Creating Safety in the Diagnostic Testing Processes of Family Medical Practices

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CREATING SAFETY IN THE DIAGNOSTIC TESTING PROCESSES
OF FAMILY MEDICAL PRACTICES

A thesis submitted in partial fulfillment
of the requirements for the degree of
Master of Science

By

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B.S., University of Utah, 2005

2008
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ABSTRACT


Four mid-Western family practices were studied using three methods (observations, interviews, and an audit of patient records) in effort to discover the dynamics and constraints of their diagnostic testing processes. We have found further evidence that errors do occur at many of the steps in the processes, but that the patterns of those errors are not independent of each other and are a function of systemic factors unique to each practice. Furthermore, while many employees or steps in the process may be considered a source of error, they were also shown to be major sources of quality and safety in their testing respective systems. Safety was created when employees recognized the natural feedback loops that allowed them to learn to compensate and correct errors.
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ACKNOWLEDGMENTS

Although this document only bears my name, it has been a collaborative project with someone who has become a good friend, Nancy Elder. I want to thank her for extending an invitation to me to cross over into the domain of family medicine for my research. I have certainly learned many valuable lessons through our collaboration.

I would also like to thank John Flach, my other co-advisor, for allowing me to go out into the world and break the traditional experimental paradigm that is typical for a Master's thesis. I hope that this document will be able to open the doors to others who wish to do something non-traditional. John’s efforts have guided me (in this sometimes messy process) and helped me produce a valuable piece of research.

This has been a long process and I am thankful to my wife and daughter for their support and understanding as I have had to dedicate myself feverishly to accomplishing this task. This is for all of those nights that Rebecca has had to go to bed without me.
I. INTRODUCTION TO MEDICAL TESTING

1. A Walk Through the Testing Process

The physician had just finished examining his patient, a woman in her mid-forties, who had come in for what he referred to as a “yearly checkup.” The patient appeared to have been in good health and so the physician decided to order three tests: a Pap smear, a mammogram, and a lipid panel. As the physician indicates the ordered tests on the test requisition form, he turns to the patient and tells her about how they will proceed with the planned screening tests.

“After I take the sample for your Pap, you will need to go over to the lab area and have a phlebotomist draw some blood for the lipid panel. When you get home, you will need to schedule a mammogram on your own because we don’t have the facilities here,” said the physician. She then remarked, “when you have your appointment set up, call us back and let us know when and where the appointment is scheduled.”

After having explained this to the patient and after taking the Pap specimen, the physician excuses herself and steps out of the room. Outside of the exam room, the physician calls for her MA to take the specimen to the lab area where it will be processed and sent to the reference laboratory to be analyzed. After handing the specimen to the MA, the physician returns to the exam room and begins to speak to the patient, “Ok, your Pap is on its way to the lab, so unless you have any questions, you are free to go.” The patient does not have any questions, so the physician reminds her, “Don’t forget to go have your blood drawn for the lipid panel.”
Leaving the patient to gather her belongings, the physician gathers the patient’s chart, exits the exam room and starts toward the nurse’s station. At the station, the physician sets the chart down, on top of an already growing pile of charts, and grabs a test requisition form from a hanging wall folder nearby. As the physician begins to fill out both the test requisition form and the encounter form, which is used for recording the services provided, she begins a conversation with her office nurse, who had just finished speaking on the phone with another patient. The physician explains what she had done with the patient and asks the nurse to remind the patient to schedule a mammogram.

“Sure,” says the office nurse, “I will if I’m here when she comes out. The patient on the phone called for her test results again and I can’t find them or her chart. The records department can’t find the chart either. I need to go look for them so I can call her back.” As the nurse says this, the physician grabs another form, a referral for outside testing, fills it out, and then hands it to the office nurse, asking, “Will you give this to the patient when she comes out?”

By this time, the MA walks by and says to the physician, “Your next appointment is waiting in room three.”

“Ok, I’ll be there in a minute,” replies the physician as she turns to the MA and asks, “will you finish filling the requisition and encounter form out for me? I haven’t had a chance to look at my next patient’s chart yet.”

“No problem,” replies the MA as she takes the forms and takes a seat at another nurses’ station around the corner so she can finish filling out the forms. She sits down and begins to enter the test requisition into the terminal that is connected to the lab area. Before she can finish, the phone begins to ring. After a few rings, nobody seems to be answering the phones, so she peeks around the corner and sees that nobody is in the office nurse’s area. “I guess that means I’ll get the phone.”
At this point, the patient has finished gathering her belongings and exits the exam room. On the way out of the exam room, she passes the empty office nurses’ area and begins to head out the door towards the exit. As the patient begins to open the door toward the waiting room, the office nurse returns to her area after having just come back from looking for a missing chart, which she had located in the physician’s private office. “Ms. Jones,” calls the office nurse to the patient as she begins to step out the door, “before you go, I need to see you.” At this, the patient returns to the office nurses’ station. The office nurse gives the patient the referral form and explains, “When you call and make an appointment for the mammogram, you need to call us back and let us know when and where the appointment is. Give them this form when you have the mammo done.”

The patient tells the office nurse that she understands that she needs to call back and then asks where the lab area is so that she can have her blood drawn.

The office nurse then begins to give directions to the lab area when the MA returns with the completed requisition and encounter forms. “One more thing, you need to take this encounter form to the front office before you leave,” says the MA, and then adds, “I guess I could just show you where the lab is, if you want to follow me.” The patient agrees to this and the two head towards the lab.

Upon arrival at the lab, the MA gives a copy of the encounter form to the patient and takes the other half with her to put into the chart. The MA then tears one of the copies of the requisition form and hands it to one of the phlebotomists. The MA then introduces the patient to the phlebotomist and explains that the physician wanted the patient to have a lipid panel.

“Sounds good,” responds the phlebotomist, “we got the printed requisition just a few moments ago from our printer after you entered it into the computer. We were waiting for her to get here.” “It sounds as if your story and our story match up,” notes the
At this, the patient sits down in the drawing station and prepares to give some of her blood. Seeing that the patient is safely in the lab, the MA returns to her other duties. The phlebotomist, on the other hand, begins to draw the patient’s blood and prepare the Pap specimen for courier pick-up. When the blood has been drawn, the patient takes the encounter form and goes to the front desk to check out. After checking out, the patient leaves for home to make an appointment for a mammogram and to await the test results.

Two days pass and the lipid panel results return by a special printer in the mailroom that is connected electronically to the reference laboratory. One of the office nurses walks into the mailroom to grab her physician’s mail and sees a stack of test results. She then begins to sort and file them into mailboxes according to the ordering physician. After filing the results, she returns to the nurses’ station and begins to affix the results to their respective charts. As she attaches each result to the front cover of the chart for review, she reviews it herself and highlights critical and abnormal results. She has previously noticed that her physician has not always signed every result and has on occasion signed off on critical results as if they were normal. Since the physician that she works with made these errors, she makes it a point to regularly review the results and highlight abnormal results before she gives them to the physician for review. Her training as a registered nurse allows her to do this, but she knows that some of her fellow office nurses may not have the training to double check their physicians’ work because they are not technically nurses (their title is merely nominal). When she is done screening the results, she pushes aside a few piles of papers and charts which are stacked across her desk space to clear a spot for the new pile of charts with results that need to be reviewed by the physician.
The physician, after seeing a patient, walks over to the nurses’ station and sees a new stack of charts that was not there a few moments ago. “Are these charts for me to review?” she inquires.

The office nurse affirms that they are and the physician grabs the stack of about 15 charts and spends a few moments reviewing each of the charts, signing her name on each of the results pages. A few minutes pass, and the physician becomes aware that the MA has not alerted her about any patients awaiting her, so she continues working on the charts. After a few minutes, she comes to Ms. Jones’ chart.

“Looks good,” says the physician to herself, as she places her signature and a quick note about the good results on the result sheet. She then asks, “Any word on our patient having scheduled a mammogram?”

“Nope, but I’ll check with the billing office,” replies the office nurse.

“If she hasn’t, will you please call and remind her to make the appointment?” asks the physician. At this, the MA appears and tells the physician that there is a new patient in one of the exam rooms, and the physician leaves. The office nurse takes the results sheets and begins to make copies of them so that she can mail them to the patient. After making the copies, the phone begins to ring off the hook. Between the phone calls and physician requests, she is not able to return to the letters until much later that day. As the end of the workday draws near, the office nurse forgoes her double-check of the physicians’ signatures of the results in order to get the letters ready to mail. She places the original result into each chart and then sets the charts in a basket to be picked up by the file room workers to be placed back on the shelf.

As she places the charts into the cart, she recalls that Ms. Jones’ chart was still awaiting the Pap and mammogram results, so she pulls them out of the cart and sets them on her desk to await the results. “I know this really annoys the file room workers,” she
thinks to herself, “but I’ll forget to check on the results if I send it back.”

Two weeks pass and the Pap results return from the lab but are mistakenly thrown away when it sticks to the back of a piece of junk mail, but nobody was aware of this. Meanwhile, the office nurse is again searching through the charts on her desk for test results that had been requested by another patient, she sees the chart of Ms. Jones. The sight of the chart triggers her memory, and she begins to wonder why the chart is still on her desk. After all, the test should have been back by now. After finding the results, she calls the reference laboratory to ask about Ms. Jones’ missing result.

The reference laboratory technician picks the phone back up and reports that the results were sent yesterday, but that he would be happy to send them again. To make sure she does not miss the results again, the office nurse checks the printer periodically throughout the day until the results return. When they arrive later that afternoon, she takes the results and places them on the front cover of the patient’s chart, and sets it on top of the pile of charts that needs reviewing that day.

II. The Problems of Medical Testing

The previous narrative provides a typical example of the testing process in action, which subsequently may not inspire much confidence in the reader about the quality of the testing process. It has been estimated that at least one diagnostic test is ordered on behalf of a patient in an 29-38% of primary care visits (as cited in Hickner, Fernald, Harris, Poon, Elder, and Mold, 2005). Considering that the National Center for Health Statistics (2006) estimates that there were over 910 million visits to physician’s offices in 2004, there are at least 264-346 million tests ordered yearly in the United States. This number grows even larger considering that the previous statistic only reflects the ordering of a single test per visit, and as the previous narrative suggests, many tests may be ordered at one time. With
the large number of people that have medical tests completed, if errors occurred in only a small fraction of these tests, the health of millions of people may be at risk.

Unfortunately, the matter is not if they occur, but when errors. The medical literature is rife with error estimates, examples, and taxonomies of medical errors (Kohn, Corrigan, & Donaldson, 2000; Dovey, Meyers, Phillips, Green, Fryer, Galliher et al., 2002; Hickner, Graham, Elder, Brandt, Emsermann, Dovey et al., 2008). To make matters worse, it appears that not only do errors occur during the medical testing process, but there is no single step in the testing process that is immune from the occurrence of error (Hickner et al. 2005).

The purpose of medical testing is to increase the quality of healthcare of a patient by producing information that will be used to treat the patient and provide a means by which follow-up care can be administered. Information gained from medical testing is only effective when it leads to increased healing or decreased suffering through more accurate diagnosis and treatment of medical conditions. When tests are never ordered, misfiled, lost, never reported, or followed-up on, then the information from medical tests has become less effective, less safe, or may even become counterproductive.

III. Why this Research?

With all of the research already completed on medical error, what does this research have to offer that has not already been stated elsewhere? We feel that our research will add to the existing corpus of research by approaching the topic from a different angle. Many investigations and research articles on medical safety tend to focus on identifying and naming errors, which errors are then categorized and incorporated into large medical error taxonomies (e.g. Linnaeus-PC Collaboration, 2002). The identification and counting of errors has an intuitive appeal because it provides a numerical metric of
how safe that system supposedly is. Once the errors have been “discovered,” recommendations are provided to avoid the occurrence of such errors in the future. However, there are two major drawbacks with this type of approach to improving system safety that stems from the need to operationally define “error” in order for it to become observable and countable. By operationally defining errors, context is often stripped from the whole phenomenon in this counting and naming paradigm, leaving only meager portion of a much richer story and phenomenon.

The second problem is that context-free errors frequently implicate the human as the culprit in error research and investigations. Stopping at the level of human operator has some face value, since the human is often the most proximal, both spatially and temporally, to the accident or error. Investigations into why a test result was not signed off might result in findings such as “loss of situational awareness” because the physician was thinking about other things instead of focusing on the test results or the physician was too busy to spend an adequate amount of time reviewing the charts. With either case, the physician seems to be at fault, but is that the whole story? By moving further back in the causal chain of events, we might see a much richer description that provides more insight into the phenomenon than just that of the physician’s “error” as the cause of the accident.

For instance, if a physician was too busy to do an adequate job, why was she so busy? Perhaps there were too many patients scheduled that day, leaving little time to review the results in the charts. Perhaps on top of the limited time, the physician’s regular MA was gone, leaving a substitute MA who was less efficient than the regular MA to fill in because she was not familiar with the way that this physician worked, leading to the physician having even less time than normal. But why was the schedule packed so tightly and why was the MA gone in the first place? The schedule was packed tight because it was flu season and more patients were trying to be seen and the office is encouraging more
patient appointments because the office was struggling financially. The MA was gone on vacation because she was scheduled to leave during these weeks. Why was the MA allowed to leave on vacation during flu season and why is the office struggling financially? The questions could be asked *ad infinitum*. Each question leads the investigator further and further away from the accident proper, but each step down the “causal chain” in the investigation shows that there are multiple “causes” of the accident or error. None are sufficient in of themselves, but all necessary to come together at one point in time. Accidents are the result of the confluence of multiple factors, not from a single component.

What is it that makes a cake? Is it the eggs, the flour, sugar, or the heat from the oven? It is the combination of all of the above in the proper sequence and conditions.

This is why investigations must move away from the concept of “human error” as the *cause* of error and recognize that human error is, instead, a *symptom* of the problem. This requires an investigator to rethink the notion of cause and effect (Dekker, 2002). As a symptom, “human errors” should be the starting point for error investigations rather than the finish line. Along these lines, Hollnagel (2006) has suggested an alternative approach to error investigations where “safety research should focus on the accidents that did not occur and try to understand why.” In so doing, the focus shifts from error to safety. This is the direction that we have taken our research to investigate the testing processes of family medical practices. By following this advice, we have changed our focus from *error* research to *safety* research by searching for behaviors and processes in the testing system that help make the testing system work in the first place. Simply stated, the purpose of this research has been to investigate the reasons why medical testing works most of the time, given that the process can fail at any step.
IV. Brief Methodological Overview

How does one begin to understand a sociotechnical system such as medical testing in order to look for factors that contribute to its safety? We have approached this challenge through conducting an analysis of the work domain. There are multiple such analyses, which Roth (2008) has denoted as “cognitive analysis methods.” Some of these methods include “Work Domain Analysis” (Rasmussen, Pejtersen, & Goodstein, 1994), “Cognitive Work Analysis” (Vicente, 1999) or Cognitive Task Analysis (CTA; Crandall, Klein, & Hoffman, 2006). Despite their minor differences, all share the goal of explaining a work domain in terms of how work is accomplished in the face of complexity, uncertainty, and time pressure. The research from this thesis will serve those who are involved in patient safety programs by providing a stronger foundation and appreciation for the workspace in which health care workers must navigate and reveal a clearer picture of what is important to the safety of the testing systems.

We have chosen an eclectic approach to our analysis of the work domain, primarily grounded in Crandall, Klein, and Hoffman's (2006) CTA, which consists of a combination of interviews, surveys, and observations to provide information that either method alone would miss. One of the interesting features of multi-method research in an analysis of a work domain is that the information gained from one method will inform the interpretation of results from the other methods. This synergistic relationship between methods and results necessitates a brief overview of each method at this point to provide an overall view of the process.

There were four methods used to collect data for this study that were approved by both the University of Cincinnati and the Wright State University Institutional Review Boards. The first included the use of surveys sent to the office managers and the clinical directors and inquired about the demographics of the patient base as well as the number
of physicians and other staff employed in the site. The second method included naturalistic observations and shadowing, where we walked through the sites making note of actions and conversations of the staff in regards to the testing processes. Observations also revealed which staff roles participated in the testing processes as well as who the key employees were. The third method was an audit of patient health records. The questions that we asked while reviewing the charts are indicators of good practice, both in terms of making sure that the patient is receiving the best possible care as well as making sure that the site has some legal protection by having adequate documentation. Semi-structured interviews with staff members constituted the final method. Interviewees were chosen to try to get a broad range of the types of problems and opportunities for catching errors that occurred during the various stages of the testing processes. The key employees, or those who seemed the most knowledgeable, were particularly sought for interviews.

Having provided an overview of the methods, it should now be noted that the second, third and fourth chapters of this thesis will describe the aforementioned methods in more detail as well as the results of our findings. The final chapter will discuss the findings in a larger, combined context and provide suggestions for improving medical testing.
2. COMPARING THE PROCESSES: LESSONS FROM NATURALISTIC OBSERVATIONS

I. Introduction

This chapter will provide some of the context in which those in the testing system find themselves. In doing so, we will lay a foundation for understanding some important questions about the safety of medical testing. We will address the question of the nature of medical testing in family practices in terms of the number of different testing processes the factors lead to those differences. We will also discuss the similarities of the testing processes between offices and some factors that lead to the unique variations of the processes.

A logical place to establish a foundation for understanding the testing processes would be to begin with a procedural baseline, such as what would be found in a standard operating policies and procedures (SOPP) manual. However, none of the observed sites possessed an SOPP manual for the testing systems to which we could go for reference. For lack of such manuals, we had to develop our own set of standardized operating procedures through observations and interviews to describe the testing systems at every site. We used previous research by Hickner, Fernald, Harris, Poon, Elder and Mold (2005) on the testing process as a general framework which led us to focus specifically on how each site ordered, implemented, tracked, responded to, documented, as well as notified and monitored patients.

The steps we focused on come from a basic normative model that is referred to as the Error-Free Testing Process (EFTP; Hickner et al., 2005; see Figure 1) since it assumes that the ideal error-free process would occur in this manner. The EFTP consists of three stages
that are each comprised of multiple processes. The first stage of the EFTP, the pre-analytic stage, consists of all of the preparatory work before a test specimen is analyzed by a medical laboratory such as requisitioning the test and gathering a test sample. The second, or analytic stage (which we were not concerned about in this research because it most often occurs off-site), consists of the physical processing of the sample at a medical testing laboratory. All the steps that occur once the laboratory has sent back the test results to the medical office such as test result tracking, return to the physician, physician response to and documentation of the results, patient notification and documentation thereof, patient monitoring, and follow-up make up the final, or post-analytic stage.

With the process parsed into these particular stages, the EFTP serves as a convenient way to describe the testing process in general functional terms (see Vicente, 1999). Although this model is accurate, we will show that the EFTP belies the involved and interactive nature of the testing process in practice.

Those involved in medical testing, such as medical assistants (MA) and physicians, will attest to the complexity of their systems, but even they have a limited understanding of them. One consistent finding throughout our research was that no single person in any of the sites knew what was happening throughout the entire testing process. Most physicians were unaware of what happened to the test requisition after it left their hands to go to their MA. Medical assistants could often not describe what happened once they
gave it to the front office staff. Not even the medical directors or office managers had a firm grasp of the system as it operated in their office.

If the testing process is more complex than the EFTP, so that even office managers and medical directors are missing the whole picture, what does the testing system really consist of? To answer this question, we needed to construct a model of the processes. The model took the form of a series of process flow charts to help describe what happens during the medical testing process.

II. Naturalistic Observation Method

A. Participating Sites and Staff

Four family medical practices in greater southwest Ohio were selected for participation in this study. This was a convenience sample, but the diversity of the sites covered a wide range of characteristics that are typical of family medical offices (see Table 1). The sites that we selected varied on geographic location (e.g. rural, suburban, urban), physician diversity (e.g. gender, race, ethnicity), practice size, technology level (e.g. paper charts [PC] or electronic medical record [EMR] systems), and whether the site had a residency program.

In exchange for participation, each site was given a $400 dollar honorarium. In addition, each site was also provided with a report that outlined what we felt to be the site’s strengths and weakness that we had discovered relating to their testing processes. The report included the process flow charts that had been created from observations and interviews, results from an audit of patient charts, and results of a survey that was given to patients about their experience with the testing process. Table 1 was constructed from the data collected via surveys that were completed by the office managers in advance of our visits.
B. Observation Procedure

As mentioned previously, we could not reference any SOPP manuals because no site possessed one. In order to have a standard with which we could make comparisons of what was normal or what was a “work-around,” we developed our own process flow charts for this purpose. The data used to create the process flow charts stemmed primarily from our observations at each of the sites. Our observations began with inquiries to staff members about the testing processes in general. As we tried to piece the processes together from this reported information, we quickly realized that incorrect and incomplete descriptions were being offered to us because employees themselves did not have a complete picture of the system. Although, we noted that employees who were cross-trained between multiple roles (e.g. such as MAs who took turns in the laboratory, file room, and helping patients or who had been “promoted” to a different role) were able to provide a larger and more accurate version of the processes than those who were only trained in a single role.

Table 1.
Site Demographic Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>Suburban</td>
<td>Urban</td>
<td>Rural</td>
<td>Suburban</td>
</tr>
<tr>
<td>FT:</td>
<td>7</td>
<td>2</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>PT:</td>
<td>6</td>
<td>2</td>
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<td>PT: 3</td>
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<td>0</td>
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</tr>
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<td>Total:</td>
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<td>9</td>
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<td>Total: 1</td>
</tr>
<tr>
<td>Number of Staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residency Practice</td>
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<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>EMR</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Labs Used</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

*Note. FT = Full Time, PT = Part Time, Res = Resident Physicians at Site 3*
Although the information given to us by the employees was not perfect, the information was enough to form a rudimentary (and often incorrect) description of the processes, which provided us with a starting point for further refinement through additional observations and clarification through interviews. Once a preliminary understanding of the process had been formulated and agreed upon, we divided up and visited separate locations throughout each site to observe the employees at work.

We observed employees in one particular location until we felt that we had an adequate understanding of the role of those employees in that area. When we felt confident that we had learned what happened at that stage of the process, we moved on to another location in the office and started again. At some point during the observations, we would observe an area that had already been observed by the other researcher. This redundancy was a planned mechanism for us to compare each other’s findings and determine if we had missed any important steps. We avoided observing patient-physician interactions for privacy reasons, although we did use information gained from patient-physician interactions that took place in public areas such as hallways or waiting rooms.

As we took notes from our observations, we also started to develop preliminary process flow diagrams for use as a reference in comparing normal operations versus workarounds. We also asked employees if they would verify the accuracy of these process flow diagrams during informal discussions as we observed them at work.

We also allotted about 10-15 minutes during each of the formal interviews to further discuss and refine the flow charts further. At the end of each day of observations, we meet together briefly and compare notes and flowcharts, revealing any discrepancies in the preliminary flow charts. We noted from our observations and interviews that we often received conflicting information from those whom we observed. As we tried to resolve these discrepancies with further observations and interviews, we realized that there was
no a single manner in which the testing process proceeded, but rather there were multiple ways that different teams preferred.

III. Results: The Realities of the Testing Process

The best way for us to describe the testing processes through the use of the flow charts. However, in order for the flow charts to have any meaning, we must quickly provide the key to understanding them. We will then follow-up with a brief introduction of the key test types, people, locations and documents involved to lay the foundation for what testing entails. We will then follow with a comparison of the differences found between the testing processes that were observed.

We found that in practice, there are multiple ways in which the steps of the testing process could be completed. A simple visual comparison between the EFTP (Figure 1, p 13) and the flow charts (see Figures 3 to 6, pp 21-24) quickly reveals that the testing processes requires more adequate detail than the six higher order steps displayed in the EFTP. This section will take the EFTP steps from their general function descriptions and decompose them into more specific, lower levels of abstraction in order to document them in our process flow diagrams so that we can compare the ways to complete the processes.

A. Reading the Flow Charts

The process flow charts follow a "swim lane" format that is organized according to the roles of the people that are involved in the testing processes. Along the left side of each of the flow charts is a column of roles (e.g. physician, medical assistant, etc.) which represent the particular roles that are relevant to that testing process. Not every role in the office is listed in this column because not every role in an office necessarily has a role in the testing process. All steps in the testing process that are completed by a particular
role will be found in boxes of various shapes along the lateral corresponding swim lane.
The shape of the box carries a particular meaning. Figure 2 summarizes the various shapes and their interpretations.

There are two different arrow types found throughout the flow charts. When possible, we tried to discover the alternative steps for completing the processes. The solid line indicates the most commonly observed (or reported pathway), while the dashed lines indicate the alternatives pathways.

The steps of the testing processes are grouped within one of two shaded gray areas (light and dark) which indicate their location in the three stages of testing. The steps that fall under the darker shaded area correspond to the pre-analytic stage as mentioned from the EFTP (Hickner et al., 2005). The lightly shaded area represents the steps of post-analytic stage. There is also a minor third area, the white space, which corresponds to the steps of the analytic stage. We refer to this as a minor area because we did not directly

Figure 2. The process flow chart legend.
observe anything in this stage because most tests are sent off-site for analysis, leaving us with very little to diagram.

Before proceeding, it should be noted that we have tried to make our boxes represent the same level of abstraction and detail, but in some cases we have combined steps into one box in order to make the boxes and connectors fit into a coherent picture of the process. We also were not able to observe every possible way in which one step leads to another, such as how the ordering and requisitioning occurs. For instance, we might not have observed an MA filling out the forms from a physician’s verbal order for an imaging test, but that does not preclude its possible occurrence. Since it is possible that we did not observe all possible behaviors and that staff may not have reported all other possibilities, we may have left some alternative pathways out of the flowcharts. Because we do not have every possible pathway represented in the flow charts, some caution is needed in comparing the steps of the flow charts together.

B. Test Types, Key People, Locations, and Documents

Having introduced the flow charts, we will proceed to discuss the testing processes in more detail. In particular, we will discuss the testing types, the employees involved in the testing processes, the various locations involved, and the various documents used. As can be seen from the flow charts, these aforementioned factors differed not only from process type to process type, but from site to site as well—hence the reason for developing 16 separate process flow charts rather than a single, all-encompassing chart.

Before moving forward, we need to clarify our terminology. The word process is often used synonymously with system, but we have differentiated between the two. We refer to the specific pathways for each category of test at each site as a process, while
1. Testing Types

While there are many different medical tests that can be performed, we noted that there are four major categories in which most tests used in family medicine would fit. These four categories of tests also determine the specific pathway in which an order is transformed into information that can be used to improve medical treatment. The pathways share many steps with their counterparts in other offices, but are still unique to that office.

**Imaging tests**

The first category that we noticed was diagnostic imaging, which included radiographs (X-ray images), magnetic resonance images (MRI), and computed tomography scans (CT). These tests were grouped together because the process required a specially trained technician to operate the imaging equipment in addition to specially trained physicians to interpret the images. We primarily focused on radiography during our research because it was more prevalent in the practices that we observed and we therefore had more opportunities for study the radiographic portion of the process. The processes for MRIs or CTs were reported to have followed the same pathway as the radiographs.

**CLIA certified tests**

The second type of test that we focused on was a group of laboratory tests that are classified as moderate or high complexity and must be performed in a certified laboratory. Both the tests and laboratories are regulated by a law known as the Clinical Laboratory Improvement Amendment (CLIA). We refer to this type of test as **certified tests or CLIA tests.** Example of certified tests would include prothrombin/International Normalized
Figure 3. Process flow for imaging tests at Site 1.
Figure 4. Process flow for imaging tests at Site 2.
Figure 5. Process flow for imaging tests at Site 3.
Physician
Treats patient
Prints lab order on printer
Informs patient about imaging test
Makes appointment for patient
Takes image

EMR
Database
Patient
Radiology Suite
Central Administration
MA

Figure 6. Process flow for imaging tests at Site 4.
Ratio (PT/INR), hemoglobin A1c (HbA1c), and complete metabolic panel (CMP). As technology becomes available, some CLIA certified tests, such as those previously mentioned are being waived (see next section) as long as the office has the proper equipment. However, none of the sites in which we did our research had this type of equipment.

**CLIA waived tests**

The third and fourth type of laboratory test processes consist of medical tests classified as low complexity and do not require CLIA certification. The *MA performed waived test*, such as a urine pregnancy test, strep (streptococcus) screening, or finger stick for blood sugar, can be completed by an MA with a physician’s order. The second waived test type, which we have termed a *physician performed waived test*, requires that a physician (or other provider) collect and analyze a specimen such as microscopic urinalysis, potassium hydroxide preparations, and cervical wet mounts.

2. People

Once the physician decides to order any test, multiple people become involved in the testing process so that the test requisition can be transformed into information that can be used to better care for the patient. This section describes the major roles of the people involved.

*Physicians/nurse practitioners*

Physicians are typically the initiators of the testing process when they make the decision to order a test, but there are some exceptions such as MAs routinely ordering and performing simpler tests for the patients with (and sometimes without) express permission of the physician. Nurse practitioners may also order tests. However, since physicians ultimately take responsibility for patients, we have referred to this role as *physician* on the flow charts.
Unless physicians are performing the test themselves, as in the case of a microscopy, they typically drop out of the testing process at this point until the test results return to be reviewed and a clinical decision must be made.

Nurses

We observed very few registered nurses (RNs) and only at Sites 1 and 3. Although highly trained, we noted that the RNs functioned more as MAs; doing more clerical work than traditional “nursing.” The RNs spent most of their time answering phone calls, organizing patient records, and filling out test requisitions. Although they did occasionally engage in direct patient care, most often it was care that could have been provided by an MA. Overall, we did not notice anything that would require a nurse to be labeled as anything but MA, in terms of the testing system and process flow charts.

Medical assistants

MAs are responsible for many clerical tasks relating to the testing processes (e.g. filling out test requisitions, tracking test results, calling to report patient results, etc.) as well as for providing basic care to patients, including the collection of specimens.

According to the Bureau of Labor Statistics (2006), MAs do not necessarily have to have special training in order to function in this role, although many employers and some states require certification. For those who decide to have special training, there are two routes; one being a one-year program resulting in certification and the other route is a two-year program that results in an associate’s degree and certification. Although an MA may have a certificate or degree, they still may not be qualified to perform certain procedures such as give shots or draw blood, as each State may set requirements for the need for additional course work or a competency exam. Most of the MAs with whom we interacted had at least the one year of formal training.
In addition to referring to nurses as MAs in the flow charts, there were other employees such as a certified nurse assistant (CNA) and some general office staff (who may not have any official medical training) that might have been referred to in the charts because they fulfilled many of the clerical components of the MA role.

**General office staff**

This title refers to a clerical role that does not require formal training or certification. The general office staff typically made appointments, sorted mail and test results, answered phone calls, and filed patient charts. There were MAs and nurses who functioned in this capacity, although most other general office staff seemed to have had no formal medical training. Those that function in this capacity are referred to as *office staff* in the flow charts. The clerical duties that are performed in the testing processes of all the sites overlap between the general office staff, MAs, and file clerks. Keep in mind that not every office staff member played an active role in the testing process.

**File clerks**

File clerks are employees who have the responsibility to care for the patient records in terms of storage and handling. In some cases, the file clerks created the paper chart for new patients. The main job function of the file clerk was to pull and re-file patient records for and after usage.

**Patients**

Patients have the largest stake in patient care because their own health is at stake. The role of patient, in terms of the testing system, is to provide a specimen, go to the hospital for imaging tests if needed, pay for services, await test results, and to make a follow-up appointments if needed.
3. Locations

There are seven main locations that are involved in the testing processes, but not every site or process will require all locations. This next section discusses some of the locations in greater detail and is explained in roughly the order in which the process flows. Maps of the sites (see Figures 7 & 8) have been included to provide a general sense of the layout and relationship between the various locations.

Exam rooms

The exam room is the area in which a physician examines the patient, but it also has a role in the testing processes. Exam rooms may also play the role of draw station for physicians and MAs in some cases. They may also be the location where healthcare workers notify the patient of patient’s test results.

Nurse stations

Nurse station is a generic term for the workspace that nurses and MAs occupy for much of the clerical work that needs to be done. These stations varied in size from a small, hanging foldout desk on a wall to a small room or area with many cupboards, desks, chairs, and counter space.

Phlebotomy (draw) stations

Phlebotomy stations, also known as draw stations, are areas that are designated for the collection of biological specimens, typically for certified tests that need to be sent to a reference laboratory for analysis. Most often there is a draw station located in an office, but this need not be the case. Offices that are part of a larger medical complex may also share a draw station. In some cases, a patient may need to visit an off-site draw station that is affiliated with a specific reference laboratory or hospital. These off-site draw stations may either be free standing or physically connected to the hospital or reference laboratory.
Reference laboratories

A reference laboratory is a CLIA certified medical laboratory that analyzes patient specimens for physicians’ offices. Most family practices cannot afford the cost of operating their own in-house laboratory, so specimens are “referred” out to certified laboratories for analysis. Reference laboratories usually serve many physicians’ offices in a local area, but some laboratories may specialize in rare or highly complex tests and may only be one of a few laboratories serving the entire United States.

Delivery of the patient specimen to the laboratory most often occurs through a laboratory employed courier. The reference laboratory returns test results back to the medical office in a number of ways, including electronically, fax, phone, mail, or through a printer that is networked to the physician’s office. It was also not unusual for the laboratory to redundantly return results using multiple methods, typically through the special printer and by mail or fax. Some reference laboratories will station some of their phlebotomists at the draw station of a physician’s office.

Hospitals/testing centers

Many patients must be referred outside of an office to a hospital or testing center for certain tests such as electroencephalograms (EEGs), electromyographs (EMGs), as well as CLIA and imaging tests that require more work and skill than can be provided in a typical physician’s office. Testing centers are much like an off-site draw station, but are not limited to biochemical tests. We refer to both hospitals and testing centers as hospitals because most of the medical staff usually spoke about referring patients to the hospital. Furthermore, we did not notice any effects on the process of a hospital versus testing center, leaving hospital to be an adequate title for our placeholder in the flowcharts.

Private Physician Offices
Every practice had at least one private office that one or more physicians could use for reviewing patient charts, transcribing notes, writing letters, etc. Many physicians were seen to have used their offices infrequently and only for short durations. With the exception of Site 4, most physicians seemed to review test results and make clinical decisions outside of their offices.

*File rooms*

Paper patient files need to be stored somewhere. Offices may store only recently used patient charts in an easily accessed area while sending older charts to be archived off-site. The charts that are easily accessed tend to be found on shelves in a room that is dedicated for storing the charts, known as the file room. File rooms may have a dedicated staff (i.e. file clerks) or may be readily accessed by physicians, MAs or other office staff.

*4. Documents*

Ordering tests can occur either through electronic means or through the use of paper records, or through a combination of both. This section will review the paper documents that are used to order and keep track of tests that have been ordered in the offices that use paper documentation.

*Billing sheets*

Billing sheets are also known by other names such as super bill, fee ticket, and encounter form. The name used changes from site to site, and in some cases, from person to person. However, as we listened to the staff members at all of the sites refer to these forms, they all seemed to understand each other no matter which term was used. The billing sheets are used to keep track of the services that have been rendered so that the insurance (or patient) can be billed. Billing sheets were custom created and professionally printed forms that were unique to the particular office or network of offices. They contained a list of the most commonly performed procedures (sometimes including most
common tests) to allow for the physician to merely check a box rather than have to hand write the procedure or test on a form.

**Test requisitions**

Test requisitions were also professionally printed forms like the billing sheets, but differed in that they contained only testing options. Not every site used a dedicated test requisition form, as some sites used the billing sheet to requisition tests. If the site did use a dedicated test requisition form, it was in conjunction with a billing sheet. Unless otherwise specified, we will refer to both the billing form and the test requisition as simply the test requisition.

**Test results**

Test results returned from the reference laboratory, hospital, or testing center in a number of ways, but always on official forms. All sites contracted with at least one reference laboratory or hospital laboratory, meaning that all offices were electronically networked to the laboratories to some degree. This network allowed test results to come back via a special printer that was electronically linked between the site and the laboratory. Official faxes and letters in the mail were also common means to receive results from the laboratory. Waived tests that are done in the office sometimes had an official form, such as a small card, for recording results.

**Results mailers**

Some offices prefer to call all of their patients on the phone with all results, including “normal” results. Many offices returned test results to the patient through mailing a copy of the official results form (which was received from the laboratory), a typed letter from the physician or postcard with a brief note and results written upon it. Copies of these mailers were often kept and added as part of the patient record.
C. Overview of Site Characteristics and their Effects

Although we briefly mentioned some demographic information at the beginning of this chapter, it is important for us to briefly describe some of the characteristics of the sites that impact the processes. We recognize that complex systems are non-linear, and therefore a word of caution is given with respect to the inference and direction of causality in the relationships that we will discuss next.

1. Office Staff Size and Makeup

The largest site in terms of the number of full time providers is Site 1. Although Site 3 has a higher reported number of providers, it should be kept in mind that 12 of those providers are residents, and as such, only work part time which means that they take turns working for a few days throughout the week. There is an important distinction in part-time work that needs to be made. Although part time refers to working less than a 40 hour work week, there are two ways of achieving this. One is that the residents work a few hours every day the other is to work full days only a couple of days a week. Site 3 has opted for the latter. This means that all 16 providers will never be available at one particular time. Since the residents rotate shifts, residents may not be in the office when their patient’s test results return from the laboratory as would the staff physicians. Since results need to be screened and reviewed for critical or abnormal results, one physician is assigned to be the physician-of-the-day (POD) and is responsible for reviewing every test result that returns on that day. Site 2 has a similar policy of having a single provider review all test results although they do not have a residency program because a few of their staff physicians rotate their shifts through a few other offices that are also owned by the same parent healthcare network.

Site 1 has a long history in the community meaning that it has many patients. It has been reported to us that multiple generations of families have been seen at this site. For
instance, if one were to look up the record of a small child, there is likelihood that one would be able to find the medical records of the child’s parents and grandparents as well. The long history contributes to a larger patient base which leads to a need for many providers. However, providers also require support staff such as MAs and general office staff. Having many physicians tends to increase the number of support staff needed. Site 1 had so many employees, that their management reported that the practice actually lost money, and if it was not for the income from their association with their associated university, it would quickly go out of business. Running an organization on a negative income was reportedly the reason that the in-house certified laboratory was closed down.

Site 4, having the least amount of staff (only employing a single full-time MA/office staff member besides the physicians) must operate so that the MA can do everything that the physicians do not. A few times a week, an additional employee will come to help out in the office. This part-time employee is one of several MAs from another medical office from the healthcare network.

A reported problem with having a residency program at Site 3 is that the rotation of residents’ work schedules makes it extremely difficult to get full attendance at the weekly and monthly safety meetings. Since not all residents make the meetings, they do not have the opportunity to learn from their team’s mistakes, nor can they contribute their own experience to the team. Some MAs have reported that residents have often made statements such as, “well, this is not my own practice, so why should I care how they run things here?” We found this to be unexpected since Site 3 was doing the most to encourage staff to participate in quality and safety improvement (which will be covered in more depth in Chapter 4).

Site 3 had reported that their MAs had been experiencing enough job dissatisfaction that management felt that the problem needed to be addressed. One of the
major complaints was that the MAs were getting tired of repeating the same role assignments because of their strict division of labor policy despite the fact that two individuals doing very different jobs were both considered MAs. For instance, an MA with the expectation to help patients as well as do some charting work would find that she was permanently assigned to work in the draw station or to only file patient records. To remedy this, the management decided to rotate the MAs throughout all tasks on a weekly basis, so that all MAs would have an opportunity to experience a variety in their work. The rotation of MAs through the tasks purportedly alleviated the MAs’ job dissatisfaction and has had the added benefit of having cross-trained MAs. We noticed that the MAs at this site were much more knowledgeable of the system as a whole, which we attribute to their cross-training and exposure to the larger picture. Additionally, many of the improvements made in their system originated with MAs who had a broader view of the process. In other offices, no single person could tell us what every role did, but these MAs functioned as multiple roles over the course of a month and had the opportunity to learn how their actions seeing a patient and filling out paperwork would affect the person reading the paperwork and tracking the results.

Site 2 had previously had problems tracking the outstanding test results because the responsibility fell upon the shoulders of every MA. Having responsibility diffused was not advantageous in that the system suffered from the free-rider problem, where each MA assumed that someone would do their job for them and as a result the tracking was rarely ever completed. To remedy this, management decided that every month, one of the MAs would be assigned to be the MA-of-the-month (MOM). Although it was the individual MA's responsibility to track the test results for her team, the role of the MOM was to double check the work of the MAs to make sure that the tracking was being completed. From what
we saw in our brief visit, the MAs were shirking their responsibility and leaving the tracking almost entirely to the MOM.

2. Record Keeping

Sites 1 and 3 had dedicated file clerks who worked specifically in the file room. All other sites either had MAs or office staff pull and file the patient records. The file clerks at Site 1 were responsible for creating and tracking the physical location of the patient charts. The file clerk at Site 3 was responsible for double-checking the records for completeness and accuracy before filing them away.

At Site 1, once a patient makes an appointment, the front office staff makes a note in the computerized scheduling system, which is checked nightly by the file clerks so they can pull the charts for the next day. In order to facilitate the pulling of charts, they print out a manifest of all appointments for the next day. This manifest also serves as a mechanism to track which charts are still in use. On the day of the appointment, the file clerks deliver the charts to the patient’s office nurses and MAs. The charts stay with the MAs or office nurses until the physician is finished with them and returns them to the office nurse. The office nurses then place the charts into a cart that is used to transport the charts back to the file room.

Keeping track of the charts may seem relatively simple if the charts stayed in one location, such as the nurses’ station, but they seldom do, resulting in the loss or misplacement of the chart. The office nurses with whom I spoke mentioned that they spent a large portion of their day tracking down lost charts. They also reported that they had found these misfiled charts in every major location of the office, such as physician offices, the front office, other nurses’ stations, and in large piles of charts in their own nurses’ station.
A visual inspection of the nurses’ stations reveals how easily it might be to misplace a chart. While observing the office nurses at their stations, we counted over 78 charts piled in various stacks throughout the workspace in one of the stations. This is a conservative number of charts due to the fact that the charts were not physically handled by us as we counted them, so additional charts could easily have been overlooked. All of the nurses’ stations tended to have many piles of charts spread throughout the workspace.

The file clerks keep record of the charts that have been checked out and will try to retrieve them after a given time period. When they go to collect the charts, they have to search the large piles in the nurses’ stations as well as the physician’s private offices. Every MA and office nurse interviewed said that they spent a significant portion of their day searching for charts for which the file room clerks are looking.

The current filing system at Site 1 ought to work such that charts go to the file room to await something that needed to be added, such as a test result. When results arrive, the chart is to be requisitioned, located, brought to the physician for review, and sent back for re-filing until needed again. However, there is often a problem that occurs when multiple types of tests are ordered because the results do not return at the same time. This means that the chart goes between the file room, nurses’ station, and the physician’s office multiple times, which provides additional risk for chart misplacement. Also, if a second result that arrived later never returned, the chart would stay filed indefinitely, meaning there would be no reminder to the MA, physician, or file clerk that the file was incomplete. One physician recognized this problem and made it a point to take her patient’s charts into her office until she was finished reviewing all outstanding tests, that way she knew that they were complete before filing. However, this was also a reason that file clerks spent so much time searching for charts.
3. Medical Assistants

Some MAs reported to check patient charts for errors when they could which has led to a number of errors in the charts being discovered, while other MAs reported that they did not double-check them for accuracy. Unfortunately, our exploratory research did not allow us to be able to determine which factors led some MAs to double-check patient charts, although we suspect that personality traits such as conscientiousness and a concern for patient safety play a role as well as difference between the training levels and experience. At each site (with the exception of Site 4 which only had one MA), there were a few MAs who were regularly reported to be the best or most knowledgeable by physicians, other MAs, and other office staff. A concern for patient safety seemed to play a role in that some of the MAs that were recognized to be the “best,” reported that they regularly stayed longer than their counterparts (as one MA put it, that her job, “did not end at 5:00 pm”) so that they could finish completing the work that needed to be done for the day. A few of the “better” MAs expressed their feelings about their desire to treat all patients as if they were family, referring to feelings of personal responsibility to make sure that their patients were well cared for.

4. Patients

At least one interviewee at every site mentioned a difficulty with patients is that they can be a threat to the safety of the testing process, particularly through their failure to follow up on test results or failing to show up for appointments for specimen collection that occur off-site. A quote from the clinical director from Site 2 sums the concerns of all interviewed personnel when he stated that he felt as if he “had to build a big enough mouse trap to keep all of the patients in the testing system.”

However, patients also play a very important role when they call in to ask about their results. It was reported a number of times in the interviews and observations that the
call by the patient was the first step in discovering that something was wrong, such as the result having not been returned from the lab. It is unfortunate that errors in the testing system were not caught before the point that the patient called, but a call from the patient can be a last double-check or line of defense to correct an error before the chart is filed away without follow-up.

5. Physical Office Size and Layout

The physical locations of the various locations are important components to understanding the nature of the unique testing systems. The maps on Figures 7 and 8 provide an indication of the relationship of the various locations within an office, but because our floor plans were based upon the emergency fire escape plans, our maps were not based on measured area and are therefore not drawn to scale. They are approximations of the spaces represented.

Although we were not able to measure the floor area of the offices, Sites 1 and 3 were the largest of the four. Site 4 was by far the smallest. The reason that we are mentioning the office size is because it has important implications for the processes, especially in terms of storage. Sites 1 and 3 had many patients and therefore many more records than the others. Site 1 had a large room in their basement that had dedicated file clerks to tend to the records. Site 2 had records that were stored near the main office and were easily accessible to all employees.

Site 3 had two areas for holding patient records. Their main file room was off of the main office and was tended by an office staff member. The second area was a series of cabinets in the office draw station. The storage room in the draw station stored only the records that were awaiting test results to return from the reference laboratory or hospital. Many staff members felt that this was a nice feature because it provided an opportunity to
Figure 7. Floor plans for Sites 1 and 2.
Figure 8. Floor plans for Sites 3 and 4.
regularly review and track records. Regularly reviewing the records reportedly provided opportunities to catch errors that had previously been made in the records.

Since Site 4 had EMR, one would assume that there would be no need to store paper records or results. The building was a newer building and seemed to have been designed with EMR in mind since there did not seem to be any areas that would have been particularly conducive to the storage and retrieval of records. Site 4 certainly did not have any spare rooms or closets to deal with the issue of records storage. However, due to an unforeseen circumstance, there is a need for storage space after all which Site 4 deals with by having a large stack of results on the little counter space that there is.

Reference laboratories

The redundancy of test results causes many MAs and office staff extra work because they often had to pull charts to add the results only to find that the results had already been reviewed and filed. However, in speaking with MAs and other office staff, it was mentioned that they were also thankful for the redundant results in cases where the original results had been lost or misplaced.

Nurse stations

Site 1 had two major nurse stations; one for each half of the building. They also had multiple smaller satellite nurse stations that were located throughout the building. Site 2 had one large nurse station that was centrally located. Site 3 had one large nurse station that was divided into two halves. They also had a number of hanging wall desks that were installed for physician usage, but the desks served many of the same purposes of a nurse station and a private office. The front office of Site 4 served as the nurse station because of the limited space and staff. The large file room in the basement of Site 1 created a need for file room staff and the need for them to travel around the office picking up and delivering charts. This setup means that
the charts would normally be transported often if it were not for the work-around of just keeping them on a desk until they were ready to file, rather than send them back often as the policy states. This setup is a huge threat to the quality of the records because they are poorly controlled.

**Private physician offices**

The physicians at Site 1 would sometimes store patient charts in their private sites so that they would retain control over the location and what would happen to their charts. The physicians in Site 2 were never observed using their private offices. Instead, they seemed to be using a dedicated area with computers and a desk that was very similar to a nurse station. Multiple physicians were observed to congregate together, reviewing notes and discussing patients in this area. The physicians at Site 3 commonly used their offices for reviewing records unless they were the physician for the day in which case they often stayed at the nurses’ station and reviewed the records. The physician’s at Site 4 reviewed records only in the office because of a need to access the records electronically via computer.

**Hospital/testing centers**

Site 2 mentioned that they had problems with patients going to the hospital for testing referrals. The most common excuses, as reported by the office staff, were that the patients did not have enough money to pay for the tests, did not have enough money to pay for the bus ride, or they could not afford to take the time off of work. Site 3 was located within a few city blocks of the hospital, and patients could often leave the office and have their tests completed without a long wait.

**Test results**

Some electronic ordering systems also provided a means to receive the results electronically as well by allowing the physician or MA to access the laboratory's database
and allow the office to print a copy of the results. Site 4 only received electronic results that were sent to the email inbox of the ordering physician. However, the other three paper chart sites would typically receive a paper copy of the results, but could also print a paper copy from the system if needed. Site 1 received most of their results from a printer that was networked to the reference laboratory, such that the printer would automatically print the results once the analysis was completed. Site 2 received many of their results from the hospital through their fax machine. Site 3 printed their results from the computer or received them in the mail. However, Sites 1, 2, and 3 could all receive their results from fax, manual electronic printing, or mail.

Site 4 was in a unique position where they were located in a building that was owned by Organization A. They had previously been owned by Organization A, but had been sold to Organization B at the beginning of 2007. Organization A also owned and operated the EMR system as well as the phlebotomy station/laboratory. Since Site 4 was no longer a subsidiary, Organization A provided very little support. The laboratory that was located in the building would automatically record the results which could be accessed by the physicians, but any tests that were done outside of the affiliated hospitals or medical centers, would have to be digitized by an outside organization and then sent to Organization A to add to EMR. This often did not occur in a timely manner. The MA noticed that the results were not arriving and so she would go collect the paper versions and store them in the office in a pile on the counter because there was no space for them to be filed anywhere. The physicians only noticed that some of the results were missing, but it was not until we began asking questions that the physicians realized that none of the outside test results had been added to the EMR for the last six months.
Some sites had no forms for the results of the waived tests and resorted to using sticky notes for CLIA waived tests. These were reportedly prone to falling out of the charts, which is a threat to the safety of the system and ultimately to the patient.

D. Differences between the Sites and their Processes

This section will be comprised of four main sections corresponding to each test type. Each section will first provide an overview of the process in general terms that apply to all sites. After the overview, the differences in the process will be discussed in terms of the process, personnel, locations, and documents involved.

1. Diagnostic Imaging Tests

Process overview and similarities

Although this section focuses mainly on the specifics of radiographic imaging, there are many similarities shared with other types of imaging tests. This section will provide the common basic pattern of steps required to successfully execute this process at all four sites.

To place a little more detail into the EFTP steps, the ordering and implementation of imaging tests begins with a physician ordering a test. A test requisition is filled out (paper and/or electronically) by a physician or MA and at this point, different sites diverge in the manner in which they proceed through the process because of the different resources available to each such as specially trained technicians or equipment that are required for further processing. Access to such resources may be found off-site such as in a hospital or on-site if the office has the financial means. Whether the imaging occurs on-site or off, each site has a different arrangement as to how the patient is to meet up with the technicians and equipment.
If the radiographs were taken on-site, such as Sites 1 & 3, they were reviewed initially by the radiologic technologist as well as the family physician in what is known as a wet-read (*wet-reading* is a hold-over term from when radiographs were developed by hand in a darkroom and where the liquid chemical developing agents would literally still be dripping off of it was hung on a light box for review). The family physicians, however, were not able to make final decisions on the interpretation of the results which would need to be made by a radiologist. In order for the images to be read by a radiologist, the images would need to be sent via courier to the location of the radiologist for official interpretation, which was usually at a hospital. If the sites did not have on-site facilities, such as Site 2, then an additional appointment would need to be made for the patient.

Regardless of whether the image was taken on- or off-site, the image still needs to be reviewed by a radiologist. There is a need for specialists to make final decisions about the specialty medical test because family practitioners only have a little training in reading such images. Getting a radiologist to review the image requires further transportation of documents through the system, which may create additional opportunities for problems to arise.

Once the radiologist reads the image over, the results are typically returned to the ordering physician of the family practice in the form of a letter that returns either electronically or through the postal service. The ordering physician will then use that information to guide further treatment options after making a clinical decision. The results are then stored in the patient record and the image itself must be stored separately (in the case of paper charts) because of the difference in size of the patient chart and image film. In theory, the EMR system should also have the images stored electronically, but as we will discuss later, this is not necessarily the case.
If the patient presented with a broken bone or other acute need, reporting the results to the patient is typically “built into” the appointment where the physician treats the ailment. If the image was to look for some other need, such as to screen for kidney stones, then reporting the results was likely to follow the regular reporting routine though phone calls or letters.

Process differences

Recall that we mentioned that no two processes were exactly alike in any of the sites. Some of the differences in imaging tests will now be discussed. For instance, Sites 1 and 3 had a radiography machine on-site. Site 1 employed a full-time radiologic technologist while Site 3 had a technician on call. This was very convenient for patients in that they did not have to schedule an additional appointment to have these tests completed. This allowed patients to have the radiographs taken and then be wet-read by the ordering physician on the same day. Having the ability for ordering physicians to review radiographs before sending them to be read by a radiologist allows the physicians to make preliminary decisions regarding treatment before the official results had been pronounced, which is extremely helpful when dealing with urgent problems such as broken bones.

Site 2 required all of their patients go to the hospital or other facility to have this type of testing done because they did not have any such facilities in their office. Site 4, the EMR system, had a radiograph machine located on the premises but it was operated independently from the Site 4 and we were unable to study its role in more detail.
2. CLIA Certified Tests

Process overview and similarities

Figures 9 through 12 show the process flow charts for certified tests. As with the imaging tests, certified tests must be analyzed off-site because of the need for specialized equipment and specially trained staff to analyze the specimens. It is possible for a family practice to have their own in-house certified laboratory if they have the money to hire a laboratory technologist, purchase the necessary equipment, and undergo a certification process. However, most offices find this uneconomical. Site 1 had at one point operated an in-house certified laboratory prior to our research visits, but the medical group that owned Site 1 had recently closed down operations. Presumably due to the expense of operating the laboratory, since cost is one barrier to even establishing an in-house laboratory in the first place.

To order a certified test, a specimen needs to be collected from the patient and an order needs to be made to the appropriate reference laboratory. The orders are usually made on paper requisitions and then ordered again via a computer or terminal that is networked to the laboratory because the reference laboratory has its own separate process. Since laboratories have a different system for ordering tests, offices must fill out requisitions for in-house tracking and billing and then another requisition to meet the requirements of the reference laboratory.

Once the paperwork has been filled out, the specimens are collected by qualified staff, typically MAs or phlebotomists, and are labeled and sent to the laboratory for analysis. Specimens may be collected via courier or may be hand delivered to the laboratory if the draw station is collocated within the laboratory. Once the laboratory analyzes the test, the results are (in theory) returned to the office. Our interviews
Figure 9. Process flow for certified tests at Site 1.
Figure 10. Process flow for certified tests at Site 2.
Figure 11. Process flow for certified tests at Site 3.
Figure 12. Process flow for certified tests at Site 4.
indicated that errors sometimes occur due to the failure of the laboratory to return test results. Verbal reports indicated that this could either be due to the fact that the laboratory never received an order or specimen or because the laboratory never completed the test.

Failing to receive results from the laboratory is of great concern to the offices that we visited. Every site mentioned that they had experienced this problem with their reference laboratories, prompting many offices to begin some sort of tracking system to keep track of the tests results that were still out-standing. Sites that used tracking systems also used them to keep track of imaging tests as well. While tracking systems may be used for both radiographs and certified tests, those sites which reported concerns receiving results cited problems with the certified laboratory, not with the radiologist.

When test results do return from the laboratory, the offices try to ensure that a physician will see the test results as soon as possible so that a clinical decision can be made. Once a decision has been made, the results are reported to the patient, either via phone, letter, mailer, or at a follow-up appointment.

Process differences

Sites 1, 2, and 3 had draw stations on-site (see Figures 7 & 8, pp 39-40). Site 1 had a draw station that was staffed by phlebotomists that were employed by the reference laboratory, which created a difficult dynamic where the office management had little control over the manner in which the phlebotomists performed their duties.

In the first three sites, when a physician would order a test, a paper requisition would be filled out and taken to the phlebotomists (or MA) who would then enter the requisition electronically into the network linked between the office and laboratory. One interesting result of this is that the physician becomes one step removed from the actual ordering the test. While the physician may fill out the paperwork, the phlebotomists or
MAs are often the ones who enter the test information into the computer system that is connected to the laboratory. The physician relinquishes her control over to another. However, the phlebotomist or MA, at least, are another set of eyes to double-check the physician's work.

Sites 2 and 3 used their nursing/MA staff to draw specimens from their patients. In these cases, the tests would also be ordered via paper requisition, but then be entered electronically into their computer network associated with their reference laboratory. Since Site 4 was in a medical center that shared a reference laboratory, all patients were sent to the draw station in the building that was associated with the main reference laboratory.

Sometimes a test would need to be ordered that could not be accomplished by the regular reference laboratory. This occurs often with very specialized tests or when a patient’s insurance will only cover laboratory tests that are processed by a particular laboratory. In these cases, the office may be able to collect a sample on-site and send it to the laboratory as normal, but sometimes this is not possible and the patient would have to travel to another location for the sample to be collected. These off-site locations for draw stations could either be a free standing location or be physically connected to the specialized reference laboratory or hospital.

Site 3 used the exam room as the primary phlebotomy station when the patient could provide a specimen at the present visit. Otherwise, if the patient had to return later to give a specimen, such as when fasting, then the patient would visit the official phlebotomy station during a nurse’s visit at a later time.

An important finding from the comparison of the locations of the draw stations (including radiology suite) is differences in regards to opportunities to clarify test orders before drawing a specimen is completed. For instance, it was reported to us at Site 1 that
there were cases where the physician (or MA if she was filling out for the physician) ordered the wrong test on paper and the phlebotomists and MAs were able to note the mistake and have the paperwork fixed before continuing. For instance, the radiologic technologist noted that physicians sometimes marked the requisition improperly, leading to an incorrect order such as when a patient presents to the radiology suite holding a left arm but the requisition notes that the right arm was to be filmed. If the radiologic technologist (or phlebotomist/MA) was not in the same building as the physician, then they would either have to follow the orders as stated on the requisition or try to contact the ordering physician. Sharing a workspace with physicians allowed for the radiologic technologist (and presumably the phlebotomists) to communicate more easily and allow for resolution of discrepancies on the requisition.

3. CLIA Waived Tests

   Process overview and similarities

   As mentioned earlier, this category of tests is broken into two subgroups; MA performed and physician performed tests. These tests are very similar in process with the exception of who collects and analyzes the specimens. Once a waived test is ordered, either the physician/MA will collect a specimen and analyze it. These tests are the least complicated in terms of skill and training required for analysis, but also in terms of the number of steps, people, locations, and documents involved. One of the nice features of waived tests is that many of the results are immediately available to the patient, which may reduce the likelihood that the patient would not be notified of the test results.

   Process differences

   The physician waived and MA waived tests are similar to each other in many ways. Due to the simpler nature of the tests, there are fewer steps than in the other categories. The process flow charts for these waived tests (comprising Figures 13 through 20) are
Figure 13. Process flow for MA performed waived tests at Site 1.
Figure 14. Process flow for MA performed waived tests at Site 2.
Figure 15. Process flow for MA performed waived tests at Site 3.
Figure 16. Process flow for MA performed waived tests at Site 4.
Figure 17. Process flow for provider performed waived tests at Site 1.
Figure 18. Process flow for provider performed waived tests at Site 2.
Figure 19. Process flow for provider preformed waived tests at Site 3.
Figure 20. Process flow for provider preformed waived tests at Site 4.
divided into the MA and provider performed tests. The major differences that can be seen are the use of office staff at Sites 1, 2, and 3. The MA at Site 4 is the only non-physician and also plays the role of office staff. At Site 1, the office staff places the results in the records and prepares the record to be picked up by the file room clerks. The office staff at Site 2 place the results in the records and file the records themselves. Site 3 has office staff that specifically double check the records for accuracy before filing the records away. Site 4 does not typically require manual input of results into the records because the records are electronic. However, as mentioned earlier this is not always the case since not all tests are completed by the on-site equipment.

IV. Discussion

The previous section has laid a foundation for understanding the four main testing processes in the four observed family medical practices. The process flow charts demonstrate clearly that medical testing is much more complicated than the EFTP would suggest. Each office had a unique system that was made up of unique processes. The reason for the distinctiveness of these processes is largely a function of the number and type of employees and the physical layout of the office. These factors along with regulatory legislation further constrain the testing processes and lead to many local adaptations of these processes at each medical office.

If the testing systems are more complex than the EFTP, then it is no wonder that no individual employee was able to provide a detailed overview of their testing systems. Within the context of local factors and legislation, two factors emerge that explain why no single individual could explain the whole system. They are the disjointed nature of the work and the lack of standardization in the procedures. While there is a certain amount of standardization (such as medical coding) and certain standards that laboratories must
meet, there is no way that any legislative body could dictate the exact manner and order in which the testing processed must proceed that would allow all offices to be able to comply.

Over the course of the process, multiple people have their part in the operation as well as having to transport the information in whatever form (e.g. test requisition, results, results mailer) over multiple locations. The information itself drastically changes form over the course of the process. Individuals were very knowledgeable about their role in the process, but no single employee follows the entire process from start to end, let alone what happened directly preceding her part or what occurs immediate after. As for the lack of standardization, many offices had multiple ways of completing certain tasks. The physicians were usually assigned to a team, such as an MA and an office staff member. One team would develop their own version of the process over time as to how the process will be accomplished, such as regularly reporting results via phone, but another team may prefer to send letters. The inconsistency between groups within offices makes it difficult for any single person to keep track of how the system operates.

Medical testing is a complicated sociotechnical system. When so many individuals with different roles and training are put together in a process that requires a transformation of information into a completely different form of information (e.g. an idea for a test order turns into a test requisition which turns into a specimen which turns into a test result which turns into a diagnosis which turns into a treatment) it is no wonder that errors are found throughout. Medical testing is a classic case of Perrow's (1984) Normal Accident Theory at work. The next chapter will examine some of the errors that have been found in patient records and discuss what those errors can tell us about the testing systems.
3. PATTERNS OF ERROR: AUDITING PATIENT RECORDS

I. Introduction

As mentioned previously, Hickner et al. (2005) found that it was possible for errors to occur at any stage of the testing process, and given the complexity found at the four sites from our work analysis, it is easy to understand why. However, seeing the potential for error is not the same as empirical evidence. In our research, we attempted to directly observe errors as they occurred in real time. Given that our time constraints limited the number of errors that we could observe in this manner, we also collected historical data in the form of critical incident reports and an audit of patient medical records to provide us with additional examples of errors. Our goal in gathering examples of errors was to find patterns of errors in the records that might reveal something about the nature of the testing systems, such as the presence of weak links or opportunities to catch errors.

In that we examined both paper and electronic records, we need to briefly note a distinction that will be made in the terminology. The most common record was the paper format which we refer to as charts. The electronic records are simply referred to as electronic medical records. For the greater portion of this document, we do not distinguish between the two and will use the generic term, records. If differentiation of terms is required for clarity, we use the specific terms.

In order to use the patients’ records as a means to count as evidence of errors that were found, we had to make the assumption that documentation in the records of the testing steps meant that the steps had actually been completed. In reality, some steps may have been merely “checked-off.” For instance, it would be hard to believe that a physician’s
signature would indicate that she had not seen the result, but it does not guarantee that
the physician understood the result or accurately integrated the results into the
physician’s understanding of her patient’s health. Additionally, if an MA were to note that
the patient’s results had been mailed, there would be no way to verify if the results had
been mailed. After all, the results may have been in the envelope ready to be mailed, but
instead fall into a crack between the desk and floor. We recognize that assuming that
documentation as an indicator of completion may not always be correct, but
documentation is the only way those medical facilities have to support themselves in
medical malpractice/negligence litigation suits.

On the other hand, the failure to document a step does not necessarily mean that
the step was not completed; it may mean that the error was only clerical rather than
procedural. For example, we found some examples of patients being notified of their test
results, despite the fact that there was no test result in the record. This suggests that the
result was never returned to the record after use. The steps between may have been
completed, but the lack of a test result or physician signature does not mean that the step
was not completed.

II. Audit Method

Our intent for the record audit was to find examples of error at every step in the
testing processes and to look for patterns that might emerge in the occurrence of those
errors. We felt that that given the limited time that we had at the various sites, we had to
be judicious with the manner in which we divided our time among the various research
methods that we had planned. We felt that a sample of 25 records per site would be
sufficient to help us obtain our goals of finding errors and patterns of those errors in the
records.
A. Sampling

Charts were selected to be audited by pulling them off of the file shelves in no particular order. Depending on the size of the file room and the amount of records held in the file storage area, we tried to get at least one chart per filing cabinet or shelf. Once a chart was pulled from the shelves, it was immediately screened to ensure that it met the audit criterion (which was the presence of a test order or test result from the preceding 12 months), thus keeping as many records as possible immediately available in the storage area for the staff. When a patient record contained many orders or results from different visits over the preceding 12 months, such as patients with chronic conditions that require regular testing (e.g. patients beginning a Coumadin regimen), we only used the most recent set of tests.

Our reason for using either a test order or test result stems from the problem that sometimes records did not have the requisition but had a recent test result. If the chart did not meet the criterion, it was replaced and another was drawn and screened. Each researcher independently pulled an armful of records and took them to an office space located on-site where the formal audit could commence. Due to our independent sampling, a miscount occurred twice during the audits at the first two sites resulting in the audit of two additional records. The miscount left us with a total of 26 records for each of the first two sites and 25 for each of the last two sites.

While sampling charts to be audited, we mentioned that we screened out record that had not had a test ordered in the preceding 12 months. We did not keep track of the number of records that were screened out, which means that we cannot provide an indication of how many patients had tests ordered in the preceding 12 months. However, we can give some indication of how prevalent errors are once a test has been ordered. The
frequencies of error once a test had been ordered proved to be a more complex issue than we had expected and will therefore be discussed at greater length later in the chapter.

The audit for the electronic records was conducted a little differently because there were no physical records to pull from file room shelves. We also could not use a filtering feature on the EMR system to provide a list of records that matched our criterion because either the system was incapable of such a function or because the physicians, MA, and technical support staff did not know how to do such a thing. Without the ability to query the database of existing records, we had to improvise by searching the EMR system by the date of service. To do this, we accessed the electronic scheduling calendar which allowed us to view patients by date of treatment. This allowed us to filter out patients’ records that did not meet the 12 month criterion.

We then went through each of the preceding 12 months and picked two dates of service in each month in no particular order. Once the dates of service for each month had been selected, we chose the first patients listed and opened their medical record directly from the scheduling function and screened it for test results. If no test had been ordered, we viewed the next patient’s record from the same date of service until a patient had been located that met the criterion. In a few cases, we had to choose a different date altogether because no patients had received orders for medical testing. If the screening process indicated that the patient record met our criterion, then a formal audit of that patient’s record was conducted at that point. This process was repeated until we had audited 25 records where tests were ordered or results were present within.
B. The Formal Audit Process

1. Overview

The formal audit consisted of a manual search through each file to look for important and documentable indications that certain steps in the test processes were being completed. We used a custom form to keep track of the number of test results per chart that met the requirements needed to satisfactorily answer the following questions: (1) Given a test result, was there an order in the record? (2) Given a test order, was there a result in the record? (3) Were the results filed in the appropriate place? (4) Was there a physician signature on the test results? (5) Was there any documentation of the physician’s response to the test results? (6) Was there any documentation that the patient was notified of the results? (7) Was a method indicated on how the patient was notified (e.g., via mail, phone call, etc.)? and (8) Was there any documentation of attempted follow-up for abnormal results?

Table 2 provides an overview as to what we determined to be “best practices,” what our criteria was for deciding whether the associated test group contained an error, and what the policies of the sites were pertaining to charting. Policies were very important keys in understanding the patterns of errors.

2. The Problem of Error Rate Calculation

Earlier, we mentioned the difficulty in providing some type of error count or error frequency. A logical error rate would be the quotient of some type of error count to some measure of opportunities for errors. To provide a meaningful ratio, we needed to use the proper unit of analysis, error count, and opportunities for error. While this sounds obvious, the challenge lay in determining the proper counts because the many ways in which each could be counted. We were surprised to find that these counts were not as
Table 2. Audit question matrix

<table>
<thead>
<tr>
<th>Audit Question</th>
<th>The Best Practice</th>
<th>Our Criteria</th>
<th>Site Policies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Given a test result, was there an order in the</td>
<td>All tests should have a documented order.</td>
<td>Looked for the presence of a test requisition or a note somewhere in the chart</td>
<td>All sites should have been doing this.</td>
</tr>
<tr>
<td>record?</td>
<td></td>
<td>note stating that a test had been ordered.</td>
<td></td>
</tr>
<tr>
<td>2. Given a test order, was there a result in the</td>
<td>All tests should have a corresponding result.</td>
<td>Looked for the presence of a test result if there was an associated order for</td>
<td>All sites should have been doing this.</td>
</tr>
<tr>
<td>record?</td>
<td></td>
<td>it.</td>
<td></td>
</tr>
<tr>
<td>3. Were the results filed in the appropriate place?</td>
<td>All results should be filed in the appropriate place,</td>
<td>Looked for whether the test result was placed near the test order or if it</td>
<td>All sites should have been doing this.</td>
</tr>
<tr>
<td></td>
<td>such as behind the &quot;Results&quot; tab of a paper record.</td>
<td>was located under the results tab section of the record.</td>
<td></td>
</tr>
<tr>
<td>4. Was there a physician signature on the test</td>
<td>Physicians should sign their names (or initial) on the</td>
<td>Looked for the presence of either a signature or initials of a physician on</td>
<td>There did not seem to be any policy on this at any of the sites,</td>
</tr>
<tr>
<td>results?</td>
<td>results.</td>
<td>the results.</td>
<td>other than at least one signature should be present on at least one</td>
</tr>
<tr>
<td></td>
<td>Physicians should also mark every test individually</td>
<td></td>
<td>of the tests per test group.</td>
</tr>
<tr>
<td></td>
<td>rather than a single signature for multiple tests.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Was there any documentation of the physician's</td>
<td>Physicians should leave a detailed description of their</td>
<td>Looked for the presence of a note explaining the physician's understanding of</td>
<td>None of the sites had a policy that expected this of the physicians.</td>
</tr>
<tr>
<td>response to the test results?</td>
<td>understanding of the health status of the patient with</td>
<td>the results.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>respect to the results.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Was there any documentation that the patient was</td>
<td>The medical office should attempt to report all results</td>
<td>Looked for the presence of a note in the record indicating if the patient had</td>
<td>All sites should have been doing this.</td>
</tr>
<tr>
<td>notified of the results?</td>
<td>to the patients, regardless of the status of the test</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>and document the contact in the record.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Was a method indicated on how the patient was</td>
<td>Patient records ought to indicate the method in which</td>
<td>Looked for the presence of a method used in reporting results to the patient,</td>
<td>None of the sites had a policy that expected this of the physicians.</td>
</tr>
<tr>
<td>notified?</td>
<td>the patient was informed of their results.</td>
<td>such as, &quot;called patient on...&quot; or &quot;sent results on...&quot;</td>
<td></td>
</tr>
<tr>
<td>8. Was there any documentation of attempted</td>
<td>The record ought to contain a note on whether there is a</td>
<td>Looked for the presence of an indication that the office made an attempt to</td>
<td>None of the sites had a policy that expected this of the physicians.</td>
</tr>
<tr>
<td>follow-up for abnormal results?</td>
<td>follow-up plan with patients who received abnormal</td>
<td>follow-up with an abnormal result, such as &quot;call for return appointment&quot; or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>results.</td>
<td>&quot;retest in 2 weeks.&quot;</td>
<td></td>
</tr>
</tbody>
</table>
straightforward as we had expected. We will now briefly discuss the reasons for the
difficulty.

One would assume that using the number of records that were audited would
provide a good unit of analysis. However, this did not prove to be the case because the
record fails to take into account that (A) multiple tests are often ordered at the same time,
(B) that those multiple tests may follow different and distinct pathways (i.e. certified,
waived, & imaging test) through the system, and (C) that similar tests that share a pathway
are not fully independent of each other (which will be discussed shortly). For instance,
consider the case of a single record that contains three certified tests and one imaging test.
While the certified tests are ordered at the same time as the imaging test, the different
types of tests quickly diverge along their respective testing pathways to different locations
and people. This divergence in pathways through their respective processes leads some
tests to be exposed to opportunities for error in one process that may not be present in the
other. A more meaningful unit of analysis must be on a lower level than the record. This in
turn left us to examine the lowest level, that of the number of ordered tests.

After considering the number of ordered tests, we realized that this was also
insufficient as a unit of analysis because of the “grouping” problem, which is, as mentioned
above, is where multiple tests are ordered together at the same time, forming groups of
tests that share a pathway through the system. However, as a group, the errors that occur
are not entirely independent from one another. If one error occurs in the process for one
test, then all other similar tests that share a common pathway are likely to also experience
that same problem. For example, since all results from the reference laboratory tend to
return at the same time and on the same page, if the physician fails to sign one test result,
then all of the other tests on the result tend not to be signed off either. From this, the
logical unit of analysis must be the group of tests (i.e. the sum of the various test types that
share one of the four pathways through the system) as our unit of analysis, which is located unit between the high-level record and the low-level ordered test.

Having solved the problem of the proper unit of analysis, giving us a measure of opportunities for error, the next problem was to determining the proper number of errors for a ratio. What is an error and how should we count them? We mentioned the eight questions that we used in the audit as evidence of errors in a test group (and subsequently in the record), but how would using total number of individual errors make sense in a comparison to the number of groups reviewed due to the fact that the errors themselves are not independent? The next section will address this question in the context of the results.

III. Results: Interpreting the Patterns

Due to the dual objectives of the patient record audit (i.e. finding empirical evidence of errors and examining the patterns of errors which emerge in the processes), this results section will be divided into two respective parts to address them.

A. On Counting Errors

We audited 102 total records and found a total of 141 test groups (see Table 3). Each record contained at least one test group since the criteria for inclusion in the study required that each record contain at least one test. As is seen in Table 5, records were most likely to have only one test group, but having two or more groups was not uncommon. Site 4 was least likely to have two or more groups, but even then, nearly 20% of their records had two groups.

Table 4 shows that errors were observed at all steps (with the exception of Site 4, where a test can order cannot be lost). In each cell, there are two numbers. The numbers in the parentheses are the total number of errors that occurred at the given step at the given
Why would we refer to the initiating errors rather than the total number of observed errors as the measure of the number of errors? We chose initiating errors because of the problem of possible error dependency. As we mentioned, some errors in the process were

number of errors of the given type in the groups at the given site.

site. The other number, the first of each pairing, is the number of times that particular error was the first in series of errors (known as the *initiating* error).

Table 3.
Test groups per record by site

<table>
<thead>
<tr>
<th>Number of Groups per Record</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>16</td>
<td>18</td>
<td>15</td>
<td>21</td>
<td>70</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
<td>6</td>
<td>10</td>
<td>4</td>
<td>28</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Number of Audited Records 26 26 25 25 102
Number Audited Test Groups 40 37 35 29 141
Number of Perfect Records 3 6 1 13 23

Table 4.
Error Matrix

<table>
<thead>
<tr>
<th>Audit Question</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order given Result</td>
<td>7 (7)</td>
<td>1 (1)</td>
<td>4 (4)</td>
<td>0 (0)</td>
<td>12 (12)</td>
</tr>
<tr>
<td>Result given Order</td>
<td>4 (4)</td>
<td>7 (7)</td>
<td>4 (4)</td>
<td>2 (2)</td>
<td>17 (17)</td>
</tr>
<tr>
<td>Location</td>
<td>0 (4)</td>
<td>1 (8)</td>
<td>2 (6)</td>
<td>0 (2)</td>
<td>3 (20)</td>
</tr>
<tr>
<td>Signature</td>
<td>7 (13)</td>
<td>4 (13)</td>
<td>1 (7)</td>
<td>0 (2)</td>
<td>12 (35)</td>
</tr>
<tr>
<td>Response</td>
<td>5 (10)</td>
<td>11 (23)</td>
<td>3 (8)</td>
<td>6 (8)</td>
<td>25 (49)</td>
</tr>
<tr>
<td>Notification</td>
<td>4 (12)</td>
<td>3 (15)</td>
<td>7 (16)</td>
<td>0 (6)</td>
<td>14 (49)</td>
</tr>
<tr>
<td>Method</td>
<td>3 (17)</td>
<td>0 (15)</td>
<td>9 (27)</td>
<td>1 (7)</td>
<td>13 (66)</td>
</tr>
<tr>
<td>Follow-Up</td>
<td>3 (19)</td>
<td>4 (20)</td>
<td>1 (15)</td>
<td>5 (13)</td>
<td>13 (67)</td>
</tr>
<tr>
<td>Total</td>
<td>33 (86)</td>
<td>31 (102)</td>
<td>31 (87)</td>
<td>14 (40)</td>
<td>109 (315)</td>
</tr>
</tbody>
</table>

*Note.* The first number denotes initiating errors. The number in parentheses denotes the total number of errors of the given type in the groups at the given site.
more likely to occur when an earlier step was missed. Merely reporting the total number of errors gives the impression that the errors are fully independent, which they are not.

Consider the case with a missing result given a test order. If the result was either lost or was never sent from the laboratory, it is obviously in the wrong place (the second error in the audit), there was no signature because there was nothing to sign (the third error), or no noted response (the fourth error), etc. Thus, all subsequent steps are influenced by the absence of the test result (the initiating error) which clearly exemplifies both the precedence constraint of the system and the non-independence of errors.

Because of the non-independence of errors, we must also account for the total number of errors (i.e. 315 total errors) in a different manner. We accomplish this by referring to the 109 initiating errors, which are the first in a string of errors in a test group. The number of initiating errors perfectly correlates to the number of imperfect test groups (i.e. groups containing at least one error) because every imperfect group has one initiating error, regardless of whether the initiating error was an isolated error or not. With the number of imperfect test groups as a numerator and the total number of test groups as a denominator, we can calculate the error ratio. Our data shows that 77% of the test groups contained at least one error. The mean number of individual errors per imperfect group and per total number of groups was 2.89 and 2.23 respectively. This suggests that most errors did not occur in isolation.

This high of a percentage of imperfect test groups does not reflect well on these testing systems. However, there is some redemption in the fact that many of these errors were simply clerical in nature and may not have had a severe impact on the actual care that was given to the patient. While it may seem presumptuous to say that errors that can be found in the records from an audit do not always lead to errors in patient treatment, consider that we found instances where results were lost after the patient had been
notified and followed-up on. Losing the test result was unfortunate, but because the patient and physician had at least been made aware of the results, the system had “worked,” at least in the sense that the patient received the proper care, regardless of the clerical error of losing the paperwork. The coupling between errors found in the record audit and what happens to a patient may be looser than what it sometimes is thought to be.

The last point that we would like to mention in this section is the increase in the number of errors over the course of the process (see the far right column of Table 6). As we mentioned earlier, if an error did occur, it was likely that there would be at least one other error present, which may also partially support the idea of error dependence. We believe that the most influential factor for this phenomenon is that there tended to be fewer policies regarding these steps (see Table 4), which meant that those steps were frequently not completed or in a manner that we did not believe to be good practice, such as signing only the top page of a multi-page packet of test results.

B. On Patterns: The Chart Audit Questions

This next section will show how certain errors and combinations of errors are possible due to systemic constraint by examining each of the eight audit questions. Each subsection will describe the relationships between the errors, how those errors in each test group can arise, and explain how (potential) subsequent errors were either related or avoided.

1. Given a test result, was there an order in the chart?

Missing order forms could arise from the loss or misplacement of the requisition or due to the failure to document the order in the chart in the first place. Site 4 was able to avoid the problem of lost results all together (with the possible exception of MA and
provider performed waived tests) because imaging and certified tests were usually completed at the in-building testing facilities, which were electronically linked to the patient’s EMR. This has the effect of permanently storing the order in the record and preventing the completion of a test without the proper order from the physician.

In the non-EMR sites, physicians sometimes give verbal orders to MAs to run certain tests, but then the MA or the physician might not remember to mark the order on the requisition or write it in the chart note, failing to officially order the test. At Site 4, since neither the laboratory nor the draw station is located in the immediate vicinity, the phlebotomists are not able to receive verbal order to which they might follow and then forget to do the paperwork. The only way that these phlebotomists can take a specimen is if there is a documented order in the EMR. The sites using paper charts did not have exclusive electronic requisitioning or electronic storage of requisitions that might prevent the occurrence of this type of error.

2. Given a test order, was there a result in the chart?

Some records have orders for tests for which there are no results. According to our observations and interviews, a number of things can happen to explain a missing result. Sometimes tests are ordered by physicians and those who transfer the information to an electronic requisition miss the tick mark for a particular test, preventing the test from ever being completed. Sometimes test results come back and are either discarded or misfiled into other patient’s charts. There have also been reported problems where the office alleges that the reference labs are failing to return tests, and in some cases, failing to even perform the tests.

This error was never an isolated error. Once this error occurred, all other steps also failed. No other initiating error had such a powerful impact. This is due to the fact that
a lack of results makes it impossible to sign a missing document, etc. when there is nothing
to sign. All sites had a problem with missing test results.

Interestingly, Site 3 was able to recover from this error once, stopping the cascade
of errors in that patient’s record. We do not have enough information to determine why
they were able to recover. When all other errors occur when there is a missing result, it
demonstrates how reliant the system is upon the result as an artifact and is a prime
example of how the testing systems are constrained by the preceding steps.

One of the best ways to prevent this problem was to track the tests by comparing
some type of list of outstanding tests against some list of results that have returned. The
three paper chart sites all had some form of tracking system (some more comprehensive
than others) while that of the EMR system was non-existent. The computer software used
at Site 4 either did not have the capability to track outstanding tests or the users did not
know how to track using the system. This is at serious threat to safety, but an excellent
opportunity for design improvement.

3. *Were the results filed in the appropriate place?*

Patient charts often have tabs or dividers that act as placeholders for keeping the
charts organized, but information may still be misfiled into the chart. Some of the
explanations for the opportunities for error in the paper charts are due to the way that
results are treated when they return to the office. Some employees were prone to place the
result on the top of the first page of the chart, making it the first thing that the ordering
physician sees when the chart is opened. This is a helpful practice because it is much faster
than having to dig through the chart and possibly missing the result. On the other hand,
many papers come into the office and are placed on top of the test results, creating a
possibility for the result to be missed in the pile of other documents. One of the nice
features of the EMR system was that it automatically files test results in the test result file
area. In all, there were so few cases of this type of error that we do not believe that any meaningful patterns were able to emerge.

4. Was there a physician signature on the test results?

Signing the patient's test results is the accepted documentable way to “prove” that the physician reviewed and thoughtfully considered the meaning of the results. Not signing the results or documenting such information elsewhere in the record is a poor practice that may return to haunt the physician should an adverse event occur.

Not signing at all can be understood if one observes the pace of the physicians at work. Usually the sites were running behind schedule and so the physicians went from one patient to the next with only a minute or so to review the chart before seeing the next patient. On occasion, the physician would have a few more minutes and would take the time to review the charts that had just received test results.

Different sites have different policies regarding physician signatures, but all sites at least required the physician's signature. For instance, when many tests in a single group are ordered, such as multiple hematological tests, all of the results may return on a single or multi-page document. Some offices may require their physicians to sign every page of the document, some only require the top page to be signed, and others may require that each test result be signed. In terms of our audit, we considered looked for at least one signature per page of unique test results. For example, if there was a two page set of results that only contained one test with many values that continued onto page two, the physician only needed to sign the top page. If the two pages of results were for two unique tests, the physician would have needed to sign both pages. Only one signature on the top page of a stack of unique results was counted as an error because it could not be determined if the physician ever saw the rest of the results.
There are some interesting cases where there were some responses to the results that did not accompany a signature. Some offices and physicians considered this to be an acceptable practice, because the logic goes that if there is a response, it should follow that the physician saw the result. We considered this erroneous because there is no guarantee that the response came from the ordering physician. Some of the MAs have reported that they will write short notes on the results if the physician fails to do so. This way the patient can still receive some feedback and indication of what the results mean for their health. While this is a means of staff creating safety, it ought to be noted by the physician.

Site 2 had a policy that all incoming test results would be reviewed by the physician of the day (POD). The POD then signs the tests and then sends the chart to be filed. Unless the results were from one of the POD’s patients, the ordering physician never receives any feedback on their patient. Furthermore, significance of test results is relative to circumstances of which the POD may not be aware. It may be that the patient was worried about having been exposed to a sexually transmitted disease and the laboratory results were negative. The ordering physician may see the "insignificant" results and recognize them as "significant" with respect to the patient; but the POD is not likely to be aware of the specific circumstances that really define what the results mean to the patient. Although the results were normal (i.e. the patient did not have the disease), the patient would probably like to receive the news earlier as a phone call rather than wait for the results to arrive in the mail like most other "non-significant" results. Not providing the ordering physician with the opportunity to address the results of her own patients also keeps her out of the loop, making the continuity of care more difficult.

5. **Was there any documentation of the physician’s response to the test results?**

Although a signature may be better than nothing, it tells very little about what the physician thought of or understood about the results. We believe addressing each test is
essential for documentation, not only for future reference, but for the patient as well since many offices photocopy and mail results to patients as a means of notifying them of their results. Unfortunately, many physicians do not engage in this practice.

Nearly half of these errors were initiating errors and were associated with errors at all remaining steps. This can probably be explained in part due to organizational policies that place less emphasis on the latter steps as a whole. It is likely that the response errors can also be explained in part because of the lack of policies to require physicians to engage in this practice. All cases where this was accomplished were done on a voluntary basis.

Site 4, on the other hand, automatically completed this task due to the nature in which their results were reported to their patients, which entailed the physicians writing and mailing letters explaining the results to the patient. The letter is written within the EMR system, which maintains a copy of the letter. In each patient's record we could only see if the letter had been written, but we had no way of knowing if the letter had been printed or mailed.

Besides the error of not having a result for a test order, this is the first step for which Site 4 had problems. This is intriguing because it does not have any observed errors for the signature step which is automatically completed once the result is opened. In this system, the results are viewed only when the physician is able to write a response letter because once the result has been viewed it was automatically removed from the “in-box,” becoming difficult to find. Since the signature step and documentation step are linked together in this system, it should follow that if the results had been viewed, then a response letter would have been present. However, since there are cases where there are missing response letters while the results have been “signed,” it shows that there is a breakdown in the system. If letters are not being written, then the physicians must be failing to write them, since the EMR system saves electronic copies. This may suggest that
there may actually be a problem with physicians not officially “signing” the test results (in that they have meaningfully read and comprehended them) and are instead losing the results to the automatic signature feature that files the results out of the “in-box” once the result had been opened, even if accidentally. The performance for this step at Site 4 may be equal to that of the paper chart systems, but such performance is masked by the automatic process that automatically “signs” the record, giving the impression that this EMR system decreases the number of records not seen by physicians.

6. Was there any documentation of an attempt to notify the patient of the results?

It has been said that, “no news is good news.” Such an attitude towards test results is an indication of a naïve belief in the infallibility of the testing process. “No news” may really have been terrible news. The only defense that healthcare providers have on this is to document that attempts have been made to contact the patient. All sites had problems with this step as an initiating error with the exception of Site 4. All subsequent steps were also prone to be imperfect as well.

7. Was there any documentation as to how the results were reported?

There are many ways to communicate results to patients. Sites 1 and 4 primarily reported results via mail, Site 2 sent a postcard with the results written upon it, and Site 3 mostly phoned patients with the results. Whatever method used, it ought to be documented to keep staff from repeating contact methods that do not work and to provide legal protection. What we saw in the records during the audits was either a note describing the method (such as “called patient on...,” “sent results on...,” or “discussed results at follow-up”) or a lack of notification method mentioned at all.

This responsibility to complete this would typically be upon the shoulders of the MAs of the sites because they are the ones who usually send out the reports in the mail or make the phone calls. The physicians at Site 3 often called patients, but it was not
determined who would have noted this in the charts. None of the sites had a policy requiring this step. Any such documentation of the method of contact would be due to the extra initiative of the employees. It is interesting to note that this step still occurs, despite the fact that it is not required.

It is also feasible that the low number of compliant test groups is due to an assumption that follow-up has occurred in prescribed manner that is outlined by the Site’s conventions or procedures. Site 4, for instance, regularly mails letters to patients. Since a written letter is the typical method, no note would be made unless the patient was notified in a manner that is atypical for that site, like a phone call. Thus, a note in the record stating that the patient was contacted would assume that unless otherwise stated, was contacted in the “default” manner.

8. For abnormal results, was there any documentation of attempted follow-up?

There were two criteria that needed to be met for us to consider a group to have made this error. First, there had to lack documentation of any follow-up. Secondly, the group must have had an abnormal result because normal tests do not require follow-up. If there was a missing notice of follow-up but the result was not abnormal, the group would not have had an error at this step.

This step is very important as a means of keeping track of which treatments have been tried or suggested as well as a legal defense. A number of physicians and office managers shared stories about patients coming back to sue the office because the patients claimed that they did not know how serious their conditions were because there was no follow-up or that the follow-up was poor. The physicians and office managers mentioned that their notes about attempted follow-up with patients was enough evidence to suspend litigation.
The only pattern that seems to emerge here is that of the high number of these errors. Just like the other earlier steps, part of the reason for such high error rates here is due to the voluntary nature of completing this step.

IV. Discussion: Learning from Patterns

It should come as no surprise to anyone who has read any literature on medical error that our research should also uncover many instances of error in medical testing. We have also found that the errors in the system do not seem to be independent of each other. The clumping of errors into patterns suggests that systemic factors are at work.

Some of these factors are the organizational policies and procedures, such as test tracking or not having a policy to write a response to the results in the patient’s record. One explanation for the results had to do with our criteria of auditing the patients’ records which exemplifies the problem of the error counting paradigm. We counted as errors certain procedures in charting that we felt were less safe than others. For instance, we believed that MAs should be noting the manner in which the patient was contacted with the results. What we counted as an error was not an error to these sites because there was no organizational policy that mandated that behavior. Likewise, there was no policy to document all responses to the patient’s results. This is one of the problems of the traditional error counting paradigm; errors are in the eye of the beholder, whether that be an individual or an organization. Only context, in this case whether it was an organizational policy or not, can determine whether certain variations are acceptable.

One of the other factors in determining the patterns of error is from the artifacts used by each site. The EMR system, in specific, had a large impact on how work was accomplished. The EMR system was great at preventing the loss of test results as long as the information returned in an electronic format. Unfortunately, it inadvertently hides problems such as the problem of physicians not signing or seeing test results because of
the automatic signature function. Later we will show that the paper chart is itself an important artifact, in that it serves as a reminder to others that something needs to be done with it. The electronic system does not provide such a powerful visual cue.

The central theme of our research is that of the creation of safety. It plays a role in the manner in which the patterns of error form, such as people recognizing the value of charting. The essence of creating safety is in the acts of individuals to meet the demands of the system. We mentioned many examples of individuals going above the call of duty to engage in safe practices that were not formal organizational policies such as MAs writing responses to patients when physicians fail to do so.
4. LEARNING FROM CRITICAL INCIDENTS: STAFF INTERVIEWS

I. Introduction

A physician may fail to sign the test results in a number of charts, but why and how an error occurred are also very important pieces of the story. Our interviews were conducted to elicit examples of incidents to provide context to the information gleaned from the chart audits and observations as well as refine the process flow charts. Our interviews inquired about two aspects of the testing system: critical incidents (i.e. incidents of failure or adverse outcomes) and acts of safety (i.e. how errors have been caught, fixed, or worked-around in order to create safety). Critical incidents provide information on failures that have occurred, while acts of safety (AOS; also known as “who or what saved the day” in Degani, Chappell, & Hayes, 1991) inform us of strengths that are present in the systems that prevent errors from becoming accidents.

II. Interview Methods

A. Participants

In total, there were 17 employees that were interviewed across all sites. Various individuals were interviewed in a range of roles at each site and are summarized in Table 5. Interviews were sought with as many applicable roles as possible, but scheduling and financial constraints limited the total number of interviews to 17.

B. Method

We used a semi-structured interview format with interview questions (or probes) based on the Applied Cognitive Task Analysis (ACTA; Militello & Hutton, 1998) as well as the CTA framework of Crandall, Klein, and Hoffman (2006). Some example probes
included: (1) Can you tell me about a time where you caught an error?, (2) When you do your job, are there ways of working smart or where you accomplished more with less resources?, (3) Tell me about how your testing system works, and (4) Does this flow chart accurately describe your testing process? Each interview lasted approximately 45-60 minutes. Interviewees were compensated $20 dollars for their time. Lunch was also provided when the interview occurred during the employee’s lunch break.

Each interview was recorded with a digital recorder and supplemental notes were taken by the interviewer. Once the interviews had concluded, the recorded conversations were summarized and added into a qualitative software program which was used to explore the themes of safety and critical incidents. More detailed versions of these cases can be found in Appendixes A and B.

III. Results and Discussion

A. Overview

There were a total of 36 critical incidents and 47 acts of safety (AOS) that were extracted from the interviews among the four sites (see Table 6). Some of the information

<table>
<thead>
<tr>
<th>Table 5. Number of employees interviewed by role and site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role</td>
</tr>
<tr>
<td>--------------</td>
</tr>
<tr>
<td>Physician</td>
</tr>
<tr>
<td>MA</td>
</tr>
<tr>
<td>Nurse</td>
</tr>
<tr>
<td>Office Manager</td>
</tr>
<tr>
<td>Office Staff</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

*Note: N/A indicates a role that was not applicable to the process. A zero indicates an applicable role for which no interview was obtained.*
that employees shared did not fit strictly into either the critical incident or specific act of safety category, but rather indicated aspects of an organizational safety culture or were actions that spanned across many parts of the system rather than at one particular step.

We refer to these as system wide acts of safety (SWAS). There were 16 SWAS that emerged from the interviews and these were included as part of the 47 acts of safety since they are believed to be part of improving the process.

Table 6.
Number of critical incidents and safety catches by site and system step

<table>
<thead>
<tr>
<th>Site</th>
<th>Audit Question</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Ordering &amp; Implementation</td>
<td>7 / 4</td>
<td>7 / 4</td>
<td>- / 1</td>
<td>- / -</td>
<td>14 / 9</td>
</tr>
<tr>
<td></td>
<td>Tracking &amp; Return</td>
<td>2 / 4</td>
<td>2 / 3</td>
<td>4 / 2</td>
<td>1 / 1</td>
<td>9 / 10</td>
</tr>
<tr>
<td></td>
<td>Clinician Response, Documentation, and Filing</td>
<td>4 / -</td>
<td>1 / -</td>
<td>5 / 4</td>
<td>- / -</td>
<td>10 / 4</td>
</tr>
<tr>
<td></td>
<td>Patient Notification</td>
<td>1 / 3</td>
<td>- / 1</td>
<td>- / 2</td>
<td>1 / -</td>
<td>2 / 6</td>
</tr>
<tr>
<td></td>
<td>Patient Monitoring</td>
<td>1 / -</td>
<td>- / 1</td>
<td>- / -</td>
<td>- / 1</td>
<td>1 / 2</td>
</tr>
<tr>
<td></td>
<td>System Wide Acts of Safety</td>
<td>5</td>
<td>4</td>
<td>7</td>
<td>0</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>15 / 16</td>
<td>10 / 13</td>
<td>9 / 16</td>
<td>2 / 2</td>
<td>36 / 47</td>
</tr>
</tbody>
</table>

Note. Critical incidents are listed on the left side of the slash, acts of safety are on the right.

Figures 21 and 22 display summarized versions of the critical incidents and acts of safety according to where they occur in the EFTP model. Note that each incident and AOS has a unique numerical identifier that corresponds to the site as well its location in the respective appendix. For example, 2.17 on the critical incidents figure would mean that the seventeenth critical incident in the appendix would refer to a problem at Site 2. The general patterns of critical incidents or safety will be discussed in the next section. The section thereafter will focus on the patterns that were specific to the EMR system.
RESULTS TRACKED AND RETURNED TO PHYSICIAN

RESPOND TO RESULTS, DOCUMENT, AND FILE

NOTIFY PATIENT OF RESULTS

MONITOR PATIENT THROUGH FOLLOW-UP

1.1, 1.2, & 1.3- Laboratory claims never to have received specimen
1.4- Phlebotomists used the wrong color of stopper.
1.5- Not enough specific information on the imaging requisition
1.6- MA failed to anticipate the testing needs of the physician
1.7- Spilled specimen

2.8- Did not properly order the certified tests
2.9- MA could not decipher physician’s handwriting
2.10- Patients do not keep appointments for testing
2.11- Reference laboratory failed to set an appointment for the patient
2.12- Laboratory claims never to have received specimen
2.13- Ordering was not done while key employee was on vacation
2.14- Forgetting to order tests due to overwork and lost notes

1.15- Lab delayed test analysis; tracking did not catch the problem
1.16- Hospital returned the wrong radiograph
1.17- Abnormal results not making it the POD
1.18- Lab had record of test order, but never sent results
1.19- Abnormal result went to absent ordering physician, not POD
1.20 & 1.21- Abnormal tests not being reviewed immediately while waiting for the rest of the results
1.22- MAs shirk tracking responsibility
1.23- Abnormal tests not being reviewed immediately while waiting for the rest of the results
1.24- Physician signed abnormal results as normal
1.25- A patient’s results were filed in another’s record
1.26 & 1.27- Needed records not in file room
1.28- A patient’s results were filed in another’s record
1.29 & 1.30- Physician never reviewed a result
1.31- Residents confuse “to-do” and “file-back” piles
1.32- Physician sends incomplete record back for storage
1.33- While interpreting results, physician’s forget whether patients were to be fasting
1.34- Mailed a letter to a patient with critical results instead of phoning
1.35- EMR system prints wrong values in letters to patients
1.36- Physician forgot the purpose of a follow-up examination

Figure 21. Critical incidents according to their position in the EFTP.
Management began to formalize training for several reasons:

1. Extra help to patients that must go off-site for testing
2. Call to make appointments for patients who are embarrassed
3. MAs "pre-order" tests so patients can be seen in the draw station before closing time, preventing a need to return on the next day
4. Walkie-talkie use allows calls for help without leaving the patient
5. Reminds patients that they should expect results, if not they should call
6. "Pre-ordering" tests to have information already for physician to use
7. Developed a resource manual to help with ordering
8. Fills out forms prior to return laboratory appointment to alert phlebotomist what test needs to be done

Unofficial Chart Audits by office nurses prevent premature re-filing. Management actively solicits examples of cases where MAs innovate. MAs highlighted patients' names on forms in conjunction with the other roles involved.

A. Increasing salience of records of patients which need regular testing (i.e., diabetics)
B. Making patient information more salient
C. A biller's double checks the test ordering
D. Increase salience of records of patients which need regular testing (i.e., diabetics)

Physician sends letters to those that do not return phone calls about test results. Management tries to develop solutions in conjunction with the other roles involved.

Office nurse writes notes to patients.

Management noticed a problem with Pap smears and therefore treats them differently to keep quality high. Management tries to develop solutions in conjunction with the other roles involved.

Unofficial Chart Audits by office nurses prevent premature re-filing. Management actively solicits examples of cases where MAs innovate. MAs highlighted patients' names on forms in conjunction with the other roles involved.

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B. General Patterns

This section deals with the general patterns of problems that have been found across the four sites. These patterns are the loss of information, command intent/communication, information salience, and “star” employees.

Medical testing is about transforming information in one form into another form, irrespective of the many physical steps or artifacts involved. The testing systems transform intangible ideas into tangible artifacts, such as test requisitions and test results. The unit of interest in the system changes depending on where one looks temporally at the process. For example, sometimes the signature of the physician is the key unit of interest and at other times the patient record itself will be. Because the unit of interest changes depending on when and where one looks, we refer to the collective of artifacts and ideas being transformed as information in order to be able to speak more generally about the transformations and discuss general patterns.

1. Loss of Information

One step in the testing processes must follow another in order for a meaningful transformation to take place, indicating a precedence constraint. The office staff have other tasks which compete for the time and resources of the charting process. This competition between tasks often leads to some amount of “down time,” where the test information is not actively being transformed. During these down times, it was not uncommon for records to be placed in large piles and get moved around the work space. During these times where staff were focused on other aspects of their work, there were many opportunities for information loss. Information loss emerged from the interviews as one of the top problems that staff face in processing test information.

There are number of ways in which the information could be lost, some of which include results being filed away without being signed, laboratories failing to send results
back to the office (either due to a lack of specimen or loss of the results in their system),
results being filed in another's record, misplacing charts around the office, not writing
enough information, patients not showing up for draw station appointments, and failing to
send a results-letter to the patient.

One of the contributors to the loss of information is the problem of transportation.
Loss during transportation is not limited to interoffice, but intra-office as well. For
instance, information could be lost on-site during a transfer between the physician and MA
as well as off-site when the information is transferred to a reference laboratory. Consider
the problem of sending patients off-site for testing. The offices without on-site facilities
must rely on the diligence of the patient to present at the facilities for testing, which
reportedly does not always happen.

Sites that have on-site draw stations still must send the specimens off to be
analyzed. In turning over part of the process to others outside of the office, the office
relinquishes their control of the process to others and is completely dependent upon the
laboratory or patient having the test done correctly if even done at all. Even if the patient
or laboratory does fulfill their role, the office is still left unaware of product status until the
laboratory sends the results.

One frequently cited problem was when there was no test result that corresponded
to a test order. The offices usually referred to this as a failure on the part of the
laboratories, but the laboratories claimed that it was a problem of the office. Unless there
is a reliable tracking system in place, it is difficult to know where the problem can be found
in order to rectify it. Whether the problem is due to a failure on the part of the office to
send a specimen, the office inadvertently throwing the results away, the laboratory failing
to properly process the specimen or to send the result, is that neither the office nor
laboratory may know what happened. After a few days, the office staff have moved on to
worrying about other job related problems and may not remember which test results have yet to return from the laboratory.

2. Command Intent and Communication

Another contributor to loss comes from the fact that although employees are part of a team and are in the physical presence of others, many of the employees work alone in the sense staff do not communicate as often or as well as they could unless their task explicitly involves the other person. For instance, when a file clerk at Site 1 goes to pick up the patient charts, she simply takes the charts without asking the office nurses if she has the correct pile of records. In another case, physicians sometimes share pertinent patient plans with the MAs or office nurses in effort to enlist their assistance by communicating their intentions.

While coordination requires time and resources, communicating one's actions with others gives them a chance to actively prepare for what is to come and is essential for “flatter organizations” which require their employees to be able to act (semi-) autonomously. For instance, at Site 1 we noticed that physicians often shared their testing plans for the patient with the MAs after having examined the patient. Since the MAs had now been informed of the physicians' plans, they could then double-check the partially completed requisition form that had been handed to them by the physician and make sure that it had been filled out correctly. When MAs accompanied the patients to the in-house draw station, the MAs verbally reported the test instructions to the phlebotomists, who then in turn checked the requisition for accuracy. The requisition by this point had been checked for accuracy at least three times; once by the physician, once by the MA, and once by the phlebotomist. If the physicians never shared their plans with the MAs, no person during the process would have ever known if the physician had made a mistake in ordering.
Contrast the previous example with that of one that happened to an associate of the author in the following example (although this did not occur at any of the sites included in our study). The patient went to have a screening test for prostate cancer from a medical center that had exclusively used an EMR system. The physician ordered a prostate specific antigen (PSA) test via computer while remaining in the examination room with the patient. The physician then had the patient report to the draw station to provide a specimen. A few days later, the patient received a copy of the test results and found that the results were for the wrong test. He double-checked the form for his name since it was possible that somebody else’s results may have accidentally been sent to him. The name was his, but the test results were for a different test. The patient called the physician about the problem and found that the physician had accidentally ordered the wrong test from the electronic system in the exam room. The laboratory had complied precisely with the physician’s orders; the physician had slipped and had ordered the wrong test.

Only two people knew what the physician’s plans were—the physician and the patient. The physician failed to notice that he had ordered the wrong test during the requisition phase and even missed it during the review stage, having signed the results as normal. The patient’s results were indeed normal for the test that was performed, but they were the wrong results all together. The patient’s ability to understand test results kept this error from becoming even worse.

Communication between the roles provides feedback and thus closes the loops in the system. Closing these information loops allow for corrections to be made as errors unfold in time because it provides the knowledge that staff in the proper places need to make the changes and correct errors.

Another problem of loss was with reference laboratories claiming not to have received patient specimens. Even if the laboratory’s courier came to pick up the specimens
and signed a document stating that the specimens were taken, there is no guarantee that the specimens will make it to the laboratory or that the specimens will be processed. The courier may accidentally place a specimen on the roof of his car and drive off, not realizing what has happened. While this particular problem may be unlikely, it exemplifies the problem facing the offices and laboratories, in that neither knows what has happened to the specimens. There is no current method of comparing what the laboratory received to what was picked up at the family practice. As of now, sending a specimen to a laboratory remains an open loop system.

We propose that one solution to this problem (which was not observed at any of the four sites) might be to request that reference laboratories fax over a list of all received specimens and orders that were received that day. Those at the family practice could then compare that list with their own records. Such a tracking system would resolve many of the problems between the laboratory and office, or at least allow the discrepancies to be resolved during the next business day rather than two weeks later when someone notices that the result had not returned. With all of the complaints that we received about the testing process, it would seem that this would be one of the best places to improve the system, particularly since it occurs early in the process and means that less time is lost if the patient is required to return again.

3. Information Salience

Part of what contributes to the loss during transportation and storage, is the low salience of the information. Almost all documents in all of the offices that we observed were on white paper. All of the words and numerical values were very similar in size, color, and font style as every other document. It is easy to imagine how test results (or other documents) may accidentally be thrown away when they looks similar to every other office document. Since many of the results that return from the laboratories arrive
via fax or printer, changing the color of paper in the printer tray would make the results much more salient and easier to distinguish from other documents.

Although we did not observe the use of different colored paper, some employees remarked that they used other means to accentuate important information such as using highlighters on the patients' test results and names. Others mentioned that they arranged their environment or processes to help them deal with the large amount of work. One MA noted that she had been given an accordion file folder to use for tracking her patients. However, when she put the papers into the folder, the folder completely hid what was inside, giving her the impression that there was nothing inside of it. To remedy this, she simply started placing the papers in sideways so that the tops of the order forms, which contained the patient's name, would poke out of the folder. She claimed this acted as a visual reminder that there were tests that needed to be tracked.

Another example of increasing the salience of important information came from Site 3. Diabetics often require regular testing and Site 3 felt that they needed to do something to help remind them that they were dealing with a population that required regular testing. They accomplished this by placing the patient's record inside of a colored folder instead of in the plain manila folders that are used for other records. The difference in folder colors increased the salience of the record and reportedly helped remind the MAs and physicians that they needed to make sure that certain tests were regularly being performed. In addition to the colored folders, Site 3 also used green plastic sheets to place inside of the patient charts that were awaiting test results. This increased the salience of incomplete charts and served as a visual warning against filing that chart back on the shelves.
4. “Star” Employees

Reliance upon a few “star” employees is another problem. One star MA mentioned a case where she was out of the office for vacation for a few weeks. When she returned, she found that her temporary replacement fared poorly in her position, leaving the system in a state of disarray. While some employees will have more potential and therefore become more valuable than other employees, no system should be in the unpleasant position of being so reliant upon that employee that their system fails without them.

Site 3 inadvertently mitigated the star employee problem while trying to reduce employee turnover. Their solution to the problem of employee turnover was to expand the roles which required that all MAs would be cross-trained across all possible MA roles, such as working with the physicians, taking specimens, and filing paperwork. In doing so, the MAs were able to close the loop and see how their actions in one role would affect them in another. Cross-training the MAs, in a way, reduces the reliance on the star employee by enabling others to compensate while the star is away.

C. The Special Problems of EMR Systems

There were a few problems unique to Site 4 because of their adoption of an EMR system. With a big push to move towards replacing paper records with electronic records, (including from industry giants such as Microsoft and Google; Lohr, 2007), EMR systems are beginning to look like they will become more commonplace as time goes on. We hope that the lessons that we have learned from the problems encountered at Site 4 may provide lessons to those designing such systems.

One of the first problems that the employees mentioned to us was that the EMR system was too complex for them. The physicians reported having been trained how to operate the system, but that the training lasted only a few hours. When we were trying to
learn the system so that we could effectively audit their patient records, the MA and physicians told us that they did not know how to perform many of the specific functions that we were looking for. They mentioned that they often discovered new features when they experimented with the EMR system and would sometimes share that information with the others in the office. While holding informal training sessions is a testament to their desire to have a safe testing process, it is unfortunate that their EMR training left them to learn their system through experimentation.

Additionally, Site 4 had no tracking system because there was a belief among the physicians that the system would take care of that function for them. The MAs recognized that there was sometimes a problem with this step, but did not make it a case to develop a solution. However, even if it was decided that tracking was important to their practice, it would have been difficult to implement such a system given that the EMR system reportedly had no feature that could provide a list of all test orders that had not yet received a result. The MA even called the technical support staff for the EMR system to ask if this feature was possible and received the reply that they also did not know if this were possible. It is unfortunate that there was either no way to monitor what the EMR system was doing or that the system was so difficult that not even the technical support staff could help. The inability to track results is a serious threat to the safety of those patients.

As mentioned previously, physicians regularly sign their initials or names on the test results once they have returned to the office. This mark should indicate that the physician has read and understood the test results. On the paper records, this was an easy mark to look for in our audit. In the EMR system, there was no place on the results for a signature (we instead had to infer that the presence of a results-letter indicated that the results had been read). When the results returned electronically from the laboratory, they came back as an email header that was added to a list of other results and appointments
that the physicians saw for that day (the medical assistant also had access to this information). When the physician was ready to review the results, he would go through his “to-do” list on the computer and find the highlighted unread test results. Once a result had been opened, either by the physician or MA (purposefully or accidentally), the EMR system auto-signed the physician’s name on the result as soon as the file was closed. One the record had been “signed,” it was un-highlighted and removed from the in-box. This process would be analogous to filing an incomplete chart back onto the shelf.

The paper record at least has the advantage of being a physical artifact that moves around in the space of the office. As a physical object, anyone can see it and open it to determine where it belongs and whether it is complete or not. As long as it remains in the open, it is able to be reviewed by anyone. Its presence actually invites investigation, since most offices are aware that stray records are a safety threat. The electronic records, on the other hand, only exist on the computer and if a mistake occurs, it might be “filed away” without the needed information, such as in the previous example. There is no physical artifact that invites employees to double-check.

Again, not having an employee ready to start the next phase of the process causes problems. Site 4 has one full-time physician and multiple part-time physicians. The part-time physicians also order tests on their patients. However, since they are part-time, they may not be in the office when they return. This would not be a problem if the results went into a pool of test results that all physicians could see or if the system could “kick” the result to another physician if it knew that the ordering physician was not there. Sadly, this is not the case. Test results, including abnormal results, will wait in the electronic in-box until the physician returns.

The last unique problem for the EMR systems is what is known as an *automation surprise*, where an automated system performs an unexpected action. For instance, while
the physician is typing out a results-letter to the patient, there is a helpful feature in the EMR system that auto-populates the patient’s test scores into the letter, saving the physician from having to manually do it. However, it was reported that this feature was not always accurate. What was printed on the letter was not always what appeared on the screen. While this glitch is obviously a design flaw, the only reason that the error was caught was because an employee was double-checking the product.

By now, it should be clear that the testing systems have many problems, but that some of the problems are overcome by the actions of individuals, who are creating safety by recognizing the weakness and adapting their behavior to compensate. Safety is being created through the use of double-checks and adding redundant measures. They are creating safety through their attempts to identify and close the loop in the open loop areas of their respective systems.

D. Safety Culture and Resilience

At Site 1, a senior ranking physician occasionally signed abnormal test results off as normal. Luckily, his MA happened to know something about test results and would review the physician’s work to make sure that he signed the results off correctly. The MA was able to fix the physician’s minor error because she knew something about the test results, because she made it a point to double check the physician’s work since she recognized this step as a potential safety threat, and because she had a working relationship with the physician who allowed her to confront him when he made such mistakes. Unfortunately, not all physicians are willing to admit their mistakes. While visiting this site, a new physician was reprimanded for yelling at the staff for what he felt was insubordination when an MA corrected him on how to fill out one of the forms. Those who double-checked each other’s work need to feel as if they could do so without being reprimanded. This
underscores the importance of the relationships between the staff members and how organizations encourage and support acts of safety (making them more resilient) or discourage them.

What is a resilient organization? Woods (2006) has described resilience as “the ability to handle events that fall outside its design envelope.” For example, the testing system was designed to work properly only when the tests results were reliably returned. When the results do not meet that assumption (e.g. they do not return at all), does a massive failure occur? Imagine three different offices with different levels of redundancy. The first office receives the test results on a printer networked to the laboratory. The second office has the printer and will also receive a second copy via fax. The third office has the printer, the fax machine, and a tracking system. If the first office misses the result or throws it away, their system will fail entirely. The second office has a second chance to catch the result from the fax machine. If they miss both sets of results, they will fail. The third office not only has two chances to get the results, but they also have an opportunity to see that the results are missing in the first place. The third office is the only office to “know what it does not know” and therefore is more resilient because of the redundancy in the system.

The other end of the continuum is brittleness. A brittle system is one that routinely fails in the face of perturbations and variance. In the case mentioned earlier about an associate of ours being ordered to have a PSA, the system in which he found himself was brittle because there were only two people who knew what the physician’s intentions were. Had the patient not noticed that his test results were not for a PSA and then not addressed the problem with the physician, the patient’s problem might never been addressed. If the patient had not been informed of the physician’s intentions; this system would have completely failed.
So far, the examples provided for resilience were focused on the agents and artifacts that make the system work in the face of perturbations. However, as we mentioned earlier, these individuals operate in the context of an organization that either supports or hinders those employees. Organizations that support those employees are more resilient than those who do not. Wreathall (2006) has outlined seven characteristics of resilient organizations, which we have summarized (Elder, McEwen, Flach, & Gallimore, 2008; italics added):

“Top level commitment: Top management recognizes performance concerns and addresses them with continuous and extensive follow-through.

“Just culture: Supports the reporting of issues, problems, events and errors throughout the organization, yet does not tolerate culpable behavior.

“Learning culture: Responds to issues, problems, events and errors with repair and true reform, not denial.

“Opacity: Is aware of how close they are to having serious problems and events due to weak safety defenses.

“Awareness: Management collects ongoing data to gather insight into quality of performance, problems and the state of safety defenses.

“Preparedness: Actively anticipates problems and prepares for them.

“Flexibility: The ability to adapt to new or complex problems in a way that maximizes its ability to solve the problem without disrupting overall work.”

Comparing these characteristics to the acts of safety found in Figure 23, it is plain to see that the majority of the SWAS came from the level of the individual rather than the organizational. Let us examine the instances of SWAS and how they represent specific characteristics of resilience in their respective offices.
Site 2 had four SWAS. Number 2.38 refers to a situation where management gave oversight to an MA every month to double-check the tracking log. This sounds like an example of top-level commitment, but on the grounds that the only thing that management did was to recognize the problem and implement a solution, it falls short of the necessary follow-through. The implemented solution does not receive much support by the staff or even management. While observing this practice, we noticed that the tracking records were weeks behind. The staff reported that the only reason that they were starting to track the results was because of an upcoming audit. While the periodic audit is a step in the right direction, they are apparently so far apart that the tracking system has become ineffective. While this example may qualify for an act of safety, it is a singular act and fails to be a resilient characteristic for Site 2.

On the other hand, Site 2 began to formalize certain training procedures in SWAS 2.40, after a number of problems and complaints due to some ambiguity about what the proper procedures were, particularly from the non-medically trained office staff. We felt this was a case of learning culture because management listened to the problem that was presented, they learned about what they could do better and then made a decision to more clearly define the office’s policies and procedures and to make sure that everyone was trained to be able to comply.

Site 3 had the most examples of SWASs and of organizational resiliency characteristics. Item 3.41 is an example of preparedness because management knows that they have good MAs, but some of them are more capable in certain job roles than others. For instance, some MAs are good with patients but are less than adequate with the charting and so management arranges for the stronger MAs to work with the weaker ones in performing the various duties.
There was an example of awareness from item 3.42, where Site 3 gathered data from chart audits on Pap smears. Management had been concerned about errors with this particular type of test due to the long periods of time in which the office had to await the return of the results. In response, management created a special process for those types of tests and audited them to try to continually improve that part of the process.

Actively soliciting examples of errors so that the office can learn from their mistakes (3.44) is an example of learning culture, just culture, and top level commitment. The management of Site 3 is committed to continuous patient safety improvement. In order to improve their care quality, they regularly solicit examples of failures. They take these examples and discuss them in teams to get ideas on how the problems can be resolve. Management also recognizes that everyone will make a mistake and does not penalize those who bring examples of error to their attention. Management is very careful to not scare or threaten their employees because they recognize that their employees are important sources of information on the health of their system. In fact, employees are often rewarded for sharing their examples of failure to management and are often asked to work with management to develop solutions (see item 3.45) and to train others in team meetings where problems are discussed (see item 3.47).

Site 4 did not report any SWAS in the interviews, but this may have been due to the low number of interviews conducted here. Site 1 provided many SWASs, but none of them would be considered organizational characteristics since they all took place on the local level. In fact, in spite of the high number of SWAS reported by Site 1, they reported many examples of it being a brittle system such as a problem with an autocratic leadership.

One physician shared an example of how the clinical director rarely asks for information regarding the health of their system or patient safety concerns. When there is time given to address such concerns, it has been reported that the director asks for input
from others but then institutes his plan without giving others’ ideas fair consideration. To make matters worse, only physicians meet together to discuss these system safety issues. When we asked a different physician about why the meetings only include physicians, we were told that they did not want the other staff members (e.g. office staff, MAs) to know that they were talking about them since many problems were the fault of the office staff and MAs. If the office nurses and MAs were present at the meeting, then some of the physicians would not feel comfortable addressing the problems. While the MAs and office staff may be part of the problem, it is likely that the MAs and office staff could report problems caused by the physicians. Not including the MAs and other office staff means that some of the most important sources of system safety and health are not available. The meetings ignore the experience and ingenuity of those who might have the most experience dealing with the problems of testing. How can an organization like this ever learn from its problems?

The sad fact remains that we did not find examples of all of Wreathall’s (2006) characteristics of resilient organizations at any site. Site 3 had many examples, but even they fell short of a perfect score; the other sites fared much worse. Despite the weak presence of organizational resilience factors, many errors and problems are being fixed before they escalate into larger issues thanks to the resilience that is created on the individual level. What this suggests is that there is much room for improvement on the side of the organization to developing the characteristics that foster resilient behavior.
I. On Wildfires, Banks and Testing Errors

Donovan and Brown (2007) make an interesting case about wildfires that seems to go against conventional wisdom. They argue that the Smokey Bear policy of fire exclusion (i.e. that all forest fires should be prevented or extinguished as soon as possible) is a poor strategy for forestry management because fires are a natural part of the forest's life cycle. When fires are always prevented or immediately extinguished, the natural cycle is broken.

The policy of fire exclusion has had two important detrimental consequences for forests. The first is a diminished fire resistance for some native tree species and the second is the increase of the fuel load (i.e. small brush, dead leaves, dead wood, etc.) on the forest floor. These two consequences combine to form the potential for a catastrophic fire.

Under normal conditions, the fuel load on the forest floor would be rather light, which means that the fire would burn quickly, leaving the surrounding trees relatively unscathed as the fuel quickly burns itself out. With a greater fuel load, the fires burn much hotter and longer, giving the fire more time to spread to branches and surrounding trees and greatly increasing the severity of the fire. When in combination with the decrease in natural fire resistance, it takes even less time and energy to bring a tree to the point of combustion. As more trees combust, the heat becomes even more intense and makes further burning more likely.

A small fuel load wildfire might have had some terrible consequences if it were allowed to burn such as damage to houses and or property, but by preventing or immediately extinguishing the “little” fire, the forest has increases its destructive potential.
Donovan and Brown (2007) suggest that forestry managers consider if the benefits of the Smokey Bear policy are worth the risk of the catastrophic wildfires in the long run. Wildfires are indeed a problem, nobody wants their property destroyed, but they are necessary on the other hand if the catastrophic fire is to be avoided. Any policy will be associated with certain benefits and costs, which is why the total elimination of wildfires is a naïve view. It simply fails to look at the bigger picture. Forestry managers need to work on being managers of wildfires rather than strictly extinguishers of wildfires.

Another great example of the problem of eliminating small problems at the expense of the larger picture comes from Taleb (2007). Accordingly, decades ago there were many more small regional banks than there are today. Many of these banks struggled to offer some of the incentives that the larger banks could and had subsequently had harder time staying financially viable. As customers dwindled away, the small regional banks failed or were purchased by larger banks. This made the larger banks less likely to fail because they were less dependent upon the success or failure of a single branch, unlike the small local banks that were much more sensitive to the economic performance of a single branch.

While the small banks failed, it meant trouble for many of those with accounts with that bank. The larger banks, being more stable, seemed to be a better alternative because they were less likely to fail. However, when large banks fail (e.g. such as the IndyMac bank with $32 billion in assets; Mullins & Palmer, 2008), the damage is much farther reaching and is much more detrimental to the economy than if it had been a small regional bank that had failed. While $32 billion dollars is a lot of money, it is a mere fraction in comparison to ailing Freddie Mac and Fannie Mae, which are responsible for nearly half of the mortgages in the United States and have a combined worth of about $5 trillion dollars (Benner, 2008). Needless to say, their failure would be a lot more problematic than the failure of the average mortgage lender.
While these two examples seem to have little to do with medical errors, the commonality is that they are all systems that experience some “error,” whether it is a physician failing to sign a test result, a wildfire destroying property, or the failure of small bank. Decision makers must examine and address these errors in their systems in some way. Historically, forest managers, have chosen to immediately suppresses fires, banks have merged with others to become more profitable and economically viable, and physicians have purchased system tools to help them reduce the number medical errors. Given that errors can lead to wasted effort and lost financial resources, it is completely understandable that people would try to eliminate errors.

While we certainly agree that medical testing could greatly be improved, we warn that in the quest to totally eliminate all errors, many of the important dynamics necessary for the stability and safety of the system might be removed. Not all errors are of equal worth—a missing signature is not the same as a missing result and in the rush to eliminate lesser errors, organizations may be running the risk of setting up a situation for the creation of catastrophic failures.

We are not advocating that some errors should be allowed to stay in a system, but we are suggesting that the potential for smaller and less meaningful errors may need to be left in the system in order to avoid the larger problems. We use the phrase “potential for error” because while errors are bad for the system, sometimes it is often that those areas that seem like the greatest liabilities are also the sources of the greatest strength. It is at this juncture where errors are caught and mitigated and where safety is created.

Recall the example where the patient had a PSA test ordered for him by his physician on the electronic ordering system while in the exam room with the patient. The physician told the patient that he was going to order a PSA, and then proceeded to enter the test information in to the computer. The electronic requisitioning process eliminated the need
to fill out two requisition forms, one on paper and one electronic. It meant that the
physician did not need to relate that information to anyone else, keeping the patient’s
information more confidential and diminishing the opportunities for the MAs to lose the
patient’s information or mis-enter the patient’s information into the system. Having the
ability to requisition tests in the examination room is a system that eliminates many
common problems, but it also means that other problems, such as the incorrect test was
ordered and analyzed, can arise.

Had the physician filled out the forms by hand and spoke to the MAs or nurses, other
people would have been in the loop about the status of the patient and may have been able
to catch that the wrong test had been ordered much earlier in the process. Instead, the
entire process failed this patient, who had to repeat the whole process over again, which is
a much worse error than if the MA had to verify the physician’s original requisition. The
system that was designed to eliminate some of the clerical errors (which could have also
led to this same outcome), created a situation where the system was bound to fail
completely for the patient.

The elimination or prevention of all errors is impossible, human behavior will
always carry with it some degree of fallibility. Some amount of errors will be inevitable
given the complexity of the systems in which we often find ourselves. No team of experts
could design system defenses and protection for all the possible ways in which that system
could fail. For this reason, we need to move away from the witch hunt for errors and
instead look for ways in which we can make the system more robust by supporting the
natural dynamics in the system that typically keep it operational and safe. Given the
inevitability of errors, the best bet to manage error and improve patient safety is to shift
the focus on making the system more error-tolerant (i.e. resilient) rather than error-free.
Westrum (2006) gives three major meanings to the term which are the ability to prevent “something bad from happening,” “the ability to prevent something bad from getting worse,” and “the ability to recover from something bad once it has happened.” Resilient systems will adapt and try to compensate for the errors while brittle systems will struggle to bring the system back to a safe operational state, such as having to restart the entire testing process with the patient in the above example. However, the only way that the system can be resilient is if those who create the safety have the required information in order to make meaningful decisions. The way in which operators receive this information and create safety is through the use of two dynamic mechanisms, that of feedback and feedforward loops. Patient care quality and safety can increase when these mechanisms are supported by the organization. We will now address this issue in more depth.

II. Revisiting the Error Free Testing Process

The presence of feedback and feedforward loops is the systems that we observed makes it necessary to revisit the EFTP model that was introduced at the beginning of this paper by Hickner et al. (2005). The lack of incorporated feedback into the original EFTP model is one of two problems that need to be rectified in order to improve its accuracy.

Let us examine the first problem with the following safety catch example. In this case, one MA at Site 3 noticed that physicians ordered patients to have blood tests without noting whether the specimen should come from a patient that was fasting or not. When the results returned from the laboratory, the physicians would ask the MAs if they could remember whether the patient had been fasting. The MAs would often not be able to provide an answer to this due to the amount of time that has elapsed from the time of the order and because the MAs might have rotated their roles throughout the office by that time, leaving the physician to ask an MA who was not involved with that patient. When the
physicians asked the MAs about the fasting status of their patients, the physicians unintentionally provided feedback to the MAs that there was something wrong with the system.

The MA who shared this example was able to learn from the problem and adapt her behavior in anticipation to this potential error by writing the fasting status of the patient on the test requisition. This example perfectly illustrates that the testing systems are not open loop systems as the EFTP portrays. There was a natural feedback loop in the system (i.e. the physicians regularly asked for this information) and this particular MA was able to capitalize on it and fix the problem. The feedback loops allow employees to learn and adapt their behavior to compensate for problems that arise. Once feedback and adaptations are introduced into a system, it becomes a closed loop adaptive control system.

Open loop systems, such as the EFTP (see Figure 1, p 13), would only be successful if every step was error free. In a closed loop system, errors in the process could be regulated via dynamic mechanisms (i.e. the behaviors that form the feedforward and feedback loops) out of the system making the success of the system less reliant upon the perfect execution of every step. Since our research also shows that errors frequently occur yet can still “work” given that employees can actively correct errors, we see that the current EFTP model incorrectly model the process as open loop. The current feedforward model must be updated to reflect those dynamic mechanisms that regulate the system. The feedback and feedforward loops serve to allow the operators in the system to adapt and tailor their behavior to compensate for the weaknesses that have been recognized. A more accurate model of medical testing would be as the closed loop system found in Figure 23. Let us now discuss these regulating mechanisms in further depth.
As an adaptive control system, the modified EFTP would have feedback loops that lead from each step into itself and into the preceding steps. For example, in the “Patient Notified” step, physicians and MAs would learn that some patients are tough to reach using a certain notification method, such as calling on the phone because of a disconnected line (not unlikely given the recent decline of landline phones in lieu of mobile phones), and would adapt and send a letter to the patient instead. This way, the “Patient Notified” step becomes more resilient. Furthermore, The MAs might learn that because the patient’s phone has been disconnected that the next time that the patient comes in, the patient’s records will need to be updated.

Figure 23. The improved EFTP model with associated feed-back and –forward loops.

Information from one step will also feed back into previous steps such as when a physician monitors the patient through follow up and finds that the patient’s condition has not responded to treatment. When the physician asks the patient to return for further
testing and treatment, the physician’s testing decisions will be informed by the feedback provided from the follow-up. The MA who started making notes on the patient’s fasting condition (under the “Test Ordered and Implemented” step) came from feedback gained at the “Documentation of the Response to the Test Results” step.

Not only are the steps connected with feedback loops, but the modified EFTP model is also connected by feedforward loops that connect to themselves and the steps that follow. The feedforward loops are the anticipated adaptations in behavior that the employees make in order to make the system work, whether that be the MAs asking patients for updated personal information so that the results can reliably be returned, MAs note that the patient is fasting, or physicians specifying their intentions for the patients’ treatments. In theory, the most resilient system would have every step connected by both feedback and feedforward loops. This research has uncovered many of those loops, which are noted as the acts of safety and failures in the appendix. Nearly every example of an AOS or failure is an example of either being a feedforward loop that was informed by a feedback loop or where errors were missed because of a lack of feedback to allow staff to know how to respond it.

While the potential for feedback and feedforward loops is certainly present in many of these steps, not all steps make use of them. This failure to use them comes typically in the form of one employee never speaking with other employees about the problems that are encountered. Many of the interviewees mentioned both examples of tips that they had for others performing the same task as well as had a list of things that bothered them that others did at other steps that made the job more difficult. Communication is the key to provide feedback that allows for a more resilient system, but sometimes those communication channels are not open. Secondly, many of the staff felt at times that there was nothing that could be done to remedy some of the common errors
because they felt like it was not their job to work-around the problem or because supervisors did not approve of the corrective actions. Feedback is important, but without the ability to make use of it, it does not do any good.

The second problem of the old EFTP model is the assumption that an “error-free” outcome will be the result of the culmination of error-frees steps. We can only partially substantiate this assumption. We did indeed find examples of error-free patient records, indicating that the good outcome was a result of error-free performance. However, finding that many errors were being actively prevented, mitigated, and repaired before they escalated into larger failures show that good outcomes do not necessitate that every step happen perfectly. Accordingly, we believe that the “error-free” portion of the EFTP model ought to then refer to the error-free quality of the output rather than the throughput. Mistakes can still occur in the process, but as long as they are fixed, then a good outcome is still possible.

In summary, we believe that the key to safety is resilience, where errors can not only be prevented, but be actively mitigated or repaired in real time. Therefore, we propose that a more realistic model of medical testing would reflect the principles of resilience by adding feedback and feedforward loops. Future research and improvements need to take these loops into consideration. Any adjustments will alter these loops. It is very possible that by removing the opportunity for small errors, the system has lost a major source of safety by severing these loops. Before making decisions on how to change the system, serious consideration ought to go into determining how the proposed changes will affect the system. Even more importantly (and perhaps more cheaply), major changes may not even need to be made to the system (i.e. such as purchasing new equipment, such as EMR) if the organization would take time to develop feedback channels and empower staff with the ability to correct errors. In order to do this, the organizations will need to
have a culture that supports these types of behaviors. We will now turn to developing such a culture.

III. A Culture of Quality and Safety

Consider two contrasting examples of organizational culture from our observations and interviews. One site mentioned regular meetings to discuss quality and safety issues on a regular basis and openly solicited ideas for improvement from all employees. At another site, a physician complained that she often had to email both the office manager and clinical director with concerns that she had to increase the likelihood that one of them would respond, to which they reportedly rarely did. She also reported that safety concerns were rarely addressed at the staff meetings, even though she might have recently emailed a number of concerns about patient safety. This physician also went on to relate how when she was once asked to talk about a safety problem and generate a solution, the clinical director discounted everyone’s ideas and decided that the problem would be handled his way, leaving many to wonder why the clinical director even bothered to ask for input.

What incentives do individuals (of whom we have already shown to often be a source of safety) have to try to improve the systems in which they work if the culture does not support such behaviors? I watched in shock while an employee was reprimanded for having done the “wrong” steps while completing some paperwork for the testing process. It turns out that while the employee did deviate from the prescribed steps, it was to compensate for a failure that would often occur later in the process. The only reason that this employee was caught was because she was overheard by a physician while she was describing her part in the testing process to me. The provider immediately castigated this staff member in front of me, other staff, and patients. One can only guess the real lesson that was taught—that of “our system is perfect as long as you don’t go changing our predetermined and prescribed methods of doing things.” Such an attitude surely does
nothing to promote a culture of respect, resilience, safety, or quality. This section is
dedicated to providing some suggestions to organizations for creating a culture that will
support staff in the struggle to deal with the inevitable error.

A. Engineering the Culture

So how do you create a culture of safety and quality? Management needs to stress it
in their language and actions (Liker, 2004). We noted that some offices were quick to
punish their employees for problems that arise. After our interviews, we returned to the
various sites to provide a summary of our findings. At one of these meetings with the
management of Site 2, the office manager indicated that she fired one of her employees for
failing to complete a certain task.

Granted that certain steps should not be left out such as returning the results to the
patient, some steps are an arbitrary means to an end rather than an end in of themselves.
There is a difference between returning results and the way in which the paperwork
should be organized, filed, or stored. Since no investigation was completed on why the task
was not completed, no lesson can be learned about why the step in the process was
skipped. In addition to failing to learn from the process, the firing of the employee might
have sent a clear message to the rest of the staff, which is to "cover up your mistakes
because management believes that the system is more reliable than its employees."

If employees do not feel that they can talk without fear of reprisal, the office
management is incentivizing cover-ups and silence, keeping an office from ever receiving
feedback on what is wrong with the process. During the interviews, many of the employees
had to be assured that this information could not be tied to them and that it would in no
way affect their employment status. Even when that assurance was given, there was some
hesitancy to speak to us about mistakes that they had made. When the feedback loop is
never closed through discussion, the system cannot ever learn to adapt, which is crucial for resilience.

While we are not advocating that employee should never be reprimanded under any circumstance, management needs to be very careful about doing so because any action that they make will affect the culture. Every action that is made will have repercussions for the work environment and culture. Reason (1997) has developed a culpability decision tree that managers ought to consult and consider when dealing with issues with employee behavior (see Figure 24).

According to the decision tree, management needs to ask questions about the nature of the accident or error. Notice that culpability decreases as the decision tree moves to the right. At the far right, the outcome is known as a blameless error, or an error that could not be predicted and that anyone could have made. The dotted line is a special caveat to the willful violation of standard procedures in the case when the procedure would be incorrect in the particular circumstance. The “pass substitution test” refers to the question of whether any other employee given the same education, training, experience, etc. would be likely to make the same mistake. See Reason (1997) for more details on this, but the point is that management needs to be very careful of the messages that it sends when dealing with accidents and errors.

B. Improving the Process

1. Genshi Genbutsu

Employees must develop knowledge of the system that can only come from experience in the domain if they are to learn step in the process affects the other steps. The process of studying the process by careful firsthand observations is known as genshi genbutsu in quality improvement circles. The admonition to go firsthand and see the
Figure 24. Reason’s (1997) culpability decision tree.
process has become a heavily endorsed requirement for improving organizational systems (Ohno, 1978/1988; Liker, 2004). This act of observing the process is essential to gain the knowledge of one’s role and is a precondition for the formation of the feedforward loops that strengthen the system.

Unfortunately, none of the sites made it a point to actively engage in systematic observations of their sites as a means of finding problems with their systems. Typically, management at these offices relied solely on reports rather than firsthand knowledge that they had gained through personal experience with the system. The MAs at Site 3 were doing this to some degree because of the manner in which they rotated through the various MA jobs. However, it was only the MAs/nurses that were able to benefit from firsthand experience with a larger portion of the process. For this reason, it is no surprise that they seemed to understand more about their whole process than anyone else in that office. It is that firsthand experience with many different parts of jobs in the system that allows them the opportunities to close feedback loops and add feedforward loops by having the relevant information on how to combat errors in the weaker spots of the processes.

Management does not act in a vacuum. There is a division of labor in offices, which means that each role will become experts in their respective area. While genshi genbutsu is important for everyone to develop a detailed overview of the process, one will never become as experienced as those who are actually in that role. It is a shame that some of the office managers and clinical directors did not seem to recognize the expertise of those working for them. Without recognizing that expertise from being intimately involved the process, management will likely have an incomplete understanding of the important quality and safety issues. It becomes very important, then, to meet with those various roles, to solicit information from them, and come to a consensus about future changes and
plans. After all, those at the sharp end may know more about how the plans will affect the system than those at the top.

2. Taking Responsibility for Quality and Safety

Offices considering lean practices need to make sure that all employees feel that quality and safety are their responsibility (Liker, 2004). There were staff members who recognized problems from past experience and made it a point to correct the errors from continuing on through the process, but not everybody did this. Some employees mentioned that they saw mistakes but never corrected them because it was not their role to do so. A culture of quality and safety means that everyone recognizes that quality and safety is their responsibility and that they feel empowered to “stop the line,” or keep the chart from moving forward until the problem is resolved. Management needs to step up and impress this upon their employees and then support those employees in their attempts to better the system.

3. Standardization and Visual Control

Some employees claimed to regularly review the charts that they find lying about. Some of those employees have even provided examples of errors that were caught during one of these informal audits. However, not all employees seemed to have engaged in this practice. There are many reasons that one could suggest for this, such as too little time, too little motivation, or that it fell outside of their job responsibilities. While quality and safety is the responsibility of everyone, some help could be provided to assist those who audit the charts by making the audit easier. This can be accomplished by standardizing the charting process and by adding visual controls (Liker, 2004).

Standardization and visual controls would be helpful in the charting process, but they are also more general and apply to the system as a whole. They serve to make the process more transparent by making deviations more readily apparent. Errors are less likely to
keep hidden when there is no place for them to hide. Returning to the charting example, notes and documents for a single consultation might be spread throughout the entire chart. When most of the employees have a unique manner for doing a particular job, it is difficult for others to detect variations and problems in the system.

Standardization does not mean that the procedures are set in stone. If an MA finds a better way of completing the work, adopt the new procedures. This was reportedly the case to some degree at Site 3 where it was mentioned that procedural manuals were currently being written by the employees who had noticed and addressed the biggest problems in testing that they were facing. In addition to making the employees feel like they contributed something meaningful, a standardized procedure allows new employees to learn the best current techniques. Some of the employees that were interviewed mentioned that they learned their job from shadowing an experienced employee. The experienced employee taught the new employee some useful “tricks of the trade,” but those skills were only known to the experienced employee and the person who was trained by them. Why are those “tricks of the trade” not common knowledge to everyone in the office? What if the experienced employee forgets to teach that skill to the new employee? Resilient organizations cannot afford to lose such information.

We mentioned earlier that some errors were more serious than others. We believe that two of the most serious errors are the ordering of the wrong tests and the loss of the results. There are a few different ways in which results could be “lost.” These reasons might be misfiling into the wrong record, failure to return from the laboratory, and accidentally discarding the result after returning from the laboratory (at any number of points in the process). As we often heard stories of problems with the laboratory, the results could also be lost in that the test was never ordered. With all of these possibilities
for leakage, tracking is extremely important and we feel that better visual controls are needed to improve tracking systems.

A visual control is a mechanism or characteristic that makes the throughput more readily apparent or manageable. They are an effective means to increase productivity by allowing workers to spend less time sorting through the clutter. It allows them to control the process more effectively by allowing them to focus on what is most important. An example of a visual control would be using colored paper for the results to make them more salient so that they are more distinguishable from the rest of the paperwork.

There were many examples of visual controls that we noticed in our observations. Of the examples that we observed or felt were needed, we felt that there were three in particular that should become best practices. In addition to colored results pages, we would also like to see more offices using the colored sleeves that flag the records as “awaiting results,” which keeps records from being filed away prematurely. The other visual control would also address records from being filed away before completion by the use of a checklist that could be stamped upon the results page. The checklist would provide a quick indication of where the record should be in the process.

While we believe that these three controls would prove beneficial, we are not aware of any research on the topic that investigates their potential effect. Future research is warranted before advocating that these controls become best practices.

IV. The Final Word

This research has further supported previous research that errors are commonplace in medicine, particularly in the diagnostic testing systems of family medicine. Our patient record audits have also shown that the types of errors that occur are a function of their respective processes and are somewhat dependent on each other. This dependency manifests itself as patterns in the ways that the errors combine.
We have also shown from our flow charts that the testing process is complex, not only because of the number of steps involved, but because the transformation of information took place over multiple locations and by various people. It is not even accurate to say the there is a single manner in which tests are processed, as every site has at least four different processes that are dependent upon the type of test that is ordered. In addition to the variation of the testing processes within practices, there is also was considerable variation between them as well.

While errors occur in these complicated testing processes, hidden within them are also the means to help catch, mitigate, and prevent these problems. These means are the possible feedback and feedforward loops that connect each of the steps in the process. We use the term possible because not every system took advantage of these opportunities to close the loop. Although, that is not to say that some of the loops are not being closed, after all, many employees reported that they engaged in safety enhancing behaviors that closed these loops. Every practice is different, and depending on the system, every practice will have different possible loops that need to be discovered and brought to the forefront for the benefit of the employees and patients.

As we now draw near to the conclusion of our research, we would like to leave with one last item for consideration. It is often said in business and industrial engineering that waste needs to be eliminated from any system (Liker, 2004; Ohno, 1978/1988). The theory is that there are too many steps being taken that drain resources, whether those steps be actual physical steps (in reference to unnecessary transportation) or steps in terms of the number of operations required to transform a given throughput. People even talk about transforming their systems into “well-oiled machines.” This attitude has also begun to gain currency in the medical quality and safety literature as well (Bush, 2007; Printezis & Gopalakrishnan, 2007).
Many of us can empathize with this viewpoint. We have all probably experienced the difficulty of trying to make improvements of some type within the various systems in which we have found ourselves. We have all probably wished that we could remove some of the “waste” or “friction” that prevents our progress. However, Rochlin (1993) reminds us that we should not underestimate or fail to recognize the important role that friction plays in our everyday lives and in our systems.

In physics and engineering, friction is often viewed as waste. When two objects collide, energy is transferred from one to the other, but that transformation is not perfect; some of the kinetic energy is lost as thermal energy or friction. Sometimes the goal of the system is to run as smoothly as possible, thus necessitating the reduction of as much friction as possible. Automobiles are meant to be able to roll smoothly when in neutral or drive; the last thing that a driver would want is to have to drive while pressing the brake pedal. Such behavior would cause unwanted friction that could damage the car or at least make it run inefficiently. However, if it were not for some friction, the car would not even move in the first place, nor would it be able to stop once in motion. If it were not for friction, tires would not be able to grip the road to propel it forward. If it were not for friction, then brakes would not work. When considering the system of driving as a whole, rather than on a particular component, such as braking, then it is clear that whether friction is desirable or not depends upon the context. As Rochlin (1993) points out, sometimes friction is essential.

What this analogy implies is that we should all be careful with what we do to the systems in which we work. What may seem to be friction may really be our greatest asset to our safety. The example of the patient who should have had a PSA done was a victim of a system that might not have had enough friction. Redundancy and double-checks could be
considered wasteful in a lean paradigm, but they are also known to be an effective means of increasing the probability of success.

We recognize that there can be too much friction or waste in a given system. We need to be careful that we do not “grease the brakes,” by removing those components (such as MAs in specific areas of the process) that may be the greatest asset in keeping the diagnostic medical testing systems safe. They key is to find the right balance of how much is necessary to achieve the goals of the organization.
REFERENCES


APPENDIX A

CRITICAL INCIDENTS

Test Ordering and Implementation

1.1- An office nurse, during a patient chart review of a chart that had been lingering in her workspace, realized that she had not received the test results for a patient after a few weeks. She called the laboratory for the results and they reported that they had not received a specimen. The office nurse called again a few weeks later, making a total of eight weeks since the patient had been in the office, and the lab again stated that they had not received a specimen. At this point, someone decided to call the patient back into the office again to provide another specimen.

1.2- The phlebotomists collect specimens from patients and then order the tests electronically. The specimens are then stored in a fridge until they are picked by a courier to take the specimens to the reference laboratory. The phlebotomists were being blamed by their employer, the reference laboratory, for ordering tests but not sending the specimens. The phlebotomists had no way of proving that they had sent the specimens. The phlebotomists started making photocopies of the labels that were printed and attached to the vials so that they could at least have some evidence of at least ordering the tests.

1.3- A patient was taking the maximum dosage of a particular statin to control his cholesterol. The test results showed that the statin proved to be less effective than hoped. The physician felt that she should prescribe a second drug to complement the statin agent. According to the literature the combination of these two agents may increase the likelihood of particular problems but could be combined if needed. Shortly after beginning treatment with the additional agent, the patient began to complain of an aching body. The physician ordered “all of the appropriate tests” and told the patient to stop taking the medication as a precaution. The test results did not return the next day or that day thereafter. The physician also never received a phone call, which would have indicated that the results were abnormal. After a few days, the physician was feeling concerned for her patient and called the laboratory for the test results, but the laboratory denied having record of a test being ordered. By this time, the patient had to be admitted into the hospital for kidney dialysis as a result of the medications. The results never returned but the patient did recover while at the hospital.

1.4- A patient provided a urine sample and was mistakenly placed in a vial with an incorrectly colored stopper, which indicates that the specimen should be analyzed differently than the test ordered. The reference laboratory caught the error and called the office back to let them know that they had made a mistake.
1.5- A physician was seeing a patient shortly before leaving for the day. He gave only a verbal order to his MA to set up a referral appointment for the patient to have an X-ray. The MA filled out the test referral form and called the hospital to make the appointment and the MA of the radiology department at the hospital asked if the X-ray should also include a contrast. The MA of the family practice did not know because the physician never specified either in writing or verbally. The family practice MA tried to call the ordering physician, but he was unavailable via his pager and mobile phone. Eventually the MA had to ask another physician in the office make a decision on whether to include a contrast. Once this other physician had made a decision, an appointment could be scheduled for the patient.

1.6- A patient was waiting in an exam room to be seen for symptoms that indicated a urinary tract infection. The physician reviews the patients chart and notices that there are no results on "preliminary" tests (e.g. the patient’s temperature and urine analysis) that the physician expects her MA to perform before the physician is to see her patients. The physician reported that MAs “need to anticipate their [physicians] needs.”

1.7- The MA had collected a urine specimen from the patient but spilled all of the urine in sink before it was used for the test. The MA apologized to the patient and asked the patient to provide another specimen.

2.8- MAs fill out test requisitions, there are two sections that need to be marked to order (and bill) for the test. The first area indicates the tests to be ordered, the second area is to note the procedure for collecting a specimen. The billing specialist has noticed that MAs fail to mark all of the appropriate boxes. The billing specialist has brought this to the attention of the office, closing the loop.

2.9- Many times the physicians write notes indicating what tests need to be ordered. These notes are given to the MAs for them to fill out the requisitions or to send the patient to a reference laboratory. MAs have reported that deciphering the physicians’ handwriting is extremely difficult.

2.10- Many times, MAs notice while tracking test results, that some tests have not returned. The MAs then call the patients, who then report that they never had the test done. The office nurse is then asked to reschedule an appointment for the patient. Later, the MA notices that the results have not returned due to the patient failing to keep the appointment. The excuses given have included that the appointment times are inconvenient or that the patient does not have enough bus money to make it to the hospital.

2.11- On occasion the hospital, which does much of the off-site specimen collection and testing, will not return the phone calls or send the faxes of appointment times to office, effectively stalling the testing process. The office manager has had to call the hospital appointment scheduling department to request the appointments.

2.12- Once an MA noticed that a couple of test results for a patient had never returned. She contacted the laboratory to inquire about the location of the results. The lab said that the tests had never been ordered. The MA knew that she had ordered the tests because they were specialized tests that required her to look in the reference laboratory catalogue to find the correct test codes for ordering. The patient had to return to the office to provide an additional specimen so that the test could be re-ordered. To protect herself and the office, she started to print out a copy of the
order requisition so that she would know that the specimen had been drawn and ordered.

2.13- An office nurse went on leave for a week and upon returning she found a stack of test requisitions in her box waiting to be faxed to the hospital for referrals. Some orders had waited the entire week. Nobody had faxed them for her in her absence.

2.14- A patient was ordered to have an MRI. The office nurse was busy and could not fax a request to the hospital at the moment. She made a photocopy of the billing slip/test requisition so that the original could move through the system. The photocopy would act as a reminder to schedule the appointment when she had the time. The photocopy was lost in the mix of other office papers and the office nurse forgot about ordering the test. The patient called back after a few days to inquire about the appointment for the MRI. The office nurse had to report that the test had not yet been scheduled and wrote a note to herself to order the test for the patient. The office nurse got busy again and lost the note that she had written to herself. Days later, the patient still had not heard anything and decided to come into the office and speak with the office nurse to make sure the MRI was ordered.

Results Tracked and Returned to Physician

1.15- A physician ordered a PT-INR for a patient but the test was lost. Nobody at the office had caught that the test had not returned until the patient called several weeks later to get his results. The office had to apologize to him and began a search for the location of the specimen or order. In the meantime, the patient had to be admitted into the hospital due to chest pains which he was experiencing. The results were eventually returned by the lab, but they indicated that the lab had received the specimen weeks ago but did not process it until recently.

1.16- A 41 year old woman was sent to have a CT scan at the hospital. The results came back to the office and were being previewed by the MA. She noticed in the results that it mentioned that the patient was suffering from an enlarged prostate. The MA called the hospital and told the CT technician what happened. The technician asked what she should do about it. The MA told the technician that she should pull the chart and image and explain to the physician there about what happened and to reanalyze the image.

2.17- There are reports from all of the employees that important abnormal test results are not being given to the physician-of-the-day right after they return. Speaking with the office staff about this, they mentioned that it may be their fault because it is their job to screen for abnormal results as they return through the mail and fax machine. However, the office staff members lack any sort medical training and report they do not really know what to look for.

2.18- An MA was attempting to track a result that had not come back to her. She contacted the hospital laboratory and asked to send the result again. The lab said that they would fax the result over. The MA went back to helping patients and hoped that the office staff would give the result to her when it arrived. The results never got back to the MA. She was not sure if the result was ever sent or if it got lost in the office by either the office staff or physician. She had to order the results a second time.

3.19- A physician ordered a PT-INR for a patient and the result came back the next day,
which was a day that physician would not be in the office. The result should have
gone to the team's physician-of-the-day to be reviewed, but was instead placed in
the ordering physician’s inbox to await his return. Fortunately for the patient, the
result was normal and no harm was done.

3.20- A physician had ordered multiple tests. Some of the results had returned and were
abnormal. The results had been placed aside to await the rest of the results to
return although the official policy is to give all abnormal results to either the
ordering physician or the physician-of-the-day to be reviewed. The abnormal
results were not addressed until a few days later, when all ordered tests had
returned.

3.21- A female patient came in for a yearly check-up that required Pap screen, a
screening mammogram, and some blood tests. The patient had her Pap and blood
specimens taken in the office, but wanted to make an appointment for the
mammogram herself. After leaving the office, the patient decided to skip the
mammogram, but did not inform the office of her decision. Days later, the test
results returned to the office, but the chart and results waited in the office lab/
draw station to await the return of the mammogram results, which were not
coming. The MA believed that the clinic’s policy was to hold the charts in the lab
until all results come back. (Note the discrepancy of what was reported on the
office policy; see Incident 23). No physician reviewed the chart until one MA was
reviewing the charts (which should be done weekly) and caught the error about a
month later when it was her turn to be in the lab.

3.22- The MA that is in the draw station has the responsibility to review the charts at
least once a week to make sure that all charts are in order. Some MAs do not
review the charts during their week in the draw station. One MA found charts that
had no results or even documentation of attempting to locate the results.

4.23- A woman had a typical yearly exam consisting of a mammogram, a Pap, and blood
tests. The results from the blood test returned within a few days, the Pap results
returned about a week later, but the mammogram results never came back. This
lead to the physician never addressing the results because he was waiting for all
test results to return before doing addressing them and making an official clinical
decision. The tests remained unseen for six months at which point the patient
returned for an appointment and the physician saw that the patient had tests that
had not yet been addressed.

Respond to Results; Document and File

1.24- An MA was reviewing a patient’s chart when she noticed that the physician had
signed the results as though they were normal although they were not. She
confronted the physician and he indicated that he had not realized that the results
were abnormal. The MA started pre-reading and highlighting abnormal results
before giving them to the physician for review. She also made it a point to double
check the physician’s work on a regular basis.

1.25- While searching through a patient chart, an office nurse noticed that there were
test results in the chart that did not belong to the patient. She pulled to correct
chart and filed the result into it. (Why didn’t the doctor catch this?) The MA then
notified the physician about the problem and then re-filed the chart.
1.26- A patient called to receive information regarding her test results. The office nurse ordered the chart from the file room, but the file room stated that they did not have the chart. The office nurse then began a search throughout the office to track down the results. The chart and results were found sitting in the ordering physician’s private office. The office nurse was not sure who placed the chart and results in the office because the ordering physician went on leave and would not be available to review the chart. More importantly, the results should have gone to the primary care physician (PCP), not the physician that she had seen. The physician who examined the patient was filling in for the PCP, who was on leave.

1.27- One physician noticed that results were not being filed into the charts of her patients and that her MAs kept noticing that the charts of the physician’s patients were not being signed. To keep these errors from occurring, she began to keep the charts of her patients that she had recently seen in her office rather than in the large piles at the nurses’ station or in the records room. This practice causes problems with her and the medical records department because it keeps them from being able to track the charts.

2.28- An MA at this office also reported that while searching through a patient chart, she noticed that the chart contained test results which did not belong to the patient. It appeared as if these test results had inadvertently stuck to other test results which did belong in the chart. She re-filed the results in the correct chart and did not bring it to the attention of anyone.

3.29- A chest X-ray showed an abnormality that was caught by the radiologist. The report was sent to the office, and was filed away without being addressed. The physician saw the report one year later when the patient came in for the yearly check-up.

3.30- A patient had a Pap smear and the results proved to be abnormal. However, the test was filed away without a physician’s signature. Either the physician saw the test and failed to sign it or never saw it. In some cases, reviews by physicians showed that that many abnormal Pap results were used to incorrectly diagnose and treat patients. The staff felt that errors occurred more often with Paps than other tests and decided to try to track them separately from the other tests, which included a dedicated log book and a monthly review of log addition to the weekly chart checks. It could be that Paps are ordered more frequently and so it gave the impression that this particular test failed more frequently or because Paps usually take weeks rather than days, meaning that the return of Pap tests are more likely to have to be tracked by less vigilant MAs.

3.31- There are many different places to place charts and test results, of which there is a to-do pile and file-back pile. The clinical resident coordinator reported that the residents frequently confuse the two piles and send results back to filed instead of be addressed.

3.32- A female patient came in for her yearly check up. This included a screening mammogram, a Pap, and some blood tests. The results came back for the mammogram and blood tests, but not the Pap. The physician signed the results and sent them to be filed away without the Pap test results. This would have been acceptable if there was a 100% chance that the Pap results were sent back from the hospital laboratory. However, filing the chart away without the result would mean that the test would no longer be able to be tracked. After sending the chart to be
filed, the physician realized that the Pap test was missing because his yearly check-ups for adult females always include those three types of tests and he had only seen results for two of the three tests. (Standard groups of tests probably increase the likelihood that all will be noted)

3.33- When physicians received the results of lipid panel tests for patients, the physicians would never remember whether they had asked the patient to be fasting or not. The physicians would ask the MAs if they could remember whether the patient was fasting. Many times the MAs could not recall that information. One MA started asking patients before the specimen was taken and would write that information on the test requisition to be prepared.

Notify Patient of Results

1.34- A patient on a blood thinner had a PT-INR level which was critical, indicating an immediate need to stop taking the drug. The office nurses mailed the results to him instead of notifying him in person over the phone.

4.35- The EMR system that is used will auto-populate test scores onto the lab letter that the physician is writing to notify the patients of their results. On one occasion, the TSH level that was printed out onto the lab letter was different than that of the EMR software by a degree of magnitude. The printed version had the decimal located one position to the right of where it should have been.

Monitor Patient through Follow-up

1.36- A patient that came in because she felt a lump in her breast. The doctor examined the breast, but did not notice any abnormalities. The physician knew the patient was concerned and told her to have a mammogram. The radiologist did not notice anything abnormal. The patient called the physician and expressed her anxiety about the situation. The physician told her to come back in six weeks and she would be examined a second time. When the patient returned six weeks later, the physician forgot the purpose of the follow-up and did not examine the breast or send her for another mammogram. The patient did not remind the physician of the purpose of the visit. The patient developed both breast and ovarian cancer.
APPENDIX B

ACTS OF SAFETY

Step Specific Acts of Safety (AOS)

Test Ordering and Implementation

1.1- An office nurse makes copies of the original test order for off-site tests and holds the copy at her workspace in case the patient loses the order or in case the hospital calls with questions about the order. Holding the copy in her workspace allows her to quickly refer to the order without having to request the chart. Having the copy separate keeps the copy from getting lost with the chart around the office.

1.2- An office nurse staples the original test order (which is what she makes a copy of) to the page of instructions on how to schedule off-site tests and gives both papers to the patient. She also walks through off-site scheduling process with all patients to make sure they understand the process. This is particularly true of patients with psychiatric problems or those with low IQs.

1.3- Some patients are too embarrassed to call the hospital themselves, in which case, the office nurses or MAs will call on behalf of the patient to schedule the appointment. The office nurses indicated that they will ask patients that appear intimidated by either the process or test that is to be ordered (e.g. mammogram after a lump in the breast has been identified).

1.4- The draw station located in Site 1 closes at 5:00 pm exactly because the phlebotomists must quit at that time. However, Site 1 is open after 5:00 pm, meaning that patients that have appointments are not likely to be able to provide a specimen at that visit. The patient may need to come back the next day or go to another draw station off-site. This arrangement has encouraged some MAs to send patients, with certain symptoms, directly to the draw station for specimen collection before an examination by the physician. Patients with serious coughs who arrive after 4:30 pm are also sent to the radiology technologist for a chest film, since the technologist also leaves at 5:00 pm. The MA has pre-ordered tests for years and has never been reprimanded for this behavior. This indicates that either nobody has found out about this practice or that no harm has ever come of it.

2.5- This office uses walkie-talkies to communicate with each other. The system is open, such that everyone can hear each other. This allows employees to request or provide help without having to abandon the patients. One MA related an incident where a patient fainted while she was having her blood drawn. The MA still had the needle in the patients arm and the patient began to slide off the chair onto the
floor. The MA could not leave the patient, so she called over the system to request help.

2.6- One office staff member reminds patients before they leave to expect a card in the mail that contains the result of their tests and to call if they do not receive it.

2.7- One MA will give tests to patients while she is triaging them. If the patient is taking Coumadin, she will automatically give them a PT-INR. She also gives a rapid strep test to those with sore throats, urinalysis for those with lower back pain, and will test vision and hearing for children’s check-ups. She completes these tests without express permission of her supervising physician, but the physician knows that she does and is glad that she tries to make the process run “more smoothly.”

2.8- The office staff are not medically trained, but are expected to know where patients are to be sent for off-site reference testing. The office staff mention that the hospital has many different sub-departments, and so it becomes confusing when they try to schedule an appointment for a female patient to have a mammogram and there are a few options to send the patient’s appointment request, such as the radiology department or the oncology department. The office staff report that the various departments will either call the office or fax a note indicating that the appointment should go somewhere else. This provides a feedback mechanism so the office staff can learn from their mistakes.

3.9- When patients are told return in the short future for a test (a standing order), one MA will pre-fill the requisition and place it on top page in the patients chart so that the first thing anyone sees when they open the chart is a reminder that the patient needs to have a test completed.

Results Tracked and Returned to Physician

1.10- One MA tracks the results of her patients in addition to having the office nurse track them. Tracking results is the responsibility of the office nurses.

1.11- One office nurse used the copy of the referral form for off-site testing as a way to keeping track of patients that have been referred. She would check the returned results against the pile of off-site referral forms and if the results had not returned, she would contact the patient and ask if the test had been completed.

1.12- Site 1 has many physicians that work part-time, meaning that there are days where the physician may not come into the office. One MA will collect the awaiting test results and pre-view them, ensuring that critical or abnormal results will be addressed as soon as possible.

1.13- One office nurse would pre-read the test results before the physician, and on important tests, would schedule appointments for the patient to come and speak with the physician. That way, the appointment would be made even if the physician forgot have the appointment for the patient.

2.14- One MA has a special accordion folder for tracking her test results. To track the
2.15- CLIA waived and certified tests are ordered with the billing sheet. The office billing specialist reviews the billing sheets for accuracy to make sure that the office is billing for all services rendered. Reviewing the bills accurately has the benefit of making the office more financially sustainable, but the specialist also acts as a safety net for test ordering. For instance, an MA may mark on the billing slip that she drew a blood sample but forgets to mark that the sample was for a particular blood test. The specialist has noticed a few times when this has occurred and has been able to go back to the MA and ask for clarification of what the test was. The test is then noted on the billing sheet and becomes an accurate means of tracking the test. The billing specialist will speak to those that err, providing feedback.

2.16- This Site notes the charts of diabetic patients with a purple page which is used to track the A1C results. The purple page is more salient than the white papers around it. The purple color also acts as a reminder that the patient should regularly be having tests and should therefore be having results come back regularly. When the diabetic patients come in for routine tests for diabetics, one MA will fold the purple page in the chart so that it sticks out of the chart perpendicular to the fold in the chart, becoming a flag to remind herself and the physician to check on the patient’s results.

3.17- One MA asks patients if they are fasting or not for certain certified tests and notes the fasting status on the requisition.

3.18- One MA, who is recognized around the office for her skill, reports that she will stay later than her shift to finish what needs be done. This is especially true right after the MAs rotate their positions in the office and the MA who preceded her failed to do everything that the position required and so she now needs to catch up.

4.19- The physicians at Site 4 do not have the training on the EMR system to take advantage of many capabilities. They often learn new abilities while experimenting with the EMR system and will share their new discoveries with each other in informal settings.

Results Tracked and Returned to Physician

Physicians would write comments on test results page which would then be sent to the MAs to notify the patient and for filing. The MAs should have been noting their attempts to contact the patient. After the physicians’ notes and the MAs’ notes, the results page would be so full of notes, that there was difficulty reading the handwritten notes to know if the chart was ready to file. One physician added dates next to his notes so that he could at least know when he reviewed the results, but that was not very helpful to the records clerk who was trying to decide if the chart was completed. To solve this problem, the office implemented a tool which came as a suggestion from one employee who had seen it at another office. The tool is a stamp which contains a checklist of the steps that need to be completed before filing the chart away. This way, the records clerk only needs to make sure that all
the check boxes have been marked instead of having to read all of the notes scribbled over the page and trying to decide whether the chart was complete and ready for filing.

3.21- The physicians have a policy to write out notes on the test results, not merely sign their initials.

3.22- Some physicians use the requisition sheet as a means of keeping track of which results have returned. One physician will make notes for himself regarding the location status of the other tests. For instance, when he orders three tests, and only has the results for two, he will note on the requisition that he is still awaiting the arrival of the third test and then date the note. The note is a way to sum up the reason for why the chart has not been filed in case anyone was to look in it.

3.23- A middle-aged female patient had her annual exam, which included a mammogram, Pap, and blood work. When the results from all the tests except the mammogram returned, he remembered that he was still awaiting the mammogram because those three tests are typically ordered together for a yearly female exam. He then added a sticky note to the chart indicating that the mammogram results were still pending.

Notify Patient of Results

1.24- A recommended practice for reporting patient results is for the physician to hand-write a note to the patient about the meaning of the results. If a physician fails to do this, an office nurse will write a note herself.

1.25- Office nurses regularly call patients when the patient’s test was abnormal. Some physicians will take time to speak with the office nurses about the meaning of the results before the office nurse calls the patient. If the office nurse does not feel comfortable reporting the results, they may opt to have the physician make the phone call.

1.26- Many office nurses will attempt to send a copy of the test results if it was abnormal or not. This increases the likelihood that the patient would receive information regarding their health status.

2.27- Some physicians will write a note on the results cards indicating that the patient should return to discuss their test results. When the patient calls to make that appointment, one office staff member checks that patient’s chart to see if the results have been properly filed. She has found through experience that just because the patient has received a copy of the test results, the actual results may not have been filed or are lost. This acts as a double check to ensure that the results will end up being reviewed by a physician and filed away properly.

2.28- One physician will work with the MAs in determining which patients have been difficult to notify of their results. He writes letters to those who do not respond to phone messages.
2.29- When abnormal results return for a patient, one physician reports that she reviews the results, writes that the results were abnormal, and writes the range of normal values for the patient.

*Patient Notification*

2.30- One physician will write on the billing slip for the patient to come back in the future to discuss the results. The patient will take home a carbon copy of the billing slip, which has the reminder to return.

4.31- Before sending the letter with the patients’ test results, he will review the patient’s chart and look for other tests that may need to be done in the future. He looks for gaps in his knowledge of the patient’s health and considers tests which would fill those gaps. This is particularly in patients of certain populations and meets certain risk criteria such as ordering colonoscopies on patients who are over 50 years of age and have a family history of colorectal cancer. When he decides that the patient ought to have a certain test completed, he will mail a test order form to the patient in the letter containing the results.

*System Wide Acts of Safety (SWAS) or Step Independent Acts of Safety*

1.32- A few office nurses have indicated that they will occasionally request patient charts for unofficial audits. The audits are not intended to look for anything in specific; there are just general audits to see if the chart looks to be in order.

1.33- Some medical tests, usually MA or physician waived tests will come with control mechanisms to ensure the quality and accuracy of the tests. Some MAs will ensure the accuracy of the tests by using the test control measures. For instance, pregnancy tests often come with a chemical solution used to evaluate the validity of the pregnancy tests. In addition to the chemical solution, some of the MAs will keep a sample of urine that came from a woman that they knew to be pregnant.

1.34- One MA regularly used sticky notes as a means of asynchronous communication when she needed information from someone who was currently unavailable.

1.35- One MA will audit patient charts for completeness when the patient calls for results.

1.36- One physician failed to receive responses from the clinical director and office manager regarding testing procedures and other patient safety related issues. The physician then started to email both the director and manager in the same email to increase the likelihood that at least one of them would respond.

2.37- One office staff member praises patients for healthful behaviors, such as keeping appointments for imaging and other off-site tests. She will also reprimand patients for breaking those appointments.

2.38- The lab manifest book used to be poorly maintained and updated, meaning that
tracking the results was extremely difficult, because the responsibility belonged to all of the MAs. This led to the free rider problem, where many MAs would not bother to keep the manifest up to date because they knew others would do it for them. The management has now made the upkeep of the manifest a responsibility of a different MA per month. The office reports that the manifest is more up to date than it has been.

2.39- On MA will highlight the patient’s name on the various documents that come her way. She also has begun to highlight the values or evaluation of the test results when they return.

2.40- The office management and clinical director have noticed that the MAs and office staff have a very informal training period for new employees. In order to help them, they have tried to formalize some of the procedures in writing.

3.41- The office management has recognized that certain staff members are less competent at certain task than others, such as keeping up the laboratory records. To keep the processes working, they will often try to keep the less capable employees from those tasks by scheduling them to work in other areas.

3.42- The office treats Pap tests differently than other tests because their own research seemed to indicating that they were having more problems with them such as losing the results, treating the patient incorrectly based upon the results, and not signing the results. This includes a special shelf in the lab/draw station for holding the charts of patients needing Pap results. Once the results return, the MAs will note the results which are abnormal in a book dedicated to abnormal Pap results. This Pap log is then audited on a monthly basis to make sure the Pap results were present in the chart, that the physician notes his comments, and that the plan of action was consistent with their policies and procedures.

3.43- One physician will specifically think consider certain patient cases throughout the day. When he is concerned about a particular patient, he will write the patient’s name on a sticky note and place in his in-box, so that he is frequently reminded that he needs to check on a particular chart.

3.44- The clinical director reports that she makes it a point to her staff that they can report errors to her without fear of retribution because learning about how the error occurred was more important. She noted that several employees will regularly report errors to her.

3.45- The management and clinical director have listened to the suggestions and complaints of their employees about patient safety and the testing processes. Management has worked in conjunction with the employees to develop and implement systems and checks to improve their processes.

3.46- Before leaving for the day, one physician mentioned that she will check her in-box to make sure that nothing critical is missed.
3.47- Site 3 was concerned about patient safety, and so they formed a quality improvement committee, which included representatives from the nursing staff (MAs), the front office support staff, physicians, as well as the nurse manager and the office manager. The meetings are held quarterly. This meeting is in addition to the monthly team meetings, where patient safety issues are also discussed. As an organization trying to improve their processes and gain employee “buy-in,” management has recognized that the employees know the processes better than management and has given the charge to the employees to write the policies and procedures themselves. Management will then review the proposed policies and procedures in the quarterly meetings. This way, everyone has a chance to see how the policies and procedures will affect them and have a chance to make further suggestions before finalizing anything.