduction and removal of waste from the system. Efficient care could be measured by evaluating the costs of care by organization, provider, community, or patient (Ransom, Joshi, Nash, & Ransom, 2008).

Part of the role of an advanced practice nurse (APN) leader is to help the organization keep up with and ahead of the changes that will help the organization thrive in its own marketplace. An effective technique of APNs is to help organizations find efficient, cost effective ways of doing business (Porter-O’Grady & Malloch, 2007).

Even though economists generally separate the concepts of efficiency and quality, doing so in respect to healthcare may not be easy or meaningful. Since inefficient care utilizes more resources than are necessary, it is wasteful care. Thus, care that involves waste is deficient—and therefore lower quality and can be harmful either directly or indirectly by displacing more of the resources for useful care (Ransom et al., 2008).

While it is estimated the direct cost of laboratory testing accounts for less than 5% of the total health care costs, laboratory results drive 60% to 70% of major health care decisions, including admissions, discharges, and/or initiation of therapies. APNs and health care
organizations have an obligation to patients to actively manage costs by ensuring the appropriate services are delivered at the appropriate time (Jackson, 2007).

There is limited availability of information about the incidence and prevention of unnecessary duplicated tests. Since performance measurement is essential for system transformation, research is needed to determine the incidence and associated costs of unnecessary duplication of laboratory tests. Certain laboratory tests may be duplicated more than others. In fact, clinical practice experiences identified a particular set of tests that seemed to be frequently and unnecessarily duplicated (see Table 1). These clinical experiences were validated by a preliminary inspection of data provided by the information technology (IT) report writer for the hospital laboratory system at the proposed study site. This motivated the conduct of the study described here. In addition, a particular test, the Acute Hepatitis Profile (AHP) was selected for additional analysis for two reasons. First, the time when the result of the AHP test was likely to change is very clear in the literature and allowed for an evidence-based time-specific interval to be determined for this test (Porter et al., 2007). Second, the AHP test computerized alert was initiated at the study site, creating a unique opportunity to evaluate whether the alert reduced unnecessary duplication of the AHP test. Results from this study may assist APNs in determining if institutional processes need to be evaluated or computerized alerts should be implemented in their institution to improve quality and efficiency of patient care.

**Purpose of this Study**

This study has two phases. The purpose of phase one is to evaluate the frequency of ordering duplicate laboratory tests in hospitalized patients over a 12-month period and the costs associated with this practice. The purpose of phase two is to determine if the use of a
computerized alert or prompt will reduce the total number of unnecessarily duplicated Acute Hepatitis Profile (AHP) laboratory tests.

Research Questions

Phase 1

1a. In this sample of hospitalized patients, what was the prevalence of duplication of the selected laboratory tests (Table 1) over twelve months?

1b. What were the costs associated with duplication of these laboratory tests?

Table 1: Selected Tests and Unit Costs.

<table>
<thead>
<tr>
<th>Test</th>
<th>2011 Unit Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Hepatitis Profile (AHP)</td>
<td>$97.00</td>
</tr>
<tr>
<td>Antinuclear antibodies (ANA)</td>
<td>$201.00</td>
</tr>
<tr>
<td>B12/Folate level</td>
<td>$26.25</td>
</tr>
<tr>
<td>Thyroid Stimulating Hormone (TSH)</td>
<td>$159.00</td>
</tr>
<tr>
<td>Ferritin</td>
<td>$129.00</td>
</tr>
<tr>
<td>Iron/Total Iron Binding Capacity (TIBC)</td>
<td>$48.00</td>
</tr>
</tbody>
</table>


Phase 2

2a. Did the use of a computerized alert or prompt reduce the total proportion of unnecessarily duplicated AHP tests within a three-month period?

2b. What were the differences in the costs of duplicated AHP laboratory tests between the pre- and post intervention time periods?
2c. Describe and compare patient, test, and system factors (Table 2) pre- and post-implementation of the AHP computerized alert for patients with duplicated AHP tests.

2d. Among all patients in the pre- and post-alert study periods, what patient, test, and system factors predicted duplication of the AHP test within a 15 day period?

Table 2: Patient, Test, and System Factors.

<table>
<thead>
<tr>
<th>Age</th>
<th>Gender</th>
<th>Ethnicity</th>
<th>Number of specialists on case associated with duplicate order</th>
<th>Length of hospital stay</th>
<th>Mortality</th>
<th>Initial tests normal or abnormal</th>
<th>Order status (routine or stat)</th>
<th>Test duplicated more than one time</th>
<th>Month test requested</th>
<th>Presence or absence of computerized alert</th>
</tr>
</thead>
</table>
Research Assumptions

The assumptions of this study include the following:

1. All laboratory tests in the medical record were ordered by the clinician and do not reflect a CPOE system error.

2. Any three-month period of records is representative of test ordering behavior observed during the other nine months of the year.

Definitions of Terms

Conceptual Definitions of Terms

The following terms are defined for this study:

1. An unnecessarily repeated or duplicated test. An unnecessarily repeated test is defined as one that follows a previous test of the same type during the patient’s length of stay in the hospital and one in which any change in the test result is unlikely to be clinically significant. This includes a redundant test that could be eliminated with little loss of information. Though there are no customary definitions for categorizing a test as redundant, this word often refers to those ordered tests that would be cancelled by clinicians if they were made aware of prior results of that test (Bates et al., 1998; Bates et al., 1999; Jha et al., 2009; Weydert, Nobbs, Feld, & Kemp, 2005). For the purposes of this study, the phrase unnecessarily repeated test is used interchangeably with a duplicate or redundant test.

2. Clinical provider order entry (CPOE) systems. CPOE systems are computer-assisted information systems that allow clinicians to write orders, including prescribing medications and treatments (Schedlbauer et al., 2009).
3. *Computerized decision support systems (CDSS)*. CDSS systems are connected with the CPOE to offer support for clinical decision-making by incorporating clinical and patient data (Garg et al., 2005; Schedlbauer et al., 2009).

4. *Computerized alert or prompt*. A computerized prompt or alert, generally speaking, is a message that pops up on a computer screen to convey information to the clinician regarding important information about the patient and the rationale for the alert. Usually, it has an “Ok” button to click to indicate that the user has read the vital message and would like to continue (Payne, 2000; Weiss & Walter, 1996). For the purposes of this study, the terms *computerized alert or prompt* are used interchangeably.

5. *Near misses* are defined as tests that were ordered but later canceled by the ordering clinician, laboratory system, or nurse.

**Operational Definitions of Terms**

The following terms are defined for this study:

1. *An unnecessarily repeated test*. During Phase 1, an unnecessary repeated test was identified if the test was performed earlier during that same hospitalization and an actual result was final and present in the EMR for the same patient for the same test (e.g. the test had not been cancelled in any way or discontinued prior to the final results) and any change in their values likely would not be clinically significant.

During Phase 2, an unnecessarily repeated AHP test was identified when the AHP test was performed within 15 days of an actual result being final and present in the EMR for the same patient. Clinical evidence indicates the results of an AHP test are not likely to change over a 15-day period (Porter et al., 2007).
2. *Cost per event of repeated unnecessary test.* Only the 2011 direct hospital charges for each selected test were evaluated and costs were held constant during both phases of the study period (i.e. January 6\(^{th}\), 2010 to April 6\(^{th}\), 2011). During Phase 1, the number of unnecessarily repeated tests was multiplied by the unit charge for the tests to give a total annual cost of unnecessarily duplicated tests in each test category (Table 1). During Phase 2, for both periods of data collection, pre- and post-intervention, the number of unnecessarily duplicated tests over a total of three months’ time was multiplied by the hospital charge for each test duplicated. Indirect costs, such as staff wages, supply costs, or cost of adverse events were not included in this calculation.

3. *Near misses* were identified by any test that cancelled or discontinued after the original order was placed in the EMR for the same patient and for the same test.

**Summary**

The intention of the healthcare delivery system is to maximize health, decrease the overall burden of illness, and to increase the value of individual and community resources allocated to healthcare (NQF, 2009). Laboratory testing of hospitalized patients can occasionally be superfluous particularly duplicated testing (Nies et al., 2010). Duplicate testing lowers quality of our healthcare system because it uses more resources than necessary (Ransom et al., 2008).

A descriptive retrospective review of patient medical records for 2010 was conducted during phase 1. During Phase 2, data regarding the number of AHP tests ordered and duplicated were compared for a 3-month period pre- and post-implementation of a computerized alert intervention which was introduced to reduce unnecessary duplication of this particular diagnostic
test. The aims of this two-phase study were (1) evaluate the frequency of ordering duplicate laboratory tests in hospitalized patients and the costs associated with this practice; and (2) determine if the use of a computerized alert or prompt would reduce the total number of unnecessarily duplicated AHP laboratory tests.

This chapter discussed the background and significance of the problem of unnecessarily duplication of laboratory tests. The research purpose, research questions, research assumptions, and conceptual definitions of terms were described. The significance of this study for advance practice nursing was described. In the next chapter, a synthesis of the literature and research evidence will be presented.
CHAPTER 2: SYNTHESIS OF THE RESEARCH EVIDENCE

The purpose of this chapter is to synthesize relevant research related to the problem of unnecessary duplication of laboratory tests. First, this chapter discusses the quality, efficiency, and costs associated with unnecessary duplication of laboratory tests. Second, this chapter discusses administrative interventions that reduce unnecessary duplication of laboratory testing. Third, this section discusses relevant literature on test ordering behaviors, and test stability and timing of unnecessary duplication of the acute hepatitis profile laboratory tests. Fourth, this section discusses a relevant framework to measure efficiency and how it relates to the current study.

Cost, Quality, and Efficiency of Unnecessary Duplication of Laboratory Tests

The U.S. health care system faces several challenges including the critical requirement to improve safety, quality, and efficiency of health care, control rising costs, and increase access to care. Several studies have been done to evaluate cost, quality, and efficiency of laboratory utilization with emphasis on unnecessary duplication of laboratory tests (Jha et al., 2009; Walraven & Raymond, 2003).

Authors Jha, et al. (2009) used literature based data to estimate the cost of adverse events and redundant tests to provide evidence that addressing these situations could generate costs savings while improving quality of patient care. These authors performed a literature review to provide estimates of the incidence, preventability, and marginal additional costs of adverse events and then reviewed the National Inpatient Sample data to estimate the number of patients at risk for preventable adverse events or redundant testing. Their results suggested eliminating
redundant laboratory and radiology tests would have saved an additional $8.2 billion in 2004 or an additional 2.7% of total inpatient costs.

These results were even more apparent in teaching hospitals, which represent only 10% of all hospitals but 20% of all hospitalized patients, where eliminating preventable events and redundant tests could save more than $11 billion or 45% of the total costs savings for the entire nation. Furthermore, even facilities with less than 100 beds could collectively save $1.6 billion by eliminating avoidable adverse events and $900 million by eliminating unnecessary tests. Although these estimates are likely conservative, they can be useful to clinical managers and policy makers since these two areas of concern are particularly ripe for preventative interventions and measures to improve efficiency (Jha et al., 2009).

Another population-based study of redundant laboratory testing was performed by Walraven and Raymond (2003) to determine the prevalence of, and associated costs with, repetition of eight common laboratory tests, including ferritin, one of the tests investigated in this study. Walraven and Raymond examined population-based clinical databases in Canada for the laboratory tests in adults, both inpatient and outpatients, done for one year. The results of their study found the percentage of adult patients having one or more tests increased with age, with nearly 75% of those over age 65 having at least one of the study tests. Duplicate testing within one month represented 30% of all utilization (109 repeat tests per 100 people per year). Duplication of tests was more common in hospitalized patients, was concentrated to a limited number of patients, and varied considerably among tests.

Further evidence reflecting the inefficiency of unnecessarily repeating laboratory tests was provided by Kwok & Jones (2004) who performed an audit of a governmental tertiary hospital laboratory in Hong Kong to determine the number of and associated cost of eight tests
that were repeated over a 12-month period. The tests examined were common rheumatology measurements, autoantibodies, and tumor markers. In this study, the authors found repeat tests within 12 weeks of a prior request comprised 16.78% of the total laboratory workload. Furthermore, the total cost associated with unnecessary duplication was calculated to be $132,151.

The costs of unnecessary duplication of laboratory tests have been demonstrated in the literature to be considerable (Bates et al., 1998; Jha et al., 2009; Kwok & Jones, 2004; Walraven & Raymond, 2003). These findings suggest the need for administrative efforts to address the issue of unnecessary duplication of laboratory tests and improve resource utilization of health care dollars (Jha et al., 2009).

**Administrative Efforts to Reduce Unnecessary Laboratory Testing**

Several studies have been done evaluating educational interventions, utilization management interventions, and models for quality improvement to reduce unnecessary laboratory utilization in the hospital setting (Beland, D’Angelo, & Vinci, 2003; Calderon-Margalit, Mor-Yosef, Mayer, Adler, Shapira, 2005; Nielson et al., 2004; Wang et al., 2002). In an attempt to control healthcare costs and as a part of the preliminary process in creating critical paths, nurses in the neurosurgical intensive care unit (NSICU) in Hartford Hospital in Connecticut developed a quality improvement process using the IDEA model to reduce frequencies of unordered and unnecessary laboratory tests (Beland et al., 2003).

The IDEA model is a model for quality improvement and the acronym stands for the following steps used in the process:

- Identify an opportunity or problem for improvement.
• Determine all root causes.
• Establish the plan for action.
• Act on the established plan.

Authors collected data on a sample of ten NSICU patients and found that 14.2% of the laboratory tests on their first group were unordered and total charges for these tests were $5,742.34 (Beland et al., 2003).

Throughout their quality improvement process, they continued to collaborate with various departments associated with the NSICU and develop blood work guidelines to address common reasons unnecessary blood work was sent. Their initial follow up data showed a reduction in the amount of unnecessary or unordered tests being sent by nurses; however, further audits again showed an increase in unordered blood work during certain shifts and by certain nurses. These authors admit this is continual quality improvement process and they include future plans for auditing and addressing this problem in their NSICU (Beland et al., 2003).

Calderon-Margalit et al. (2005) conducted a similar administrative quality improvement intervention to improve the appropriateness of testing behavior in hospitalized patients and to reduce the total number of laboratory tests completed. Their administrative intervention involved restricting available emergency laboratory tests as well as the frequency of repeated laboratory test orders. Incorporated in the intervention were educational strategies to increase compliance by all staff members and a presentation on the problem and its consequences. Furthermore, a presentation on the new policy and feedback of the intervention’s results were reviewed with senior medical staff.

These authors reported an overall 19% (95% CI: 18.8-19.2%) reduction in laboratory tests observed during the first year after the interventions. Furthermore, the 30-day readmission
rates did not differ significantly in the year after the intervention as compared to the year prior to the intervention. However, they did note that the census increase by 3.5% in the year after the intervention. As per the cost estimates of the observed clinical biochemistry tests, the reduction in volume of tests seen after the intervention was associated with an approximate cost savings of $247,000. Even on tests where no intervention was applied (i.e. hematology tests) there was a small reduction in ordering practices likely explained by the Hawthorne effect related to the spread out effect of the intervention that restricted other tests (Calderon-Margalit et al., 2005).

Wang, et al. (2002) described a utilization management intervention performed in the setting of the coronary care unit to reduce unnecessary testing, including radiographic and laboratory testing. Using evidence-based recommendations, a multidisciplinary team developed practice guidelines for routine laboratory and chest radiographic test ordering. When possible, they incorporated expert opinion. The guidelines were then disseminated to house staff and nurses and incorporated into the computer admission order sets for the coronary care unit in a large teaching hospital.

Data were collected for a three-month intervention period and compared to data during the same three months of the prior year and compared to the same hospital’s medical intensive care unit as control data. Results during the intervention period suggested significant reductions in utilization of all chemistry tests (from 7% to 40% depending on the test); however, reductions in ordering arterial blood gas tests, chest radiographs, and complete blood counts were not significantly reduced. Although, after controlling for trends in the control data the reductions in chest radiograph (P < .001) and arterial blood gas tests (P = .04) became significant (Wang, et al., 2002).
The utilization management intervention was not associated with measureable changes in patient outcomes such as length of stay, hospital mortality, readmission to the intensive care unit or hospital, or days of ventilator support. Despite the intervention, the total number of laboratory tests in this setting remained higher than would be predicted on the basis of the established guidelines. While part of the excess may have been clinically appropriate, these figures suggest a call for further reductions in utilization and the need for further research to determine whether initial reductions could be maintained over longer periods (Wang et al., 2002).

In response to an increase in the use of expensive or duplicate testing, the Vanderbilt University Medical Center, Nashville, Tennessee, employed a resource utilization committee (RUC) to reduce variability in laboratory testing, imaging, and formulary use without restricting access to clinically indicated testing. The RUC initially identified specific patterns of unnecessary resource utilization in the hospital and then devised a plan using the CPOE system to reduce redundant testing (Neilson et al., 2004).

The first intervention the RUC implemented was a computerized prompt that appeared daily and asked clinicians whether they wanted to discontinue tests scheduled beyond 72 hours. The RUC then evaluated the results of the first intervention and subsequently did a second intervention to further constrain testing options by unbundling the serum metabolic panel tests into single tests and by reducing the ease of repeating targeted tests (chest radiography, glucose, creatinine, blood urea nitrogen, electrolytes, and electrocardiogram). During the third intervention, the RUC established a graphic display of the test results from the prior week on the ordering page for frequently ordered serum chemistry tests to prevent clinicians from claiming the previous result was not known (Neilson et al., 2004).
Results of the first intervention or voluntary reduction of testing beyond 72 hours decreased orders for metabolic panel component tests by 24% (P = .02) and electrocardiograms by 57% (P = .006), but not orders for portable chest radiographs. The second intervention produced an additional decrease of 51% for metabolic panel component tests (P < .001) and 16% for portable chest radiographs (P = .03). No further changes were observed in test-ordering trends after the third intervention. Mortality rates, intensive care transfer rates, length of hospital stay rates, and readmission rates were unchanged compared to the rates prior to the intervention (Neilson et al., 2004).

Although authors admit other activities were occurring within the hospital at the same time period of the intervention and could have influenced test-ordering behavior, peer management of a CPOE system by the RUC produced a dramatic and sustained decrease in test-ordering behavior. Since payments for hospitalized patients are based on diagnostic-related groups or fixed per diem contracts, a decrease of unnecessary testing that sustains quality of care would be advantageous for both hospital finances and resource aptitude (Neilson et al., 2004).

This section of the chapter described administrative efforts designed to reduce unnecessary laboratory utilization. In most cases, attempts to reduce test ordering were successful, with some tests being reduced more than others. The most successful administrative efforts were those that used computerized alert reminders or evidenced-based guidelines for laboratory testing, and/or constrained testing options for clinicians (Calderon-Margalit et al., 2005; Neilson et al., 2004; Wang, et al., 2002). Similar to the study by Neilson et al. (2004), which found the computerized alert reduced orders for certain testing, this study evaluated a computerized alert intervention for reducing redundant AHP tests to offer further evidence regarding the usefulness of this intervention.
Test Ordering Behaviors Related to Unnecessary Duplication of Laboratory Tests

There are several factors reported in the literature that affect clinicians’ test-ordering behaviors. Sood, Sood, and Ghosh (2007) performed a literature review on the topic and described both non-modifiable and modifiable factors affecting test-ordering behaviors of physicians. Non-modifiable factors included practice location, practice setting, age and sex of the physician, and specialty of the physician. Modifiable factors include fear of malpractice, physician regret (related to prior experience of regret if diagnosis was missed), financial incentives, physician experience or knowledge, belief systems, awareness of the cost of testing, fear of malpractice, and education and feedback. The modifiable variables are among the most important since a better understanding of these variables can have a considerable impact on test ordering and health care costs.

By and large, test ordering is a skill that changes with time and is related to several complex interacting factors. The literature review indicates several physician factors that are not evidence-based affect test ordering. Even though non-evidence-based test ordering does not always indicate inappropriate test ordering, an exploration of the reasons why physicians deviate from evidence-based test ordering could be informative (Sood et al., 2007).

Miyakais, et al. (2006) performed a study to identify factors contributing to laboratory overutilization in an academic medical department and to assess the effects of an educational feedback strategy on inappropriate test-ordering behavior. Their findings suggested senior trainees ordered more laboratory tests, but the percentage of avoidable tests ordered by junior trainees was higher. Furthermore, trainees had a low and disparate level of awareness about the cost of common laboratory tests. Several independent factors were associated with laboratory
over-utilization including patient age $\geq$ 65 years, length of stay > 7 days, and increased case difficulty (one that lead to patient death) or inability to determine a diagnosis.

The findings of this study suggested nearly 68% of the laboratory tests frequently ordered in an academic internal medicine department could have been avoided with no unfavorable effects on patient management. Furthermore, almost two-thirds of the laboratory tests ordered beyond the first 24 hours of hospitalization did not appear to have contributed to the diagnosis, while only an estimated one-fourth of the tests ordered within the first 24 hours of hospitalization seemed to be redundant. A feedback approach based on the results of the assessment produced a major, yet short-lived, reduction of inappropriate test-ordering behavior (Miyakis et al., 2006).

Other reasons cited for unnecessary duplication of laboratory tests by clinicians include ease of access to the tests, test addiction, clinicians’ inability to manage the fear of uncertainty, and the use of protocols and guidelines (Miyakis et al., 2006; Neilson et al., 2004). Furthermore, inadequate educational feedback, “routine” clinical practice, failure to check previous results, test-ordering routines that are difficult to change, and lack of experience has been suggested as reasons for excessive test ordering (Kwok & Jones, 2004; Miyakis et al., 2006). Moreover, the patients themselves may contribute to unnecessary duplication of laboratory testing since they often actively ask for tests and may attach greater value to the results than warranted (Kwok & Jones, 2004).

The degree of provider specialization also impacts test-ordering behavior, whereas the greater the degree of specialization has been associated with more test-ordering and ordering of tests earlier in the patient’s illness. Despite specialists ordering more test than internists, the tests they ordered were more likely to be focused tests and more likely to have positive results (Sood et al., 2007).
This section discussed specific clinician factors reported in the literature that affect test ordering and test duplication. Understandably, many factors involving the clinicians, patients, and the health care environment influence the test-ordering process. Both modifiable factors and non-modifiable clinical factors contribute to test ordering and test duplication, as well as certain system and patient factors. It is theorized that modifiable factors are most important since they can have a tremendous impact on test ordering and subsequent healthcare costs (Sood, Sood, & Gosh, 2007). Education and feedback is one modifiable factor this study is evaluating by examining the effect of a computerized alert intervention. The alert intervention being evaluated in this study reminds the clinician the AHP test has been recently ordered within an evidence-based test-specific time interval and notifies them of the date of the prior test.

**Computerized Alert Effects on Test-Ordering and Laboratory Duplication**

The opportunity to improve patient care using computerized alerts or prompts is one of the chief incentives for implementing sophisticated electronic health records. A landmark study was performed by Bates, et al. (1999) to determine the impact of a computerized reminder or alert on the reduction of redundant laboratory tests. This prospective randomized controlled trial included all inpatients in a large teaching hospital during a 15 week time period. The intervention involved specific tests with test-specific time intervals and a computerized reminder indicating the tests ordered was within the test-specific time period, the result was pending, or the result was given if available.

During the study period, there were 939 redundant laboratory tests ordered. Of these, 69% of the tests in the intervention group were canceled in response to the computerized reminder. Of the 137 overrides of the computerized reminder, 41% appeared to be clinically
indicated. In the control group, the laboratory performed 51% of the redundant tests ordered. On the other hand, in the intervention group the laboratory performed only 27% of the ordered redundant tests. Of all redundant laboratory tests performed, only 44% had an associated computer order (tests lacking an associated computer order had been sent to the laboratory in a labeled envelope and were ordered by clinicians on paper order forms). Unfortunately, the authors did not specify any reasons for why these tests were done without a computer order. (Bates et al, 1999). This study avoids this problem by choosing as study site at which all laboratory tests were ordered in the EMR. If any test were ordered during a computer downtime, the order would later be entered into the EMR, as well as the result, once the system was operational.

To determine if the cancellation of a test due to the computerized reminder had adverse clinical effects, the researchers examined the charts of patients where clinicians had accepted the reminders to ascertain whether a canceled test was followed within 3 days by an abnormal test result. Excluding chemistry profiles, of the remaining 225 accepted reminders, 119 (53%) were trailed by another tests of the same type within 3 days; 55 (24%) were abnormal. Yet, only 10 (4%) of these had not been preceded by a similar abnormal result within 24 hours prior to the canceled tests. Thus, only eight (4%) of these tests offered new information and of these only in two cases did the new information lead to a change in the clinical management (Bates et al., 1999).

In their study to evaluate the impact of a Serology-CDSS offering point of care alert reminders of previous serology results, Nies, et al. (2010) found the proportion of unnecessarily repeated serology tests dropped post implementation of the alert and remained stable. Conversely, Shohania, et al. (2010) performed a systematic review of literature to quantify the
expected magnitude of improvements in processes of care from computer reminders delivered to clinicians during routine charting activities or electronic ordering. Their findings suggest computerized reminders typically increased adherence to target processes of care by amounts below thresholds for clinically significant improvements. Unfortunately, these authors made no determination on whether these alerts reduced overall costs or resource use, such as hospital length of stay. Although many CDSSs may improve practitioner performance, the effects on patient outcomes remain understudied or when studied inconsistent (Garg et al., 2005), providing a rationale for this study.

There are significant gaps in the medical literature concerning the most effective methods for displaying alerts and prompts supporting the need to investigate how to present and display data at the point of care. Models about the benefits of EMRs advise significant benefits will be realized only with advanced decisional support. However, minor issues relating to human factors can have a considerable impact on the success of specific alerts and prompts and research is needed since best practices in this area have not been clearly described (Schedlbauer et al., 2009).

DesRoches, et al. (2010) used data from a national survey of EMR adoption among acute care facilities to investigate the relationship between the adoption of EMR and key metrics and accessible measures of quality and effective use of resources. Findings suggest weak relationships concerning key metrics of hospital quality and effective use of resources, and across the large number of metrics examined, the relationships were modest at best but generally lacked statistical or clinical significance. These findings imply a careful examination of the EMR is needed including examination of how it is used and how best to capitalize on it’s potential in improving quality and effective utilization of resources. To permit payers and
providers to make important decisions about implementing EMRs, there is a need for research demonstrating how these systems can cost effectively improve care processes (Walker, 2005).

This section explains studies describing administrative efforts to reduce unnecessary duplication of diagnostic tests. Of the administrative interventions described, most had mixed results in regards to reducing laboratory test duplication or overutilization. The two studies focusing on evaluating the computerized alert’s effect on test-ordering and unnecessary laboratory duplication demonstrated reductions in unnecessary duplication of laboratory testing without adversely affecting patient outcomes (Bates et al., 1999, Nies et al. 2010). Moreover, one study demonstrated a potential costs savings with initiation of the computerized alert (Bates, et al., 1999). When the alert was used in combination with constraining testing options for clinicians, the combined effect demonstrated further reductions in laboratory duplication and overutilization (Neilson et al., 2004). This added improvement might be related to the high constraint put on the clinician’s behavior, as they could not easily override the alert (Nies, et al., 2010).

While studies have looked at the effect of alerts on improvements in processes of care (Shojania, et al., 2010) or the adoption of EMRs and their relationship to quality and efficiency of care (DesRoches et al., 2010), there is limited research evaluating effectiveness of computerized alert interventions and potential costs savings, resource use (i.e. length of stay), and reduction of unnecessarily repeated tests. Research is needed in this area. Research is also needed to evaluate clinician tests ordering practices, because these can ultimately affect the success of the alert. Furthermore, there is a gap in the research evaluating whether computerized alerts can sustain improvements in system processes without effecting patient outcomes (Shohania et al., 2010; DesRoches et al., 2010).
Selected Tests for Evaluation

Six tests were selected (Table 1) for evaluation for unnecessary ordering and/or duplication. These six tests were selected because clinical observation suggested these six tests were often unnecessarily duplicated in routine practice. Furthermore, a preliminary analysis of the data provided from the IT department report writer at the study site verified that these test were frequently duplicated.

In the setting for this study, the B12 and folate levels are run together as one test. Similarly, the iron and TIBC are run as one test. No clear guidelines are readily available with specific time frames on when to repeat the acute hepatitis serology profile. However, much is known about the incubation times of all strains of viral hepatitis, and this information can be used to determine when duplication of an AHP would be redundant. Preliminary laboratory assessment of patients with acute hepatic injury should include an acute hepatitis panel. IgM anti-HAV, the indicative laboratory test of choice for acute hepatitis A virus infection, disappears by 4-6 months, while total HAV antibodies endure for life. IgM anti-HBc and HBsAg are the most dependable tests for acute hepatitis B virus infections; IgG (and thus total) anti-HBc endure for several years (Dufour et al., 2000).

Both anti-HCV and HCV RNA can be present in acute and chronic hepatitis C virus infections and diagnosis can be presumptively made by negative HAV and HBV markers, recent exposure, and a negative anti-HCV at initial presentation with conversion of positive anti-HCV within 1-3 months (Dufour et al., 2000). Incubation periods for all types of viral hepatitis are anywhere from 15-180 days (Porter et al., 2007).

In their study evaluating the effect of a computerized alert on unnecessarily repeated serology tests, Nies, et al. (2010) considered an unnecessarily repeated hepatitis serology test
was one that occurred within 90 days of the previous result. Conservatively, for this study, based on the incubation periods of all strains of viral hepatitis, if an acute hepatitis profile is repeated within a 15-day time interval it was considered unnecessarily duplicated. In the setting for this study, the AHP is ran and charged as one test and includes the following tests: Hepatitis A (AB) IgM, Hepatitis B Core (AB) IgM, Hepatitis B Surface Antigen, and Hepatitis C (AB), IgM.

**Theoretical Framework: The National Quality Forum (NQF) Measurement Framework**

The NQF, interdisciplinary, measurement framework provides theoretical justification for this study. The framework specifies how best to evaluate efficiency across patient-focused episodes of care (NQF, 2009). The NQF purports the purpose of the healthcare delivery system is to improve health, diminish the burden illness, and make the best use of individual and public resources allocated to healthcare. Hence, this study focuses on the improper care of unnecessarily duplicative diagnostic testing. Such testing is clearly not efficient care. This framework identifies cost and resource use and processes of care as key measurement domains with respect to assessing quality of care. Hence, this study estimates the costs associated with unnecessarily duplicated diagnostic tests (Table 1), and determines if the implementation of a computerized alert reduces unnecessary duplications of the AHP test and reduces associated costs of redundant AHP tests. The latter will provide insights into processes of care.

**Summary**

This chapter described relevant research relevant to the problem of unnecessary duplication of laboratory tests, including resource use associated with redundant testing and interventions for reducing unnecessary testing. Furthermore, this chapter described available literature on test ordering behaviors and test stability and timing of unnecessary duplication of
the acute hepatitis profile laboratory tests. A theoretical framework for defining and measuring quality of care was used to provide justification for this study.
CHAPTER 3: METHODS

First, this section discusses the setting for the study, sample criteria and methods of chart selection, and protection of human subjects for phase 1 and Phase 2 of the study. Second, the research design and rationale for the chosen design are discussed. Third, procedures and data analysis for phase 1 and phase 2 of the study are discussed separately.

Setting for the Study

This study was performed in two phases. Both phases of the study took place in a large tertiary care organization in central Florida. This organization has several major medical departments including internal medicine, cardiovascular and stroke units, and emergency services. The facility utilizes the Eclipsys® EHR centered on the Sunrise Clinical Manager™. The Sunrise Clinical Manager incorporates systems for CPOE and CDSS for clinicians (Eclipsys® Retrieved October 2, 2010 from: http://www.eclipsys.com/hospitals-clinical-solutions-acute-care-ehr.htm).

Sample Criteria and Methods for Chart Selection

The sample criteria and data extraction methods for chart selection were the same for both Phase 1 and Phase 2 of the study. However, the sampling period varied for the two phases. Both phases used a purposive sample of all patients admitted to a local tertiary organization, over age 18 years of age, who received an order for any of the selected tests (Table 1). Patients were excluded from the analysis if they were discharged from the hospital less than 24 hours after their admission. Furthermore, patients were excluded if their medical record was incomplete or did not contain any duplication in ordering of the selected tests. Incomplete medical records
were those records that did not contain information on patient characteristics of age, gender, or ethnicity.

Protection of Human Subjects

The Institutional Review Boards (IRBs) approval from the University of Central Florida and the local tertiary organization was obtained prior to data collection. Any amendment in the protocol was requested and approved by both of these IRBs prior to data collection.

Statistical Analysis

The statistical analysis for both Phase 1 and Phase 2 data were conducted using PASW® Statistics GradPack for MAC® database (version 17.0, SPSS, Chicago, IL, USA). A description of the analyses performed during each phase of the study will be described separately.

Phase 1 Design

A retrospective descriptive design was used for Phase 1 to evaluate the prevalence with which selected tests (Table 1) are duplicated. Data were collected for a twelve-month time period in 2010. This design was chosen to allow for retrospective chart review of the selected tests to determine which of these tests were duplicated and to determine which of these tests were “near misses.” Near misses are defined as tests that were ordered but later canceled by the ordering clinician, laboratory system, or nurse.

Phase 1 Procedures

For each laboratory test (Table 1), a computerized database review of all tests ordered and duplicated on inpatients during a twelve-month time period between January 6th, 2010 and
December 31\textsuperscript{st}, 2010 was executed. This was done to determine which of these tests were ordered and canceled and which were duplicated during this twelve-month time. These particular diagnostic tests were chosen based on a preliminary analysis of test-ordering patterns that showed that they were frequently duplicated. Additionally, unlike many other laboratory tests, duplication of these tests do not add significantly to the clinical management of patients (Heuston, 2001; Kwok & Jones, 2004; Munoz, Villar, & Garcia-Erce, 2009; Porter et al., 2007; Smellie et al., 2005). Census data during the twelve-month data collection period in 2010 was collected to determine if fluctuations in the census contributed to laboratory tests duplication rates.

Data were provided by the tertiary care organization’s Information Technology (IT) Department report writer and included the medical record number. Data were kept on a password-protected computer. Data were coded, the medical record number removed, and the original data file destroyed. Data were coded by assigning each patient a unique identifier different from the medical record number and the medical record number was removed from the data file prior to analysis in order to preserve confidentiality. The medical record number and code number list was stored separately in a locked file cabinet in a private office at the tertiary care facility for patient confidentiality.

For each selected test (Table 1), the total number of tests ordered and canceled or duplicated per total tests ordered was reported. Data integrity of the electronic database was verified by retrieving a random subset of 5 charts from the medical records using the medical record number. Charts were retrieved manually and the duplication of each test was verified and compared to the data received from the IT department’s prepared data report. It also allowed for assessment of data quality for Phase 2. As part of data verification, the demographic
characteristics for patients with AHP tests in the first quarter (Q1) in 2010 were compared to those in the last 3 quarters (Q1, Q2, Q3) in 2010 combined in order to assess if the 3-month sample would be representative of the rest of the year. There were no significant differences in the characteristics between the two periods ($p \geq 0.05$) suggesting that Q1 was comparable to the last 3 quarters (Appendix E).

**Phase 1 Statistical Analyses**

Phase 1 research questions and statistical analysis for each one are outlined below.

1a. In this sample of hospitalized patients, what was the prevalence of duplication of the selected laboratory tests (Table 1) over twelve months?

**Analysis:** Descriptive statistics were used to summarize ordering and duplication of the selected tests (Table 1) using proportions.

1b. What were the costs associated with duplication of these laboratory tests?

**Analysis:** A cost analysis was performed on the tests (Table 1) for the total number of duplicated tests ordered and completed within a twelve-month time period from January 6th, 2010 to December 31st, 2010. The annual cost for unnecessary duplication of the tests was estimated using the 2011 unit charge for each test. The total costs associated with unnecessary duplicated tests were multiplied by the hospital charge for selected test to obtain the projected annual cost associated with unnecessary duplication. The formula used for calculating total costs for one year was annual costs = unit cost for test x number of duplicated tests in one year.

**Phase 2 Design**

For this phase, only the AHP tests were evaluated. A quasi-experimental pre- and post-test design was used to determine the difference in proportion of duplication of AHP tests.
observed for a 3-month period before and a 3-month period after the implementation of a computerized alert intervention. Hereafter, these two periods are referred to as pre-alert and post-alert. This design was selected to allow a field test of the computerized alert to determine if the implementation of the alert may reduce the proportion of duplicated AHP tests. It also allowed for assessment of data quality for Phase 2.

**Phase 2 Procedures for Implementation of Computerized Alert**

As part of a hospital wide initiative to reduce laboratory duplication and as part of the normal workflow of the laboratory supervisor, a computerized alert for the AHP was created and implemented on January 5th, 2011. The computerized alert produces a pop-up screen on the computer and notifies the clinician ordering the AHP test that it is within the test-specific time frame. The alert produces a message stating “incubation periods for all types of viral hepatitis is anywhere from 15-180 days.” The test-specific time frame was set at 15 days prior to entering the order for the AHP and for 15 days in the future.

The alert indicates to the clinician that the test has recently been ordered (within the test-specific time frame and is either completed and the date, pending, or scheduled to be done in the future) and asks clinicians whether or not they want to proceed with ordering the selected test (Figure 1). The alert does not prohibit clinicians from ordering the test if they choose to ignore the alert. The alert was implemented hospital wide to display on the monitor screen from any location of entry into the system, including home and other community hospital sites.
Figure 1: Computerized Alert.


In an attempt to evaluate this system change already in progress, data were collected following initiation of the computerized alert starting on January 6, 2011 and continued over the next 3-month period until April 6, 2011. Data were collected on all patients admitted to the hospital who received an order for the AHP to determine the prevalence of unnecessary ordering or duplication of the test. Data were compared to the data for the same three months in 2010 pre-intervention time period; from January 6th, 2010 through April 6th, 2010, to determine if the computerized alert decreased unnecessary duplication. The data collected included patient, test,
and system factors (Table 2) for any AHP test duplicated during both the pre- and post-intervention time periods.

Data were provided by the tertiary care organizations IT department report writer and included the medical record number, which was coded and removed from the data set prior to analysis. Patient confidentiality was maintained on all data collected as described in Phase 1. Data integrity of the electronic database was verified by retrieving a random subset of 5 charts from the medical records using the medical record number. Charts were retrieved manually and the duplication of each test was verified and compared to the data received from the IT department’s prepared data report.

**Phase 2 Statistical Analyses**

The statistical analyses for Phase 2 research questions are outlined below.

2a. Did the use of a computerized alert or prompt reduce the proportion of unnecessarily duplicated AHP tests within a three-month period?

Analysis: A comparisons of the proportion of duplicated tests in the pre- and post-alert periods was conducted using the Z-test for the difference of the proportions.

2b. What were the differences in the costs of duplicated AHP laboratory tests between the pre- and post-intervention time periods?

Analysis: The same formula used during Phase 1, for calculating cost of duplication of the AHP tests was used in Phase 2, except over the two (pre- and post-alert) 3 month time periods. The formula used to calculating total costs for each quarter was quarterly costs = unit cost for AHP test x number of AHP tests duplicated in that quarter.
To evaluate whether the computerized alert reduced total costs of duplicated AHP, the total costs of duplicated tests ordered and completed during January 6th, 2010 and April 6th, 2010 prior to the alert intervention was calculated and compared to those unnecessarily duplicated during the 3-month post alert intervention from January 6, 2011 and April 6, 2011. Comparisons between the pre- and post- intervention costs were conducted using the Z-test for the differences.

2c. Describe and compare patient, test, and system factors (Table 2) pre- and post-implementation of the AHP computerized alert for patients with duplicated AHP tests.

Analysis: Descriptive statistics including mean, median, percentages, and range were used to summarize patient, test, and system factors related to the AHP test being duplicated pre- and post-computerized alert intervention. In addition, a series of univariate analyses (including t-test, chi-square, Fisher’s Exact, and Contingency Coefficient, depending on variance, distribution, and type of data) were used to compare the factors pre- and post-alert intervention.

2d. Among all patients in the pre- and post-alert study periods, what patient, test, and system factors predicted duplication of the AHP test within a 15 day period

Analysis: Descriptive statistics including mean, median, percentages, and range were used to summarize patient, test, and system factors in the duplicated and not duplicated populations. In addition, a series of univariate analyses (including t-test, chi-square, Fisher’s Exact, and Contingency Coefficient, depending on variance, distribution and type of data) were used to compare the factors (Table 2) that were associated with the duplication of the AHP during both pre- and post-intervention time periods. A binary logistic regression was performed
to calculate the adjusted odds ratios for each clinical factor (Table 2). The dependent variable was whether or not there was duplication of the AHP test (not duplicated = 0 and duplicated =1). The independent variables included the patient factors in Table 2.

The Phase 2 sample size of 1366 provided sufficient power to detect a significant odds ratio (OR) with OR ≥ 1.84 or ≥ 0.42 in the analyses addressing question 2d in which the obtained proportion of AHP duplication was 5.2%. This calculation assumes an alpha of .05 and a power of .80. ORs that are smaller in magnitude than these values are not likely to be clinically significant.

**Summary**

This chapter described the setting for the study, sample criteria, methods of chart selection, and protection of human subjects for both phases of the study. It also details two separate phases of the study, including each phase’s research design and rationale for the chosen design, procedures, and data analysis. The procedure for implementing the computerized alert during Phase 2 of the study was discussed.
CHAPTER 4: RESULTS AND ANALYSIS OF DATA

This study was conducted to evaluate the prevalence of duplicated laboratory testing in hospitalized patients and the costs associated with this practice. In addition, this study was performed to evaluate the use of a computerized alert intervention, alerting the clinician of an existing test, to determine if its implementation would reduce the total number of duplicated AHP laboratory tests. This section describes the results of the data analysis related to the research questions.

Phase 1

Research Questions and Results

1a. In this sample of hospitalized patients, what was the prevalence of duplication of the selected laboratory tests (Table 1) over twelve months?

1b. What were the costs associated with duplication of these laboratory tests?

Repeat AHP Testing and Yearly Costs of Duplication

During the twelve-month study period in 2010, there were a total of 3355 AHP tests performed; of these, 768 (22.9%) were cancelled tests. Out of the 2514 tests with reported final results, 196 (7.8%) were duplicated. The total yearly cost associated with redundant AHP tests was $19,012. Characteristics of duplicated AHP tests are summed up in Table 3.

Repeat ANA Testing and Yearly Cost of Duplication

During the twelve-month study period in 2010, there were a total of 3035 ANA test performed; of these 441 (14.5%) were cancelled tests. These tests were cancelled by the laboratory, nurse, ordering clinician, or by patient discharge. Out of the 2594 tests with reported
final results, 120 (4.6%) were redundant. The yearly cost associated with redundant ANA tests was $24,120. Characteristics of duplicated ANA tests are summed up in Table 3.

Repeat B12/Folate Testing and Yearly Cost of Duplication

During the twelve-month study period in 2010, there were a total of 7229 B12/Folate tests performed; of these 1355 (18.7%) were cancelled tests. Out of the 5874 tests with reported final results, 396 (6.7%) were redundant. The yearly cost associated with redundant B12/Folate tests was $10,395. Characteristics of duplicated B12/Folate tests are summed up in Table 3.

Repeat TSH Testing and Yearly Cost of Duplication

During the twelve-month study period in 2010, there were a total of 27,475 TSH tests performed; of these 5880 (21.4%) were cancelled tests. Out of the 21,595 tests with reported final results, 1893 (8.7%) were redundant. The total yearly cost associated with redundant TSH tests was $300,987. Characteristics of duplicated TSH tests are summed up in Table 3.

Repeat Ferritin Testing and Yearly Costs of Duplication

During the twelve-month study period in 2010, there were a total of 6099 Ferritin tests performed; of these, 928 (15.2%) were cancelled tests. Out of the 5171 tests with reported final results, 384 (7.4%) were redundant. The total yearly cost associated with redundant Ferritin tests was $49,536. Characteristics of duplicated Ferritin tests are summed up in Table 3.

Repeat Iron/TIBC Testing and Yearly Costs of Duplication

During the twelve-month study period in 2010, there were a total of 6158 Iron/TIBC tests performed; of these, 1003 (16.3%) were cancelled tests. Out of the 5155 tests with reported final
results, 316 (6.1%) were redundant. The total yearly cost associated with redundant Iron/TIBC tests was $15,168. Characteristics of duplicated Iron/TIBC tests are summed up in Table 3.

**Summary**

Including each of the six tests examined, there were a total amount of 53,351 tests ordered, with 10,375 of these cancelled. Out of the total amount of tests conducted (n = 42,976), 4.6-8.7% were redundant, depending on the specific type of test. The overall associated yearly cost of redundant testing for these six selected tests was an estimated $419,218. The largest proportion of redundant tests was the Thyroid Stimulating Hormone level (n = 1893), costing a yearly estimated $300,987. These totals are summed up in Table 3.

<table>
<thead>
<tr>
<th>Test</th>
<th>Total Number of Tests</th>
<th>Total Cancelled Tests</th>
<th>Total Results Final</th>
<th>Total Redundant Tests</th>
<th>Yearly Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHP</td>
<td>3355</td>
<td>768 (22.9%)</td>
<td>2514</td>
<td>196 (7.8%)</td>
<td>$19,012</td>
</tr>
<tr>
<td>ANA</td>
<td>3035</td>
<td>441 (14.5%)</td>
<td>2594</td>
<td>120 (4.6%)</td>
<td>$24,120</td>
</tr>
<tr>
<td>B12/Folate Level</td>
<td>7229</td>
<td>1355 (18.7%)</td>
<td>5874</td>
<td>396 (6.7%)</td>
<td>$10,395</td>
</tr>
<tr>
<td>TSH</td>
<td>27475</td>
<td>5880 (21.4%)</td>
<td>21595</td>
<td>1893 (8.7%)</td>
<td>$300,987</td>
</tr>
<tr>
<td>Ferritin</td>
<td>6099</td>
<td>928 (15.2%)</td>
<td>5171</td>
<td>384 (7.4%)</td>
<td>$49,536</td>
</tr>
<tr>
<td>IRON/TIBC</td>
<td>6158</td>
<td>1003 (16.3%)</td>
<td>5155</td>
<td>316 (6.1%)</td>
<td>$15,168</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>53,351</strong></td>
<td><strong>10,375 (19.4%)</strong></td>
<td><strong>42,903</strong></td>
<td><strong>3305 (7.7%)</strong></td>
<td><strong>$419,218</strong></td>
</tr>
</tbody>
</table>

*Note. AHP = Acute Hepatitis Panel; ANA = Antinuclear antibodies; TSH = Thyroid Stimulating Hormone; TIBC = Total Iron Binding Capacity.*
Phase 2

Research Questions and Results

2a. Did the use of a computerized alert or prompt reduce the proportion of unnecessarily duplicated AHP tests within a three-month period?

The demographic characteristics for the patients in the Phase 1 and Phase 2 are presented in Table 4. As can be seen from the data in the table, the samples used for Phase 1 and the pre- and post-alert periods in Phase 2 were very similar. The length of stay for Phase 1 and for the two periods in Phase 2 (pre and post-alert) ranged from 1 to 208 days. Additional sample demographics are provided in Table 6 and Appendix C.

There were a total of 1969 AHP tests performed in this local tertiary care hospital system during the combined three-month study period. Due to missing clinical data and duplication in data entry, a total of 1366 patients were available for analysis (Figure 2). In the pre-alert time period in 2010, there were 674 patients with AHP tests ordered and in the post-alert period in 2011, there were 692 patients with AHP tests ordered. The proportion of patients with at least one duplicated AHP test in the pre-alert period was 53/674 (7.9%), and the proportion of patients with at least one duplicated AHP test in the post-alert period was 18/692 (2.6%) (Figure 3). This represents a statistically significantly reduction in the proportion of patients with duplications of the AHP test following introduction of the computerized alert ($\chi^2 = 19.1$, df 1, $p = \leq 0.001$).

Figure 4 illustrates the ordering pattern and percentages of duplicate AHP tests performed each month from January to April in the pre- and post-alert time periods. Of those with duplicate AHP tests, 2/53 (3.8%) patients in the pre-alert study period and 2/18 (11.1%) in the post-alert period had the AHP test duplicated 2 or more times.
Census data was collected during both study periods pre- and post-alert. The number of inpatients in all facilities within this tertiary care hospital system during the pre-alert study period in 2010 was 27,265 patients, as compared to 24,933 patients during the post-alert study period in 2011. There was a total of 2,332 more inpatients system-wide, distributed among all facilities, in 2011 (9.4% increase) as compared to the same time period in 2010.

Table 4: Comparison of the Demographic Characteristics of the Study Populations of those with AHP Tests in Phase 1 and Phase 2 of the Study.

<table>
<thead>
<tr>
<th></th>
<th>Patients in Phase 1 N=2514</th>
<th>Patients in Phase 2 (pre-alert)a N=674</th>
<th>Patients in Phase 2 (post-alert) N=692</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (±SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>53 (±18)</td>
<td>54 (±18)</td>
<td>52 (±18)</td>
</tr>
<tr>
<td></td>
<td>Range (18-112)</td>
<td>Range (18-99)</td>
<td>Range (18-93)</td>
</tr>
<tr>
<td>Gender (% female)</td>
<td>1224 (49%)</td>
<td>336 (50%)</td>
<td>321 (46%)</td>
</tr>
<tr>
<td>Race (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>66 (2.6%)</td>
<td>22 (3.3%)</td>
<td>27 (3.9%)</td>
</tr>
<tr>
<td>Black</td>
<td>649 (25.8%)</td>
<td>162 (24.0%)</td>
<td>177 (25.6%)</td>
</tr>
<tr>
<td>Caucasian</td>
<td>1268 (50.4%)</td>
<td>348 (51.6%)</td>
<td>353 (51.0%)</td>
</tr>
<tr>
<td>East Indian</td>
<td>28 (1.1%)</td>
<td>10 (1.5%)</td>
<td>5 (0.7%)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>487 (19.4%)</td>
<td>127 (18.8%)</td>
<td>127 (18.4%)</td>
</tr>
<tr>
<td>Other</td>
<td>16 (0.6%)</td>
<td>5 (0.7%)</td>
<td>3 (0.4%)</td>
</tr>
<tr>
<td>Order Status (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Routine</td>
<td>2087 (83.0%)</td>
<td>555 (82.3%)</td>
<td>603 (87.1%)</td>
</tr>
<tr>
<td>Stat/Timed</td>
<td>427 (17.0%)</td>
<td>119 (17.7%)</td>
<td>89 (12.9%)</td>
</tr>
<tr>
<td>Mortality</td>
<td>108 (4.3%)</td>
<td>33 (4.9%)</td>
<td>30 (4.3%)</td>
</tr>
<tr>
<td>Disposition from Hospital</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home/Rehab</td>
<td>2114 (84.1%)</td>
<td>570 (84.6%)</td>
<td>590 (85.3%)</td>
</tr>
<tr>
<td>Long-term Care/Death</td>
<td>400 (15.9%)</td>
<td>104 (15.4%)</td>
<td>102 (14.7%)</td>
</tr>
<tr>
<td>Length of Hospital Stay in days (±SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>9.2 (±12.3)</td>
<td>8.9 (±12.3)</td>
<td>8.9 (±12.2)</td>
</tr>
<tr>
<td></td>
<td>Range (1-208)</td>
<td>Range (1-117)</td>
<td>Range (1-104)</td>
</tr>
</tbody>
</table>

a These data are from a subsample of Phase 1 patients admitted during the first 3 months of 2010. Statistical analyses indicate that this 3 month subsample does not differ from the remaining 9 month 2010 subsample with respect to the demographic characteristics listed in the table (p ≥ 0.21; see also Appendix C).
Figure 2: Phase 2 Results.

Note. AHP = Acute Hepatitis Profile
Figure 3: Comparison of the Proportion (Percent) of Patients with Duplicate AHP Tests Performed Before and After the Alert Protocol was Implemented (January to April 2010 versus January to April 2011) (Chi-Square; $\chi^2=19.1$; df 1; $p<0.001$).

$p<0.001$
Figure 4: Ordering Pattern and Percentage of Duplicate AHP Tests Performed in Each Month from January to April in the Pre- and Post-alert Periods.

Note: CI = confidence interval. April data include only 6 days of observations.

2b. What were the differences in the costs of duplicated AHP laboratory tests between the pre- and post-intervention time periods?

The costs associated with the duplicated AHP tests during the study periods in 2010 and 2011 were $5,141 and $1,746, respectively: a reduction of $3,395 over the 3-months after the alert was implemented (Mann Whitney U; Z = -4.04; p ≤ 0.001) (Figure 5).
2c. Describe and compare patient, test, and system factors (Table 2) pre- and post-implementation of the AHP computerized alert for patients with duplicated AHP tests.

In order to assess clinical factors that were not available in the electronic database file provided by the IT department report writer, each patient had additional data extracted from their individual medical records. During the three-month pre-alert study period (2010), a total of 53 patients (7.9%) had a duplicate AHP test performed and during the post-alert study period in (2011), 18 patients (2.6%) had a duplicate AHP test performed for a total of 71 patients in the analysis. Comparisons of the characteristics of those patients who had duplicate AHP tests performed in the periods before and after the alert intervention summarized in Table 5.
There were no significant differences in the characteristics of people who experienced a duplicate AHP test between the two study periods with regards to age, gender, or ethnicity. In addition, there were no statistically significant differences in order status (routine verses stat), mortality, disposition after discharge from hospital, whether the initial test was abnormal, the number of specialists on the case, whether the test was repeated more than once, or length of hospital stay, with all factors having a p value > 0.05. There was, however, a significant difference between the two groups with respect to the month in which the duplicate test was requested (Contingency Coefficient 0.32, p = 0.04). In the pre-alert period, the number of duplicate tests was distributed evenly over 3 months. However, in the post-alert period the majority of duplications occurred in the month of January when the alert was first introduced and remained low over the subsequent months.
Table 5: Comparison of Characteristics of Patients who had Duplicated AHP Tests in Periods Before and After Implementation of Computerized Alert.

<table>
<thead>
<tr>
<th>statistic</th>
<th>Patients with Duplicates Pre-Alert N=53</th>
<th>Patients with Duplicates Post-Alert N=18</th>
<th>Statistic and p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (±SD)</td>
<td>56 (±17) Range (24-93)</td>
<td>56 (±18) Range (23-89)</td>
<td>t = 0.04, p = 0.90</td>
</tr>
<tr>
<td>Gender (%female)</td>
<td>21 (40%)</td>
<td>9 (50%)</td>
<td>χ² = 0.59, df= 1, p = 0.58</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td>Contingency coefficient = 0.09, p = 0.44</td>
</tr>
<tr>
<td>Asian</td>
<td>2 (3.8%)</td>
<td>2 (11.1%)</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>13 (24.5%)</td>
<td>3 (16.7%)</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>25 (47.2%)</td>
<td>9 (50%)</td>
<td></td>
</tr>
<tr>
<td>East Indian</td>
<td>1 (1.9%)</td>
<td>1 (5.6%)</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>12 (22.6%)</td>
<td>3 (16.7%)</td>
<td></td>
</tr>
<tr>
<td>Order Status (%)</td>
<td></td>
<td></td>
<td>Fisher’s Exact test: p = 0.75</td>
</tr>
<tr>
<td>Routine</td>
<td>41 (77.4%)</td>
<td>15 (83.3%)</td>
<td></td>
</tr>
<tr>
<td>Stat/Timed</td>
<td>12 (22.6%)</td>
<td>3 (16.7%)</td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>5 (9.4%)</td>
<td>2 (11.1%)</td>
<td>Fisher’s Exact test: p = 0.99</td>
</tr>
<tr>
<td>Disposition from Hospital</td>
<td></td>
<td></td>
<td>χ² = 1.81, df = 1, p = 0.22</td>
</tr>
<tr>
<td>Home/Rehab</td>
<td>41 (77.4%)</td>
<td>11 (61.1%)</td>
<td></td>
</tr>
<tr>
<td>Long-term Care/Death</td>
<td>12 (22.6%)</td>
<td>7 (38.9%)</td>
<td></td>
</tr>
<tr>
<td>Initial Test was Abnormal</td>
<td>4 (7.5%)</td>
<td>3 (16.7%)</td>
<td>Fisher’s Exact test: p = 0.36</td>
</tr>
<tr>
<td>Mean number of specialists on the case</td>
<td>3.3 (±2.5) Range (0-12)</td>
<td>3.5 (±3.2) Range (1-14)</td>
<td>t = -0.22, p = 0.83</td>
</tr>
<tr>
<td>Test duplicated multiple times (&gt;1 duplicate)</td>
<td>2 (3.8%)</td>
<td>2 (11.1%)</td>
<td>Fisher’s Exact test: p = 0.27</td>
</tr>
<tr>
<td>Length of Hospital Stay in days (±SD)</td>
<td>10.8 (±12.8) Range (1-79)</td>
<td>18.0 (±25.9) Range (2-105)</td>
<td>t = -1.14, p = 0.27</td>
</tr>
<tr>
<td>Month Test Requested</td>
<td></td>
<td></td>
<td>Contingency coefficient = 0.32, p = 0.04</td>
</tr>
<tr>
<td>January</td>
<td>13 (24.5%)</td>
<td>11 (61.1%)</td>
<td></td>
</tr>
<tr>
<td>February</td>
<td>13 (24.5%)</td>
<td>3 (16.7%)</td>
<td></td>
</tr>
<tr>
<td>March</td>
<td>21 (39.6%)</td>
<td>3 (16.7%)</td>
<td></td>
</tr>
<tr>
<td>April</td>
<td>6 (11.3%)</td>
<td>1 (5.6%)</td>
<td></td>
</tr>
</tbody>
</table>

*April data includes only 6 days of observations. N = number; Chi-square = χ²; df = degrees of freedom; t-test = t.*
2d. Among all patients in the pre- and post-alert study periods, what patient, test, and system factors predicted duplication of the AHP test within a 15 day period

Given the lack of demographic and clinical factor differences between patients with duplicated AHP tests during the pre- and post-alert periods, data from the two periods were combined. This resulted in a total of 1366 patients who had at least one AHP test performed. Of these, 71 patients (5.2%) had a duplicated AHP test (with duplication group) and 1265 patients (92.6%) had a single test performed (without duplication group). Characteristics of these patients groups, with and without duplicate AHP testing, were compared using the clinical data available electronically from the hospital database file provided by the IT department report writer. Results are summarized in Table 6.

There were no significant differences between patients who had duplicate AHP (n = 71) tests and those who did not (n = 1265) with regards to patient age, gender, ethnicity, order status of test (routine or stat), and length of hospital stay, with all factors having a p value of > 0.05. There were, however, significant differences in the month the test was requested (contingency coefficient 0.12; p ≤ 0.001). It is likely that ordering patterns in the duplicated group changed once the alert was instituted, resulting in the differences between the groups (Figure 6).

There was also a statistically significant difference in mortality between the two groups, with a higher mortality in those patients with duplication (9.9%) than those without duplication (4.3%) ($\chi^2 = 4.69$, df 1, $p = 0.04$). There were also statistically significant differences in disposition from hospital. There were a larger proportion of patients with poor outcome/disposition (long-term care or dying) at 26.8% in the duplication group compared to those without duplication at 14.4% ($\chi^2 = 7.98$, df 1, $p = 0.009$). These results are summarized in Table 6.
Table 6: Comparison of Characteristics of Patients With and Without Duplicate AHP Tests During Both 2010 and 2011 Study Periods Combined\textsuperscript{a}.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Patients with Duplicate AHP (N=71)</th>
<th>Patients without Duplicate AHP (N=1265)</th>
<th>Statistic and P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (±SD)</td>
<td>56 (±17) Range (23-93)</td>
<td>53 (±18) Range (18-99)</td>
<td>(t = 1.53, p = 0.13)</td>
</tr>
<tr>
<td>Gender (%female)</td>
<td>30 (42%)</td>
<td>627 (48%)</td>
<td>(\chi^2 = 1.02, df = 1, p = 0.33)</td>
</tr>
<tr>
<td>Race (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>4 (5.6%)</td>
<td>45 (3.5%)</td>
<td>Contingency coefficient = 0.05, (p = 0.56)</td>
</tr>
<tr>
<td>Black</td>
<td>16 (22.5%)</td>
<td>323 (24.9%)</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>34 (47.9%)</td>
<td>667 (51.5%)</td>
<td></td>
</tr>
<tr>
<td>East Indian</td>
<td>2 (2.8%)</td>
<td>13 (1.0%)</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>15 (21.1%)</td>
<td>239 (18.5%)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>8 (0.6%)</td>
<td></td>
</tr>
<tr>
<td>Order Status (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Routine</td>
<td>56 (78.9%)</td>
<td>1102 (85.1%)</td>
<td>(\chi^2 = 2.02, df = 1, p = 0.17)</td>
</tr>
<tr>
<td>Stat/Timed</td>
<td>15 (21.1%)</td>
<td>193 (14.9%)</td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>7 (9.9%)</td>
<td>56 (4.3%)</td>
<td>(\chi^2 = 4.69, df = 1, p = 0.04)</td>
</tr>
<tr>
<td>Disposition from Hospital Home/Rehab</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home/Rehab</td>
<td>52 (72.2%)</td>
<td>1108 (85.6%)</td>
<td>(\chi^2 = 7.98, df = 1, p = 0.009)</td>
</tr>
<tr>
<td>Long-term Care/Death</td>
<td>19 (26.8%)</td>
<td>187 (14.4%)</td>
<td></td>
</tr>
<tr>
<td>Length of Hospital Stay in days (±SD)</td>
<td>12.3 (±17.2) Range (0-104)</td>
<td>8.7 (±11.9) Range (1-117)</td>
<td>(t = 1.76, p = 0.08)</td>
</tr>
<tr>
<td>Month Test Requested</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>January</td>
<td>25 (35.2%)</td>
<td>399 (30.8%)</td>
<td>Contingency coefficient = 0.12, (p \leq 0.001)</td>
</tr>
<tr>
<td>February</td>
<td>15 (21.1%)</td>
<td>416 (32.1%)</td>
<td></td>
</tr>
<tr>
<td>March</td>
<td>26 (36.6%)</td>
<td>466 (36.0%)</td>
<td></td>
</tr>
<tr>
<td>April</td>
<td>5 (7.0%)</td>
<td>14 (1.1%)</td>
<td></td>
</tr>
</tbody>
</table>

\textsuperscript{a}April data include only 6 days of observations. AHP = Acute Hepatitis Panel; Chi-square = \(\chi^2\); df = degrees of freedom; t-test = \(t\).
Figure 6: Not Duplicated Group Shows Consistent Ordering Pattern Across Months; Duplicated Group Shows Greater Variability in Ordering Patterns Across Months (introduction of computerized alert was the likely factor contributing to this discrepancy).

Note: April data includes only 6 days of observations.

For the logistic regression analysis, patient, test, and system factors (including the computerized alert status) found in the univariate analyses to be strongly associated with duplication (p-value < 0.20) (Table 6) were included in the analyses. This was done in order to assess which factors (including the alert) had the strongest association with duplication and allowed for controlling for potential confounders to be able to truly assess the impact of the alert as an independent predictor of duplication. Duplication was defined by the AHP test being performed on the same patient more than one time within a 15 day time period of the initial result being present in the EMR.

Adjusted OR with 95% confidence intervals were calculated and presented in Figure 7. Results specifically for: alert status, month of test, length of stay, disposition, mortality, test priority, and age are summed up in Table 7. Confidence intervals for all ORs contained the value of 1.0, except for the computerized alert status. The only independent predictor of duplication
was the presence of a computerized alert, regardless of severity of illness, time of year, length of stay, test priority, or patient’s age.

Figure 7: Adjusted Odds Ratios for Patient, Test, and System Factors Relative to Duplication are Presented in the High-Low Graph with 95% CIs.

Note. Using combined data from both 2010 and 2011, potential predictors of AHP test duplication (dichotomized into patients with duplicated versus not duplicated tests) were assessed using logistic regression analysis. Duplication was defined by the AHP test being performed on the same patient more than one time (at least two tests on the same patient). CI = confidence interval.
Table 7: Adjusted Odds Ratios with a 95% Confidence Interval for Patient, Test, and System Factors Relative to Duplication in 2010 and 2011 Pre- and Post-alert Study Periods Combined.

<table>
<thead>
<tr>
<th>Patient, Test, and System Factors</th>
<th>Adjusted Odds Ratios</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alert Status</td>
<td>0.32</td>
<td>0.18-0.55</td>
</tr>
<tr>
<td>Month Test Requested</td>
<td>1.11</td>
<td>0.84-1.47</td>
</tr>
<tr>
<td>Length of Stay</td>
<td>1.01</td>
<td>0.99-1.03</td>
</tr>
<tr>
<td>Disposition</td>
<td>1.46</td>
<td>0.67-3.21</td>
</tr>
<tr>
<td>Mortality</td>
<td>1.51</td>
<td>0.55-4.18</td>
</tr>
<tr>
<td>Test Priority</td>
<td>1.30</td>
<td>0.71-2.39</td>
</tr>
<tr>
<td>Age</td>
<td>1.00</td>
<td>0.99-1.02</td>
</tr>
</tbody>
</table>
CHAPTER 5: DISCUSSION

This chapter presents a discussion of the findings from this study. Results are examined and compared to previous research in the area of unnecessary laboratory duplication and to the conceptual framework. Implications for advanced nursing practice and recommendations for future research in the area of improving efficiency of care and reducing unnecessary duplication of laboratory testing are discussed. Limitations of this study are identified and conclusions are presented.

Discussions of Findings and Recommendations for Future Research

This multi-phase study evaluated quality of care through the measurement of performance as it relates to efficiency by evaluating the total amount of duplicated laboratory tests in the hospital setting during a single admission and the cost associated with this process. This study evaluated cost and resource use associated with unnecessary duplication of laboratory tests. In addition, this study evaluated processes of care to determine if the implementation of a computerized alert would reduce unnecessary duplication of the AHP and reduce the associated costs of redundant AHP tests.

Study findings indicated that 4.6-8.7% of commonly ordered diagnostic tests appeared to be redundant. These percentages are consistent with data from a defined group of commonly performed tests from one other study (Bates et al., 1998), but lower than percentages reported by other studies (Bates et al., 1999; Kwok & Jones, 2005; Nies, et al., 2010). It is difficult to determine why the duplication proportions were higher in some of the other studies than those obtained here. The differences may be related to the differences in the amount of overall tests performed in each test category in this hospital system, as compared to the amounts performed in
other studies (i.e. regional variations) (Bates et al., 1998; Bates et al., 1999; Kwok & Jones, 2005; Nies et al., 2010). Furthermore, these differences may be because the selected tests chosen for analysis in this study may be duplicated proportionally less than those tests selected for evaluations in other studies (Kwok & Jones, 2005; Nies et al., 2010) or because these tests were not evaluated in other studies (Bates et al., 1998; Bates et al., 1999). Variations in ordering practices presented by other studies suggest that some of the test-ordering practices are suboptimal (Jackson, 2007).

This study found the overall yearly costs associated with duplication of six selected tests for inpatients, during one hospital stay, in one local tertiary care facility, were an estimated $419,218. However, these cost estimations may be overestimated. The costs were calculated using the actual 2011 charge for each test. Laboratory charges are generally much higher than the costs associated with performing each test because they do not include the indirect costs (Bates, et al., 1998). Despite this, and the fact the proportion of duplication of the six selected tests is small, it can easily be reasoned if this rate of duplication occurred on the wide range tests, the costs of duplication could affect overall hospital revenue in a single facility. Multiply this number by multiple hospitals across the U. S. and it can easily be seen how such duplication encumbers the already burdened health care system and contributes needlessly to inflated healthcare costs in this country.

Of the six test categories (Table 1), the largest portions of redundant tests were TSH tests, resulting in an estimated yearly cost of $300,987 and B12/Folate test, resulting in an estimated yearly cost of $10,395. It is difficult to place these findings in context since there are no published studies available describing unnecessary duplication and associated costs of duplication of these two tests. However, discovering ways to reduce redundant TSH tests
represents a great target, because changes in the actual TSH level fall behind the serum TSH levels, and in most circumstances the level should be reevaluated no sooner than 4 weeks (Heuston, 2001). Thus, finding ways to reduce the number of redundant TSH tests can be a way to improve system efficiency. Similarly, targeting reduction in B12/Folate test duplication is important, as repeating this test in the hospital is rarely indicated. If the initial B12/Folate level is abnormal, supplementation of the deficient vitamin is clinically indicated (Smellie, et al., 2005). Although there are no definite published guidelines recommending supplementation duration and monitoring of B12/Folate levels, repeat levels are generally not necessary unless the cause of the deficiency (i.e. alcohol abuse, malnutrition) persists. Furthermore, patients on supplementation should, by definition, not become vitamin deficient and there is no obvious cause for repeating these levels unless lack of compliance is suspected or anemia recurs (Smellie, et al., 2005).

Of the total number of requested tests in each test category, 15.2-22.9% were entered into the EMR to later be cancelled, contributing to the overall system workload. The reasons for the cancellations varied and could stem from duplicate tests or patient discharges. Although the reasons for the cancellations were not fully evaluated in this study, it may be one area in need of further research to determine if an overall reduction of test cancellations correlated with reductions in staff workload requirements and could reduce overall resource use in this area.

Similar to previous studies evaluating various computerized alerts (Bates et al., 1999; Neilson et al., 2004; Nies, et al., 2010), this study demonstrated a significant reduction in the total proportion of AHP tests after the initiation of the computerized alert intervention. By February 2011, the trend of duplicated AHP tests dropped and remains consistently lower throughout April 2011, as compared to the same time in 2010. This is likely related to the initiation of the computerized alert on January 5th, 2011. Once the clinicians using this EMR
were familiar with the alert, the proportion of duplicated AHP dropped significantly. This reduction equated to a significant reduction in associated costs of duplicate AHP tests after initiation of the computerized alert. Although there were more inpatients within this tertiary care hospital system during the 2010 pre-alert study period, there were more AHP tests ordered during the 2011 post-alert study period. Even so, the proportion of duplication of the AHP tests was significantly lower during the post-alert time period. This further suggests the reduction in the proportion of duplicated AHP tests was impacted by the implementation of the computerized alert.

The patient, test, and system factors were similar in patients with duplicated AHP tests across the pre- and post-alert periods, with the exception of the month the duplicate test was requested. This is likely due to initiation of the computerized alert, whereas the proportion of duplicated tests were proportionally lower from February through April 2011, post-alert initiation. Thus, the alert worked overall, and not just on certain kinds of patients. These rates further indicate there is no alert fatigue in play. Rates of duplicated tests remain low in the months following alert implementation. This study attempted to identify patient, system, and test factors predictive for duplication of the AHP tests and found the only factor predictive for duplication of the AHP test was the computerized alert intervention, which reduced the number of redundant AHP tests.

After combining the two groups, those with and without duplicate AHP tests, results indicated the patient, test, and system factors were similar among those during the pre-alert study period in 2010 and the post-alert study period in 2011, with the exception of mortality and disposition (home/short-term rehab verses long-term care/death). Disposition to home/short-term rehab was proportionally higher in those patients without duplicate AHP tests. Conversely,
disposition to long-term care or death was proportionally higher patients who had a duplicated AHP test. Mortality and disposition to long-term care/death were proportionally higher in patients who had a duplicate AHP test performed. Mortality and disposition are considered surrogate markers for severity of illness. Hence, this may indicate that patients who had redundant tests were generally sicker than those patients who did not. However, further data and analysis would be needed to determine if illness severity explained this increased risk for having a duplicated AHP test.

**Limitations of Study**

This study has several limitations. First, study methods had limited rigor. This study was conducted in one tertiary care organization with multiple facilities within the organization, which may limit the ability to generalize findings to other facilities or outpatient settings. Also, the list of selected unnecessarily repeated laboratory tests is not all-inclusive. Additionally, using a non-randomized quasi-experimental design to examine the effect of a computerized alert on duplication of AHP tests may not be as powerful in establishing causal relationships between interventions and outcomes as a true experimental design.

The second limitation is related to using the actual 2011 hospital unit charge for each test for determining the costs associated with unnecessary duplication. To accurately assess total costs of performing redundant laboratory tests, total costs and associated resources (i.e. staff, equipment, test tubes, etc.) would have to be included in the calculation. Moreover, the actual test charge for each test is usually more than the overall costs to run the tests (Bates, et al., 1998), probably resulting in an overestimation of total costs associated with duplicate testing.
The third limitation is that the CPOE system was not mandatorily used in all facilities in this organization until October 2011. Consequently, it is possible that some of the cancelled tests occurring in the pre-alert period were not recorded in the EMR. However, the use or nonuse of the CPOE system had no impact on access to laboratory test result data. The laboratory data prior to October 2010 was stored in a separate computer system within the laboratory and transferred into the EMR and available electronically during pre- and post-alert time periods.

**Implications for Future Research**

Findings from this study argue for research to determine if the reduction of duplicated AHP tests following the implementation of the computerized alert are sustained over time or if the phenomena of alert fatigue would prohibit sustained reductions. This finding would support research regarding the utilization of a computerized alert with other laboratory tests, with evidence-based, test-specific time intervals, demonstrating reductions in the total amount and subsequent costs of unnecessarily duplicated tests. For example, research is needed to determine if the use of a computerized alert, set with a 4-week test specific time limit, would reduce the total number of duplicated TSH tests and/or affect treatment plans or patient outcomes. Furthermore, research is needed to determine if the implementation of a B12/Folate computerized alert would reduce its unnecessary duplication. The findings from this study regarding the AHP computerized alert argue for the success of a TSH or B12/Folate computerized alert. Research is also needed to evaluate the effect of the alerts on the diagnostic reasoning process. This research could help to develop more intelligent computer decisions support.
Lessons learned during the data collection phase of this study have implications for research planning and procedures. For example, the data obtained from the IT report writer was initially found to have a discrepancy in the amount of duplication of the ANA tests, leading to a recollection of the data by the primary investigator. The original data file reported the ANA was duplicated even if it wasn’t by “seeing the duplicate” as the pattern result of the ANA, if the ANA test was positive (i.e. positive ANA plus pattern result was read as two test instead of one). The IT department report writer, during the screen for all ANA tests, requested ANA (ab) and ANA (abs). The ANA (abs) portion in the system referred to the pattern and was not a duplicate ANA test. This is an example of a lesson learned during this study and an important consideration for researchers performing electronic chart reviews using historical data. It demonstrates the need for careful collaboration with the IT department report writer to assure that the data provided is clearly demonstrating the data being asked for and the need for data verification prior to analyses.

**Implications for Advanced Practice Nurses**

The results of this study suggest the proportion of duplication of the six selected tests and the associated costs of such duplication is a significant problem. This has clear implications for APNs because they are charged with improving population health, including directing resources into appropriate areas and reducing waste in other areas. Moreover, the results of this study suggest particular strategies the APN can employ to reduce costs associated with needless duplication of diagnostic tests. Strategies these APNs could employ include, collaborating with the IT team to implement computerized alerts for the TSH and B12/Folate tests, with evidence-based test-specific time periods, and monitoring and evaluating their healthcare system’s
laboratory utilization. APNs could investigate test-ordering behaviors in their own systems to
determine if the implementation of computerized alerts on certain laboratory or radiographic
studies would reduce health care costs in their system.

In this study, substantive and needless costs associated with unnecessary diagnostic test
duplication were observed. The findings of this study suggest a reduction in the duplication of
the AHP test using the computerized alert intervention. Healthcare policy necessitates
demonstration of “meaningful use” of the EMR for funding of the EMR. APNs could replicate
this study in their facilities to determine what increased efficiencies in care could be possible
with elimination of duplicate testing and to demonstrate meaningful use of their own EMR.

**Summary**

The healthcare delivery system has a primary objective to maximize health, reduce
illness, and improve efficiency of healthcare resources (NQF, 2009). Redundant testing reduces
the quality of our healthcare system as it uses more resources than necessary (Ransom et al.,
2008). This study found small redundancies in six commonly run laboratory tests. However, the
total costs associated with these redundancies affects hospital revenue and reduces overall
efficiency of patient care. The implementation of the AHP computerized alert was shown to
reduce the number of redundant AHP tests and subsequent associated costs in one tertiary care
hospital system. This chapter discussed the findings of this study, its limitations, and
implications for future research and for APNs.
APPENDIX A: UNIVERSITY OF CENTRAL FLORIDA INSTITUTIONAL REVIEW BOARD APPROVAL
Approval of Human Research

From: UCF Institutional Review Board #1
FWA/0000351, IRB/00001138

To: Sharon A. Bridges

Date: April 26, 2011

Dear Researcher:

On 4/26/2011, the IRB approved the following human participant research until 4/25/2012 inclusive:

Type of Review: UCF Initial Review Submission Form
Project Title: Duplicated Laboratory Tests: A Hospital Audit and Evaluation of a Computerized Alert Intervention.
Investigator: Sharon A Bridges
IRB Number: SBE-11-07561
Funding Agency:
Grant Title:
Research ID: N/A

The Continuing Review Application must be submitted 30 days prior to the expiration date for studies that were previously expedited, and 60 days prior to the expiration date for research that was previously reviewed at a convened meeting. Do not make changes to the study (i.e., protocol, methodology, consent form, personnel, site, etc.) before obtaining IRB approval. A Modification Form cannot be used to extend the approval period of a study. All forms may be completed and submitted online at https://iris.research.ucf.edu .

If continuing review approval is not granted before the expiration date of 4/25/2012, approval of this research expires on that date. When you have completed your research, please submit a Study Closure request in IRIS so that IRB records will be accurate.

In the conduct of this research, you are responsible to follow the requirements of the Investigator Manual.

On behalf of Kendra Dimond Campbell, MA, JD, UCF IRB Interim Chair, this letter is signed by:

Signature applied by Joanne Muratori on 04/26/2011 10:15:05 AM EDT

IRB Coordinator
APPENDIX B: FACILITY INSTITUTIONAL REVIEW BOARD APPROVALS
April 25, 2011

Sharon Bridges FNP-BC, MSN
1111 Arbor Hill Circle
Minneola, FL 34715

Dear Ms. Bridges:

Concerning the following Study:
Our Study # 1103504
Protocol Title: Duplicated Laboratory Tests: A Hospital Audit and Evaluation of a Computerized Alert Intervention

Under federal guidelines for expedited review, I have reviewed and approved the fact sheet and protocol for your project stated above. The study is approved under 21CFR 56.110 (b) (1) for this project since it presents no more than minimal risk and under Category 5 for expedited review which is research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes. The waiver of informed consent is approved under 45 CFR 46.116 (d) and 45CFR 46.117(C)(2) for this project since it presents no more than minimal risk and protected health information will be de-identified. The Chair has approved this study at all Orlando Health, Inc. facilities and your office. The Institutional Review Board review process is in compliance with GCP’s and included review of potential risks to subjects, risk benefit ratio, subject selection criteria and safety, content of the informed consent, confidentiality and appropriate safeguards. The project was reviewed in detail on 4/18/2011. It will be sent to the 5/5/2011 Institutional Review Board meeting and be reviewed by a majority of membership with quorum present.

Subjects may be enrolled in your project from the date of this letter through 4/17/2012. For approval to be extended after that date, a continuing review report must be submitted to the Institutional Review Board meeting prior to the deadline date. A form for continuing review is available on the IRB website (click “For Medical Professionals”) at www.orlandohealth.com. If you wish to terminate your project before the expiration date, please notify the IRB office at 321-841-5895.
Institutional Review Board approval is contingent upon:

1. Per the guidelines for expedited review and approval, you may begin enrollment as of the date of this letter. However, enrollment may not continue after the expiration date. This expedited information will be submitted to the Institutional Review Board for final review.

2. Modifications to protocol must be approved prior to implementation unless they reduce immediate danger to subject.

3. All protocol deviations must be reported to Institutional Review Board within 5 working days.

4. FDA requires you to notify the IRB of any change of Investigator or site location, amendment or changes in the protocol, significant protocol deviations, or termination of the study. Please note that you must submit all protocol amendments to the Chairman, prior to implementing the amendment.

If you have any questions, please feel free to contact the IRB Office at 321-841-5895.

Sincerely,

[Signature]

Richard Hornick, M.D.
Chairman of Institutional Review Board
APPENDIX C: DEMOGRAPHIC CHARACTERISTICS FOR PATIENTS WITH APH TESTS IN FIRST QUARTER 2010 COMPARED TO Q2, Q3, AND Q4 2010 (COMBINED) TO ASSESS IF SAMPLE REPRESENTS REST OF YEAR
|                                | Patients in the 1<sup>st</sup> Quarter of 2010  
|                                | N=657                                      | Patients in 2<sup>nd</sup>, 3<sup>rd</sup>,  
|                                |                                            | and 4<sup>th</sup> Quarters of 2010  
|                                |                                            | N=1857  
|                                | Statistic and p Value                      |                                |
| Age in years (±SD)             | 54 (±18) Range (24-93)                     | 53 (±18) Range (23-89)  
|                                | t = -1.25, p = 0.21                       |                                |
| Gender (% female)              | 329 (50.1%)                               | 895 (48.2%)  
|                                | χ<sup>2</sup> = 0.69, df= 1, p = 0.41      |                                |
| Race                           |                                |                                |                                |
| Asian                          | 22 (3.3%)                                | 44 (2.4%)                           | Contingency coefficient = 0.04,  
| Black                          | 158 (24.0%)                               | 491 (26.4%)                         | p = 0.46                          |
| Caucasian                      | 338 (51.4%)                               | 930 (50.1%)                         |                                |
| East Indian                    | 10 (1.5%)                                 | 18 (1.0%)                           |                                |
| Hispanic                       | 124 (18.9%)                               | 363 (19.5%)                         |                                |
| Other                          | 5 (0.8%)                                  |                                |                                |
| Order Status (%)               |                                |                                |                                |
| Routine                        | 541 (82.3%)                               | 1546 (83.3%)                        | χ<sup>2</sup> = 0.28; df = 1;  
| Stat/Timed                     | 116 (17.7%)                               | 311 (16.7%)                         | p = 0.59                          |
| Mortality                      | 32 (4.9%)                                 | 76 (4.1%)                           | χ<sup>2</sup>=0.71; df = 1;  
|                                |                                          |                                          | p = 0.43                          |
| Length of Hospital Stay in days (±SD) | 8.7 (±12.2) Range (1-117) | 9.4 (±12.3) Range (1-208) | t = 1.13, p = 0.26 |

Note. N = number; Chi-square = χ<sup>2</sup>; df = degrees of freedom; t-test = t.
LIST OF REFERENCES


http://www.tizag.com/javascriptT/javascriptalert.php


