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A STUDY OF PATIENT TREATMENT SCHEDULING AT THE GILLETTE CENTER FOR WOMEN'S CANCERS

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Abstract

The process of creating patient treatment schedules at the Gillette Center for Women's Cancers is currently a lengthy and time-inefficient one. The goal of this project was to provide an assessment of the patient treatment scheduling procedure and product and then to develop several alternative methods in which aspects of automation could be added. In order to thoroughly meet the project objectives, we collected information from both the clinical research coordinators who create these treatment schedules and the patients who use them. Additionally, several other facilities where treatment schedules are used were contacted to increase the extent of our knowledge on alternate processes. Finally, a set of recommendations based on our findings were presented to the sponsor to aid in the implementation of an alternative method for treatment calendar creation.

Executive Summary

This project was sponsored by the Gillette Center for Women's Cancers in Boston, Massachusetts, an institution dedicated to the care and treatment of cancer patients as well as clinical research for potential cures. When participating in a clinical trial a patient works closely with a clinical research coordinator in order to enroll in the most appropriate treatment protocol as well as to be prepared for and schedule each appointment properly. The research coordinators act as a liaison between the providers and patients. Of the many responsibilities of the research coordinators one of the most important is to schedule all of the patients' appointments with the providers on the right dates and put these appointments into something called a treatment calendar. The treatment calendar is a document created by a research coordinator that lists the schedule of upcoming appointments for the patient. For each calendar there is a lengthy creation process which takes away from time with patients and also puts additional strains on the research coordinators. The goal of this project was to determine all of the requirements for treatment calendars and the current problems associated with the creation process. Additionally, we explored the feasibility of making either technical or procedural changes to the current methods in order to make the process more efficient and effective.

In order to accomplish this goal we sought information from the research coordinators, patients, the internet, and providers of clinical care other than the Gillette Center. First, we assessed the process for creating treatment calendars currently being used at the Gillette Center. We were able to accomplish this by observing the entire process as a research coordinator went through each step one by one. Second, we assessed the effectiveness of the treatment calendars for both research coordinators and patients. After gaining knowledge on how the process worked, we interviewed each group seeking insight into how effective treatments calendars are from their perspective. Third, we developed functional requirements for a treatment calendar creation process and product. To do this we analyzed our process observations and interview results to determine what elements would be necessary for an improved program. Lastly, we evaluated alternative solutions. In order to accomplish this last goal we used the internet as a resource to identify alternative solutions that may already exist for the Gillette Center to implement into their system. We also interviewed staff at several other clinical research organizations to see how they create treatment calendars.

Sarah Malaquias and Christina Mathews were the research coordinators that we used as our main contacts to the Gillette Center. We sought information pertaining to the specific steps that were carried out in order to produce treatment calendars and feedback on any inconveniences they were encountering. They were displeased with specific process steps such as the amount of time needed to schedule appointments and the lack of software automation when creating repeat appointments. Ms. Malaquias and Ms. Mathews also gave us insight into the problematic areas with treatment calendar layout. The major limitation they identified was that of the lack of available space to place comments.

Five different patients were next interviewed to gain feedback on the product, both positive and negative. Each found treatment calendars to be an organized and helpful way to keep track of appointments related to her clinical trial. The main issues these patients found with treatment calendars were the lack of color coding of similar appointments (by location) and of

available space for additional information. Additionally, the patients suggested having contact information included on the calendar itself.

From these suggestions made by both coordinators and patients, we formulated a set of functional requirements that a system would need in order to be considered for implementation within the Gillette Center. The final functional requirements are as follows:

- The ability to create and save multiple calendars
- Automation of cyclic appointments
- Additional space for comments
- Color coding of appointment locations

The ability to save multiple calendars was the core requirement because the calendars were created for more than one patient. A system must be capable of saving and creating several calendars simultaneously in order to qualify for further consideration. Automation, an essential requirement, is the ability of a software package to decrease the amount of research coordinator labor by either a repeat function or a template. Next, additional space for comments, notes, and other *add-ins* was set as one of two strongly desirable requirements. The other strong desirable was color coding which refers to the capacity to include color in the calendar where necessary for color codes according to appointment location. Other aspects that we took into account were cost, time of installation (time to learn program) as well as time saved compared to the current system.

With these requirements in mind we investigated 14 commercially available calendaring and scheduling software packages as well as processes used by other clinical research organizations. The systems that we investigated could be classified into three categories – those not satisfying the core requirement, those satisfying the core requirement, and those pertaining to clinical research. We have concluded that there are two possibilities that the Gillette Center should consider.

The first alternative to be considered is a proprietary or homegrown system in which multiple calendars can automatically be generated by research coordinators by entering in only a few data points (protocol number, treatment start date, and group or drug name). We have found that this would take an exceptional amount of money as well as time in order to create and implement but would save coordinators a significant amount of time during the creation process as well as produce an ideal calendar.

The second option and our ultimate recommendation is for the Gillette Center to use Microsoft Excel to create treatment calendars. Doing so would meet the needs of patients and clinical research coordinators. The time required for implementing the software as well as the cost are nothing as it is already included in the computers used by the Gillette Center. Additionally, the software would eventually lead to improvements in overall efficiency. This software has the capacity to save a template according to each protocol. A detailed explanation of the steps for creating a protocol template is included in section 5.3 of the full report. Each template has the ability to repeat dates through a specific formula, create and save multiple calendars, enter in additional columns for further comments, color code, and be posted on the internal website of the Gillette Center.

Acknowledgments

Our advisors, Professors Chrysanthe Demetry and Olga Volkoff, were exceptionally helpful and supportive throughout the entire project. They aided us in problem development, research, and assessment, as well as steered us in the proper direction for completion of this project. The sponsor, the Gillette Center, as well as the employees that were directly associated with assisting us are also much appreciated. Karleen Habin helped to determine the project focus, while Sarah Malaquias and Christina Matthews furthered our knowledge of the problem itself and aided in our research. For the five patients who took the time to meet with us and provide their perspectives on the subject of treatment calendars we are also very grateful.

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1 Introduction

Clinical research is the most valuable and productive way of discovering new forms of disease treatment and cures. The process of a clinical research trial is one that is both lengthy and expensive, as it requires much time and funds for studies to be planned, established, executed, and then analyzed (Carpenter, et al, 98, 2002). As a result, many medical institutions involved in clinical research are undergoing efforts to increase their efficiency. Many organizations suffer from a low provider to patient ratio which makes the efficiency of current staff members a key factor in providing quality patient care. Everyday tasks of staff members are typically examined to look for opportunities to streamline processes while maintaining or enhancing patient care. One institution that is facing these challenges is the Gillette Center for Women's Cancers.

One of the foremost providers of clinical research in Massachusetts, the Gillette Center is housed within Massachusetts General Hospital in Boston. It is one of twelve treatment facilities within the Dana-Farber Cancer Institute. The Gillette Center offers a range of care specialized in treating women's cancers, which can either be breast or ovarian forms of the disease. Presently they admit anywhere from 700 to 1000 new patients per year. Aside from the range of specialized care available to patients, the Gillette Center also offers patients the opportunity to participate in clinical trials appropriate for their individual diagnosis. If a patient does decide to participate in the clinical trial that she is best suited for, she will be put into a specific group within the selected protocol that specifies the treatment to be given and the timing of her pre-surgery, or neo-adjuvant care. Staff members at the Gillette Center, especially clinical research coordinators, are a vital part of a patient's clinical research experience. It is the main aspect of the job of clinical research coordinators to schedule each patient's treatment appointments into a calendar (Karleen Habin, personal communication).

This schedule is known as a treatment calendar and is a list of appointments for lab work and physical assessments, as well as a timetable for chemotherapy treatments specific to each protocol. The clinical research coordinators must go through each portion of a given protocol to determine the correct time points and treatments. After determining what is needed, they must call and schedule each appointment with the proper providers. It is imperative that these calendars be created and followed accurately because the research results of the trial as a whole depend on each individual patient within the trial. The current process for creating treatment calendars is extremely time-consuming. In a business that has hardly any time or funds to spare, any efficiency that can be added is particularly helpful. In addition, Microsoft Word, the software currently being used to carry out this process, is limited in its ability to create calendars automatically. The format in which the information is presented may also have the potential to be improved (Sarah Malaquias, personal communication).

The Gillette Center is not yet aware of any existing alternatives for this process. It is possible that other institutions participating in clinical research have designed their own original systems for creating treatment calendars, but the Gillette Center has not had the time to research such solutions internally. The Gillette Center has expressed interest in the idea of having a template that will enable the research coordinators to create calendars through an automated process. A template is a document or file that is used as a starting point for a particular application so that the format does not have to be recreated each time it is used. This would save the research coordinators time and make for consistently accurate information within the

calendars themselves. The Gillette Center is also not aware of the patients' perspectives of the treatment calendars. Since a key aspect of their mission is to provide patient-focused care, it would be desirable for a review process to include their feedback.

The goal of this project was to determine all of the requirements for treatment calendars and the current problems associated with the creation process. To add another dimension to this project, we have also explored the feasibility of making either technical or procedural changes to the current methods. From research coordinators, we first acquired a clear understanding of what specifically needs to be entered into the treatment calendars and became familiar with the process of formulating them. The next step was to explore patients' comprehension and general opinion of the calendars. From these two sources of information we were able to formulate a set of functional requirements for an enhanced calendar appearance and procedure. Then, we researched different packages that were commercially available and evaluated them against these functional requirements.

In this report we present the Gillette Center with several feasible options for improvements from which they can choose and implement the most appropriate. Eventually, clinical research coordinators will have additional time to take care of their additional responsibilities instead of worrying about the formulation and accuracy of patient treatment calendars. Also, the calendar will be made to better suit patient needs to aid in furthering their overall comfort and to ease the stresses of dealing and living with their cancer treatment.

2 Background

In order to understand and appreciate the problem that this project addresses, all aspects of the issue were examined. The historical origins and evolution of clinical research are presented first. This topic will aid in explaining challenges facing modern day clinical research and its organization. The Gillette Center for women's cancers is the specific research institution on which the project focuses. A detailed description of this center is given before finally explaining the specific responsibilities of clinical research coordinators and the process for creating treatment calendars.

2.1 Clinical Research

Clinical research is one of the premier and most beneficial methods of medicinal discovery today. By testing new forms of drugs and treatments on human subjects, numerous discoveries are made in an effort to either cure or treat diseases. Within the last 70 years, clinical research has experienced several major developments. It has come a long way since the days of human experimentation and is now a highly computerized, modern area of research. These advances have done much to serve the interest of patient care and patient rights. Clinical research developments are also responsible for the standards which all clinical researchers must currently follow.

2.1.1 The Origins and Development of Clinical Research

Many major advances in the medical profession were made prior to and soon after World War II. At that point in time, many physicians still thought it was permissible to conduct experiments on people without the mental capacity to refuse or agree to testing on their own, such as infants and the mentally ill. During war time, much pressure was put on clinical investigators to come up with cures and treatments for various diseases. Cancer became a major object of governmental health policy at approximately this time (Porter, 1996, 335). Then, after the war ended in 1946, the extent of Nazi experiments came to light. The "Nuremberg Code" was published to ensure the safety of research subjects (Finn, 1999). Summarized, the code stated that an experiment with potentially damaging side effects could only be conducted when it pertained to a deadly disease. Furthermore it declared that "the voluntary consent of the human subject is absolutely essential." (Finn, 1999) At the time, much of the research that was going on was affected by the Nuremberg Code because until this point clinical trials were hardly regulated. These new guidelines set up the foundation for the clinical research rules of today.

The basis for implementing strict regulations for clinical research was further justified as a response to the Tuskegee Experiment. In 1970, the horrors of the Tuskegee Experiment were revealed to an unsuspecting nation, and this in turn led to huge changes in the way clinical trials were being run (Finn, 1996). Since 1930, the Tuskegee Experiment left 400 African-American men diagnosed, but untreated, with syphilis so that researchers could observe the natural progression of the disease. Such inhumane practices were not taken lightly by the National Institute of Health, which immediately began to establish new rules.

Then in 1979, the Food and Drug Administration (FDA) issued a new set of regulations concerned with consumer protection and informed consent known as the Belmont Report (Finn,

1996). The report addressed four main points: first, that all clinical trials must demonstrate a "Respect for Humanity," meaning no harm and maximum benefits for the patient; second, "Informed Consent," which meant that a patient must be thoroughly informed of all aspects of a given trial before formally consenting; third, "Risk Assessment," meaning that the investigators must submit an in-depth report including the extent and probability of side effects; and finally "Subject Selection," which provided fairness to all possible subjects in assessing eligibility for a given trial. These new principles are the primary restrictions of modern clinical research and also add to the extremely lengthy amount of time that trials take to develop.

In the last thirty years, clinical research made even larger advances than in years previous. By the end of the 1950s, there were fewer clinical investigators that were willing to conduct studies than there were drugs to be studied. During the 1960s there were approximately 150 hospitals that enrolled 16,500 patients in about 200 trials, a drastic increase from five years before (Cambrioso, 2002, 301). A major problem arises with a surge of this magnitude in such a short period of time. With so many patients and trials, there were not nearly enough clinicians that were capable of handling the work. As lack of staffing became an issue, an increasing emphasis was placed on improving efficiency in order to help providers offer the extensive number of patients the best possible care. With the pressures to increase efficiency, set and follow regulations, and implement a system for data management, all while providing exceptional patient care, it can be seen that it was necessary for changes to come about within clinical research.

In 1954, a clinical panel responsible for funding clinical research was set up by the Senate Appropriations Committee as part of a Cooperative System (Cambrosio, 2002, 308). A cooperative group, or intergroup, study is any form of clinical research that is conducted by more than one clinical research group (Therasse, 2002, 170). There were many problems associated with these groups because often many of their individual findings were contradictory. The now $20 million budget for clinical research led to pressure from investigators in industry, academia and clinical laboratories for extended drug screening programs (Cambrosio, 2002, 301).

It was then that developments were made to analyze research data in a statistical way (Gehan, et. al, 1994, 131). This was an important breakthrough because it meant that more treatment options could be better evaluated due to the uniformity of data recording. This in turn led to the implementation of computers in clinical research data management. Many technological advances in data management were made in clinical research because of the larger than ever budgets research institutions were granted. The level of funding for clinical research had risen to over $815 million in the early 1980s (Gehan, et al, 1994, 131). There was also a need for an organized method of data collection that had become impossible for researchers to ignore.

Computers were initially used to provide substantial and important functions in data management in the early 1970s, but it was not until the 1980s that computerization was in full swing. Prior to that time there was also no central registration, computerization, or method of quality control. Computers made it possible for these issues to be dealt with in an efficient and well documented way. Throughout the rest of the decade, much time was spent implementing a system for automation for as many data management processes as possible. By the end of the decade nearly every aspect of data analysis was performed on a computer. The extent to which research facility staff was being trained was also altered around this time. This was done in

many ways by setting newer educational requirements for staff as well as more in depth training for all of those involved.

2.1.2 Current Trends and Problems Associated With Clinical Care

Issue	Characteristics Associated With Issue
Time constraints	• Wide range of settings because of intergoups participating in the same trials • Lengthy pre-approval process for a trial to begin • Planning and documenting the research from beginning to end • Clinical activity may turn out to be too lengthy due to lack of participation within the trial • Role of hospital to not only provide the best possible care, but also to maintain the methodical nature of the research
Staffing	• Specialist skills in short supply • Professional sensitivities over roles and responsibilities • Barriers between traditional service models • Career pathways • Staff shortages and recruitment • Training, education, and research
Resources	• Availability of "new" money • Intergroup competition
Patient-provider relationship	• Focus on needs of the patient • Patients as expert in their own care • Sensitivity of assessment methods • Accommodating to the expressed wishes of the patient • Holistic approaches • Potentially threatening established clinical dogmas
Assessment	• Comprehensive assessment • Extending beyond professional goals • Relationship of service development process to research evidence • Methodology of monitoring quality care • Development of national standards of benchmarking

Figure 2.1 – Clinical and Organizational Challenges (Carpenter, et al, 2002, 99)

Although many of the obstacles that were encountered over the past 50 years have worked themselves out of clinical research, many new dilemmas have risen in their place. In Figure 2.1, a number of these problems are presented. Time constraints are a consequence of all other pressures due to the fact that each task or obstacle takes up time. There are usually a number of things that a research institution must keep in mind when initiating a trial such as the extensive pre-approval process, which can delay the beginning of the research for years, as well

as the actual planning of the trial itself. It is also the main objective of the hospital to provide quality patient care as well as maintain the accuracy of the research while doing so. Without any new developments or evidence of effectiveness and safety, a trial could be postponed or cancelled.

One of the most common challenges experienced in the field of clinical research today is that of staffing. More often than not a research institution will be severely understaffed for several reasons. For many of the positions, there are usually strict educational requirements that a person must meet in order to be eligible, which limits the number of applicants that could be considered. Also, it is very common for doctors to specialize in a certain area and this reduces the number of patients that the doctor will treat because not all patients have the ailment a doctor specializes in. There is also the issue of paying for a large staff. Without the proper funding, an organization will not be able to hire sufficient numbers of employees to perform the volume of work required.

The deep-rooted dilemma of the patient-to-provider relationship serves as an additional source of challenges faced by the clinical research industry. Even though patient needs are number one on the agenda of a care provider it is sometimes difficult for him or her to carry out the research efficiently. If a patient becomes ill, or does not respond well to the treatment of a trial, then it is the duty of the provider to put the research aside and attend to the patient. Although it is necessary to ensure patient safety, this delay also adds to the time constraints involved with clinical research. It is also important for providers to inform patients of decisions and keep them active in this process. This can require a large amount communication which is also time consuming.

2.1.3 Clinical Trial Framework

Before a clinical trial can begin, there is a preliminary step called a preclinical study. Preclinical studies ensure that new drugs and treatments are safe and effective enough to be tested in humans. Such studies are first researched on the cellular level and are called *cell studies*. When testing for cancer treatments in a cell study, new drugs or treatments are mixed with cancer cells in a dish or test tube in order to test for effectiveness. In testing whether a treatment is effective, the researchers note whether or not it is worth studying based on the new options it creates (as opposed to those that are already available). The second step in preclinical studies is *animal studies*. Just as in the cell studies, animal studies are performed in laboratories on animals to give the researchers a chance to observe the effects of the treatment on living creatures. Safety is taken into account by asking whether or not the benefits of the treatment will outweigh the risks associated with it.

After a treatment goes through the preclinical study phase in cells and animals, it then moves into the clinical trial phase in humans. During phase I of a clinical trial, the safety of the treatment is tested. If the treatment is found to be safe in humans, then it is tested for effectiveness in phase II. After phase II completion, the treatment is then tested against current treatments that are available to the public. The main point of phase III is to make sure that the new treatment being approved is superior to what exists currently. If this is the case, then the new treatment is sent to a review board and can possibly be approved by the FDA. The overall intention of the research is to create better, more useful treatments that can be produced and eventually distributed to the public.

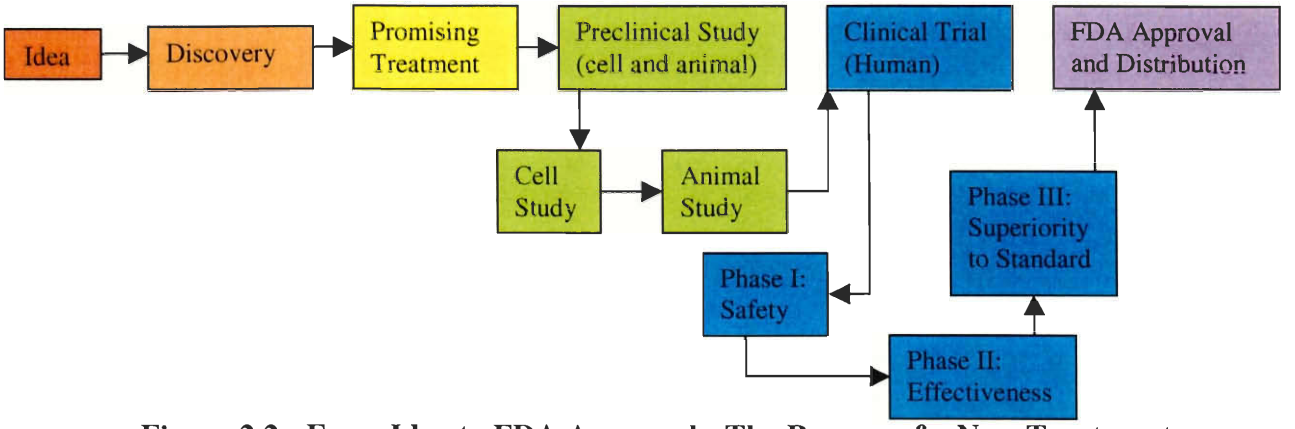

Figure 2.2 - From Idea to FDA Approval: The Process of a New Treatment

Clinical trials do not just happen overnight; each individual trial is the culmination of years of work by pharmaceutical companies, researchers, providers, and patients. Figure 2.2 summarizes the lengthy process that a new treatment takes to become federally regulated and approved. Often in cancer treatments, it takes eight years of research for a treatment to reach the clinical trial phase. Presently, only about one in every thousand new treatments will ever make it to the clinical trial phase of drug and treatment development (American Cancer Society website, 2002).

2.1.4 Providers of Clinical Research and Care

Cooperative groups are large, national groups of cancer centers that come together and conduct research. There are numerous facilities involved in both clinical research and providing care for patients. Internationally, the European Organization for Research and Treatment of Cancer (EORTC) provides cooperative clinical care within many research institutions. The EORTC has been around for more than 40 years and has set up collaborations among more than 30 groups (Therasse, 2002, 171). On a domestic scope, the United States regulates its research through the US Department of Health and Human Services. There are over 25 nationally affiliated institutes that make up the National Institute of Health. One of these, the National Cancer Institute (NCI), leads a national effort to reduce the burden of cancer morbidity and mortality. Its goal is to stimulate and support scientific discovery. The purpose of such discoveries is to reach a point in the future when cancer is rare and easily treated. Through basic and clinical biomedical research and training, NCI conducts and supports programs to understand the causes of cancer; prevent, detect, diagnose, treat, and control cancer; and disseminate information to the practitioner, the patient, and the public (National Cancer Institute website, 2002).

Academic institutions often combine with outside clinical investigators to work together to carry out clinical cancer research. Cancer centers are usually federally funded through NCI or one of the other National Institutes of Health. These federal funding agencies offer a multitude of resources including coordination between intergroups as well as funding for clinical care institutions across the country from the money that the government collects in taxes. There are

more than ten cooperative groups in the U.S. that have formed over the years in states like Virginia, Pennsylvania, North Carolina, Illinois, California, Minnesota, and Texas. These groups are the major recipients of the funding that goes to clinical research. In 1998, seven of ten of these state level groups formed the Coalition of National Cancer Cooperative Groups, Inc. in order to increase enrollment in clinical trials. Today, more than 1500 institutions participate in cooperative group trials, accounting for 60% of all patients enrolled in clinical research trials in the U.S. These groups are able to pool funds and attract donations for further research (Coalition of National Cancer Cooperative Groups, Inc., 2002).

Within the NCI there are three types of organizations in which research is conducted: companies, consumer level organizations, and health professional organizations. Industrial research is conducted by the larger pharmaceutical companies such as Merck, Pfizer, and Pharm-Eco. They are primarily business-based and are concerned with a profit-earning product. Consumer-level organizations conduct work in order to protect, educate, and unify those afflicted with disease; the American Cancer Society is one of the leaders in this area. Health professional organizations are the cooperative hospitals that work together in treating and testing new options for therapy. These types of institutions are some of the most productive and beneficial because of their research and patient-based care. Their goal is to provide the best possible care for each individual patient. The Dana-Farber Cancer Institute is one such organization and is also one of the largest in the world. The Dana-Farber Cancer Institute, Brigham and Women's Hospital, and Massachusetts General Hospital (MGH) all combine to serve as three international leaders involved in the care and research of cancer patients. Dana-Farber encompasses 12 separate, specialized care centers, each devoted to helping people fight a different type of cancer.

2.2 The Gillette Center for Women's Cancers

One of the 12 centers housed within Dana-Farber, and the focus of our study, is the Gillette Center in Boston. It is one of the premier institutions for clinical research concentrating on women's cancers. The Gillette Center, which employs 15 medical doctors and 20 ancillary employees, sees 700 to 1000 new patients a year. For a patient to be referred to the Gillette Center, she must have a history of ovarian or breast cancer or have a diagnosis of breast cancer (Gillette Center website, 2002). Currently, the Gillette Center hosts more than 75 active clinical trials for patients with breast cancer. These trials, which cooperatively enroll approximately 350 to 400 patients per month, are also available to both MGH and Dana-Farber patients.

2.2.1 Services and Staff at the Gillette Center

It is a mission of the Gillette Center to "provide the highest level of patient-focused, multidisciplinary care." A certain "standard of care" is given to those who have a history of either breast or ovarian cancer, while patients who have a confirmed diagnosis of breast cancer receive "multidisciplinary care." The main difference between these two types of treatment is that the standard of care guarantees access to providers only, while multidisciplinary care includes access to providers and specialists, such as radiology and medical oncologists, as well as the opportunity for involvement in clinical trials. Patient care, a much broader term, can be defined as individuals receiving treatment from interested and concerned medical professionals. When a patient goes to a doctor for medical advice, she expects not only to receive quality care,

but also to be received in an environment in which she is secure and comfortable (Gillette Center website, 2002).

The Gillette Center employs various specialists who are involved with patient care. Included in these specialists is a group of medical doctors and a group of ancillary employees. The set of medical doctors include breast surgeons, medical oncologists, and radiation oncologists. The Gillette Center has three full and part-time breast surgeons, four full-time and two part-time medical oncologists, and three full-time radiation oncologists. The ancillary care provider positions include one clinical psychologist, two nurse managers, one physician assistant, one breast pathologist, two social workers, four nurse practitioners, and one nurse coordinator who also acts as an educator (Karleen Habin, 2002, e-mail). The Gillette Center also employs an ancillary research staff including clinical research coordinators, clinical research assistants, as well as a variety of other professionals.

Clinical research trials are broken up into two major subsets: prevention and treatment studies. Prevention studies involve those patients who fall into the high risk category, or those patients with a genetic disposition to developing breast cancer. For this type of study, there is one clinical research coordinator involved who also acts as a research assistant. The second division of clinical trials, treatment studies, focuses on patients who have been diagnosed with breast cancer. There are three types of procedures that may be included in treatment studies. The first is surgical or local control, for which there is one research coordinator and a separate research assistant involved. The other two procedures are radiation and chemotherapy, for which there are two research coordinators and two research assistants. Regardless of the type of combination of procedures, one of the most important parts of a clinical trial is ensuring the quality of life. This is a vital part in the treatment since the clinical trials process tends to be extremely stressful for the patient and the quality, not quantity, of life is believed to be most essential (Karleen Habin, 2002, personal communication).

At the Gillette Center for Women's Cancers, a woman diagnosed with breast cancer receives multidisciplinary care (as described above). This type of care begins with three separate appointments: one to a medical oncologist, another to a surgical oncologist, and the third to a radiation oncologist. This is convenient for the patient, as the visits are all in the same day, all short in length, as well as all located within MGH. The appointments can occur every Tuesday, Wednesday, and Thursday. After these occur, there is a session, known as a "multi," in which all three doctors come together to discuss the patients they saw earlier in the day. The medical and surgical clinical research coordinators, the clinical research nursing manager, and the nurse practitioners attend; no patients are present. The purpose of a multi is to discuss what treatment option is best for each individual woman. Of course, unlike in the past, the patient is given options and is informed about what each entails (Sarah Malaquias, 2002, personal communication). At each multi, the doctors follow a certain format by discussing:

- Patient name
- Age
- Tumor discovery (self, doctor)
- Medical history (pertaining to diagnosis)
- Tumor (grade, size)
- State of patient (personal and mental)

- Patient family history (pertaining to breast and ovarian cancer)
- Consensus of treatment
- Doctor to speak to patient (give her their opinion and inform her)

If a patient's best option is clinical research, then she is matched with a specific protocol. A protocol is the documented procedure that a Principal Investigator, or head researcher, sets up for the research. Each protocol includes pre-study requirements, cycle lengths of the treatment, and other relevant data that need to be collected in order to carry out complete and thorough research. A sample of a typical protocol chart is shown in Figure 2.3. Each documented protocol varies in length, but some can extend to 60 pages (Sarah Malaquias, 2002, personal communication).

	Pre-Study	Week 1	Week 2	Week 3	Week 4	Week 5	Off Study
Cycle Number		1	2	3	4	5	
Informed Consent	X						
Physical Exam	X				X		
Vital Signs	X			X		X	X
Height	X		X	X			X
Weight	X		X	X			X
Tumor Measurements	X			X			X

Figure 2.3 – Sample Protocol Chart

One of the technical sections that researchers deal with in each protocol is what is known as a "schema," or a development of steps necessary to formulate treatment calendars. The schema is different from the protocol chart because the schema is a series of events written out, whereas the protocol chart is in row and column format. The purpose of the schema is to list the treatment cycle lengths and type of medication used for each protocol. By cross-referencing the schema with the protocol chart, a timeline of the treatment process can be formulated. The schema is used to determine the time points of a cycle and the treatment implemented in it, while the protocol chart gives any other required appointments for each cycle. Other appointments are things such as blood work, physicals, tumor measurements, and anything that pertains to patient well-being and disease progression (Sarah Malaquias, 2002, personal communication).

2.2.2 Creation of Calendars by Clinical Research Coordinators

The clinical research coordinators are the employees who work closely with protocol documents, charts, and schemas. After a patient has been approved for a clinical trial, the research coordinator schedules all of her appointments according to the cycles of the protocol. This involves scheduling the appointments via phone and then manually entering them into a calendar for the patient to follow. The scheduling and creation of calendars requires much of the coordinators' time, but is an essential service offered to the patient.

The research coordinator is responsible for a large number of everyday tasks. The research coordinator acts as a liaison between patient and provider within the Gillette Center. The coordinators go with patients to appointments and serve as aides to their consenting process. Along with escorting patients, clinical research coordinators also attend each multi session that occurs three days a week, as described in the preceding section. This is also an event that

consumes the coordinator's time. In addition to all of this, coordinators also perform screenings and analyze test results; certified coordinators can also draw blood and take vital signs. All of this responsibility is in addition to their task of creating treatment calendars for patients.

Each treatment calendar is precisely formulated for a specific patient and protocol in order to easily track her appointments and is used by coordinators and patients. Because the Principal Investigator relies so heavily on patients for the success of a clinical trial, it is important for a patient not to become confused with the process. This is why it is necessary for research coordinators to be so involved with the patient throughout her clinical research process. Without a research coordinator, the patient would have to worry about her administrative details as well as look after more of her treatment process. With the research coordinators at the Gillette Center, the patient is able to care for herself and ensure her personal wellbeing. She is also able to make sure she attends all appointments, a key factor to providing the researchers with accurate data that can be recorded and added to the assessment of the treatment being cooperatively tested.

In Figure 2.4 an example of a treatment calendar is represented. The date of each appointment is shown in the left-most column and the individual appointment pertaining to each is shown adjacent to this. These appointments may be for drug doses, blood work, or any other type of treatment. Reminders for the patient are placed in the "Comments" column. As an example, a reminder might be something like "abc-123." This would stand for an abbreviation code followed by a number for the required blood work task.

TREATMENT DATE	OFFICE VISIT	PROVIDER	CHEMO	COMMENTS
Date Cycle 1	Time Test Location	Provider Name	Time Location	abc-123
Date Cycle 2	Time Test Location	Provider Name	Time Location	

Figure 2.4 – Sample Treatment Calendar

Looking at all the tasks carried out by the clinical research coordinator, it is obvious that the position has many time constraints. The Gillette Center's clinical research nursing manager, Ms. Habin, felt that much could be done to decrease the amount of time research coordinators spend creating and recreating treatment calendars. By increasing the efficiency of the process, the coordinators would be able to spend more time being directly involved with patients and attending to their needs (Karleen Habin, 2002, personal communication).

Staff within the Gillette Center does not have much knowledge about other software programs that can handle the functional requirements, other ways to go about creating treatment calendars, as well as alternatives to the physical treatment calendars. It was the goal of this project to provide the Gillette Center with an assessment of their current processes and provide

the institution with recommendations and alternatives to the current practices related to treatment calendars. It has been our job to research existing software programs and other ways to create treatment calendars, as well as to explore alternative forms of treatment calendars.

3 Methodology

Throughout this project we focused on four main objectives. For accomplishing each of these, we needed to employ an appropriate methodology. First, we assessed the process for creating treatment calendars currently being used at the Gillette Center. We were able to accomplish this by observing the entire process as a research coordinator went through each step one by one. Second, we assessed the effectiveness of the treatment calendars for both research coordinators and patients. After gaining knowledge on how the process worked, we interviewed each group seeking insight into how effective treatments calendars are from their perspective. Third, we developed functional requirements for a treatment calendar creation process and product. To do this we analyzed our process observations and interview results to determine what elements would be necessary for an improved program. Lastly, we evaluated alternative solutions. In order to accomplish this last goal we used the internet as a resource to identify alternative solutions that may already exist for the Gillette Center to implement into their system.

3.1 Analysis of Treatment Calendars from the Perspective of Clinical Research Coordinators

Clinical research coordinators were our primary source of information for:

1) Assessing the process of creating treatment calendars;
2) Assessing the software used to do so; and
3) Assessing the effectiveness of treatment calendars.

These assessments were based on the perspectives of clinical research coordinators Sarah Malaquias and Christina Mathews, the two coordinators who handle the clinical research trial scheduling for patient appointments within medical oncology. They were our main contacts and the initial source that our group utilized to understand the process of creating treatment calendars.

Because of the exploratory nature of this research and our interest in understanding the process, we chose to use interviews and observations as our primary means for gathering information. In using the method of observation, we examined the process as though we were being taught to perform it and then asked questions based on what we saw. An unstructured interview allows the researcher to ask questions of interviewees without biasing their responses with presumptive questions. This was important to us as we were trying to figure out the actual problems with the process of creating treatment calendars as well as with the product.

In our interview of Ms. Malaquias, we first observed the process of creating a treatment calendar for the protocol 99-278. Through observing this process from blank template to completed product, we were able to visually establish a firm understanding of the steps involved, as well as possible problematic and improvable areas. However, because she was not creating an actual treatment calendar – she was demonstrating a "dry run" of the steps to us – we also asked her questions pertaining to the general nature of what creating a calendar for each patient would entail. For example, we asked her questions regarding the time of completion of each step and if the steps outlined were general or if they varied depending on the protocol (the interview protocol is located in Appendix A4. We were also able to ask her if she had any difficulties with

the process, what she found to be effective, as well as what changes she felt could be made to make the process more efficient (i.e., which parts were tedious or awkward).

In order to assess the software currently used to create treatment calendars, namely Microsoft Word, we used observation combined with an unstructured interview with the two clinical research coordinators. For our first interview, with Ms. Malaquias in mid October 2002, we used open-ended questions to gain a clear understanding of the process without leading the interview with prior assumptions. For our second interview, with Ms. Mathews in late October 2002, we were able to prepare general questions based on the answers we had received from Ms. Malaquias regarding problems or complications that she had with Microsoft Word (refer to interview protocol in Appendix A4). We were still very general in our questions with Ms. Mathews because we did not want to influence her answers by saying "Ms. Malaquias found this to be troublesome. Did you find the same?" Instead, we used our knowledge of previous answers to formulate questions in order to find similarities and differences in order to ultimately create general program or system requirements.

By having previously viewed the calendar creation process, we were able to evaluate the program visually. In order to "probe" further, we formulated open-ended questions in which we were able to obtain the specific causes of problems. Such questions were asked during each step of the creation process and the coordinators were asked to elaborate on the sources of problems encountered. We were also able to attain answers to questions relating to whether or not the coordinators found the program to be useful for creating treatment calendars (e.g. the software program does not allow me to perform this specific function).

The third type of information we sought from the research coordinators was the problems that they associate with the treatment calendars themselves. In order to attain this type of information, we created an unstructured interview protocol for the two research coordinators. General questions pertaining to aesthetics, layout, and content of treatment calendars aided us in creating recommendations for treatment calendars for future use at the Gillette Center. Again, these were kept general as we did not wish to sway their responses with any assumptions we had.

3.2 Analysis of Treatment Calendars from the Perspective of Patients

The patients are the other main users of treatment calendars and we wanted to understand their perspective on the current format of treatment calendars. To discover the problems patients found with treatment calendars, we performed the same type of unstructured interview used with the research coordinators. The patients were chosen by Ms. Malaquias, and the only criterion was that they had experience with using treatment calendars (i.e., they were in the last stage of their clinical research treatment or were finished and on a follow-up schedule). We then narrowed the selection down to five patients interview times (all different patients) which we accommodated to our schedules as we would have to meet in Boston. Once the interviews were completed, and we felt there was a certain degree of saturation in the information we received from patients, we determined what possible variations of treatment calendars could be useful to patients.

Prior to the interview, patients were provided with the types of questions we planned on asking, as well as a statement that explained our project and what we hoped to accomplish from interviewing them. In order to establish a rapport with patients, we asked them questions

pertaining to their status within their clinical trial. We also wanted to gain a feel for how much patients actually use the treatment calendars, as well as how familiar they were with them. We asked questions regarding usefulness, effectiveness, and possible variations, we sought to establish what the patient truly utilizes the calendars for and what types of changes patients would find more helpful (i.e., what part of her treatment calendar was confusing or not useful). After our initial interview, we formulated alternative calendar formats and referred to them at the end of our four subsequent interviews. We chose to do so at the end of the interview so that we did not influence the perspective or the responses from each patient.

3.3 Development of Functional Requirements for an Improved Process and Product

After conducting all of the interviews with the clinical research coordinators and patients, we analyzed the information gained. Each of the interview subjects offered insight into the functional requirements of an improved process and an improved product. The answers and data obtained from the clinical research coordinators were directed more towards process alterations and the data inputs required. Patient information produced opinions pertaining to the appearance and comprehension of the calendars. After we conducted each of the interviews we were able to integrate the results to formulate the appropriate suggestions for possible solutions, whether technical of procedural, for the proposed problems.

We used the clinical research coordinator information to determine what a potential software package must be capable of doing. It was also known what this potential solution must be capable of producing and how it must appear as far as layout was concerned. There were several points of data that were required to be present in order for the calendar to be useful to a patient. The patients had explicit suggestions as to what they would find helpful when looking at the calendars. The patient interviews yielded extremely important perspectives on the appearance of the treatment calendars.

The main objective of the sponsor was to be able to do both of those things automatically, with a single software package. From each piece of information gathered we were led to another functional requirement and even more follow up questions. This process was ongoing throughout the research. Often times, requirements that we developed were changed to better suit the needs of the system that we uncovered in later interviews.

3.4 Evaluation of Alternative Solutions

We used two approaches to seek possible alternatives for creating treatment calendars. We first contacted other groups that are involved in cancer research to learn what they use, and then we researched existing software packages through use of the internet. Other providers of clinical care were discovered by searching the National Cancer Institute's list of active clinical trials, and from there the locations of these trials were also determined. Over two dozen e-mail inquiries were sent to these groups. These e-mails contained a short description of what the project entailed, followed by a request for them to explain to us what they used to keep track of patients' appointments. (Appendix A8). There were eleven replies to these inquiries, but only three were relevant. From there we conducted one telephone interview each with the Norris Cotton Cancer Center at Dartmouth College, the Boston Medical Center at Boston University, and the University of Massachusetts Medical School. Doing this allowed us to determine what

other groups were doing, what software was available, and to determine if there was something that could be helpful to the Gillette Center.

Secondly, we researched automated calendar creation programs on the internet. Where there were demos available online we tried them in order to see if they were something that would be of use to the Gillette Center. Our other option was to e-mail any contact information on the website and ask for as much information on the program as possible as well as ask for any trial programs. Following this we took the functional requirements of an improved system that we determined from our analysis of the interviews and evaluated the alternative solutions against these criteria in order to determine if the program would be of any use to the Gillette Center. While researching these alternatives we kept in mind several points. The most important to remember was whether or not the software would provide functionality which met our requirements. Also, the cost and ease of implementation were considered. This information was found on the internet on the programs' web pages or was included in any e-mails that we received back from companies. At the end of this research we were able to present the Gillette Center with a complete analysis of each alternative and make recommendations about those that we found plausible for implementation within the Gillette Center.

4 Data Analysis

In this section, we present an analysis of the data gained from our two stakeholder groups – clinical research coordinators and patients – as well as an integration of both groups' suggestions into functional requirements. Through their suggestions, the groups presented us with essential insights into the problems and opportunities with both process and product. These suggestions led us to formulate functional requirements in which we created a list of requirements that a system would need to have in order to be considered for implementation.

4.1 Clinical Research Coordinator Interviews

When first starting the project we needed to get a full understanding of the process for creating treatment calendars, how it worked, and what changes the people working with it would want to have made. Ms. Malaquias first explained to us why she preferred using Microsoft Word to Microsoft Outlook to create the calendars. Her reasoning was simply that she did not like the printed appearance of a calendar from outlook.

Step-by-step treatment calendar creation process:

- Start Microsoft Word
- Open existing, used version of a treatment calendar
- Save As in appropriate patient's file folder
- Remove the information that is currently displayed in the calendar
- Enter the appropriate dates for the protocol that the patient is on
- Call providers' offices to set up appointments
- Wait for return phone calls with schedules appointments
- Enter the correct times and locations of appointments into the calendar
- Add any additional comments to treatment schedule

Next, Ms. Malaquias explained that she felt making the patient appointments with each doctor was the most time consuming step. For each patient Ms. Malaquias had to either call or e-mail each office to set up an appointment; waiting for a reply to an e-mail took the longest. While this step was the most time consuming part of this process, it did not involve the time used to create the treatment calendars directly. We asked Ms. Malaquias if she had any suggestions on improvements and how they would benefit her with the process. We also asked if patients or providers had any problems with the treatment calendars, and how any improvements would benefit them.

One of the potential solutions that our sponsor Karleen Habin wanted to see was an automated way to create the calendars. Ms. Malaquias agreed that if there was a system that would accomplish certain things automatically, it would save time. An automated process would involve entering a few things into a template, such as protocol number, drug name, and start date, and from which the calendar would create itself. This automation could potentially save up to 10 minutes per calendar. This would benefit the patients because it would mean more that the coordinators would have more available time to spend with them, which is important to their care. The only other suggestion Ms. Malaquias had was to post the calendar on the Gillette Center's internal website. This website is used at the Gillette Center by the staff and allows them

to see a patient's history and what appointments have or have not been scheduled. Posting treatment calendars would make viewing the patient's calendar easier for the research coordinators, the providers, and for Ms. Habin. Ms. Malaquias mentioned that several times Ms. Habin had called her about patient appointment times and if the calendars were posted internally, then she would have had the necessary information at her fingertips.

Ms. Mathews, the second research coordinator we interviewed, was fairly new to the Gillette Center. She had only been working there for a few weeks and was not yet as experienced with the treatment calendars as Ms. Malaquias was. However, she still responded in the same way to our interview questions as Ms. Malaquias did and agreed with all the suggestions that Ms. Malaquias had made to us on process changes.

Regarding the layout, contents, and aesthetics of treatment calendars, both Ms. Malaquias and Ms. Mathews were quite pleased with them. The one minor change that was suggested was to create an additional column in which they could jot down notes for themselves. Since they did not want the comments to be viewed by patients, they had ended up penciling them in on paper copies within the limited available space. If another column were created, but not viewable in the printed version, in which research coordinators could write their comments, this would then make an ideal calendar for clinical research coordinators.

4.2 Patient Interviews

Of the five patients we interviewed, there was an age range of 30-45 years, as well as a range of experience with treatment calendars. Three of the five patients have been employed in the medical field. Two of the five had completed their research trial and were in post-study protocol. One interview was held on November 14, 2002 and the other four interviews were held on December 19, 2002. Having over a month in between our initial interview and our final interviews proved useful, as we were able to create variations of the calendar currently being created by the clinical research coordinators and supply the last four patients with them. These variations were based on earlier interviews we conducted with one patient and the two research coordinators.

The patient interviewed in mid November had completed her clinical research trial and was on a follow-up schedule consisting of an appointment date every six months for five years (per the protocol of her specific research trial). After being diagnosed, Patient One, as she will be known hereafter, noticed that her memory and organizational skills were declining, so her treatment calendar was an organized way of keeping track of her appointments. Patient One would have preferred her calendar in a monthly format instead of in the "list" format as she referred to it. Through altering the structure of the calendar, there would be room to make notes about trial appointments as well as add other appointments unrelated to her trial. An aesthetic alteration that Patient One suggested was to add alerts or color code locations so that any changes were more obvious. As for the content of the calendars, Patient One recommended that if a monthly setup was not an option, then another column be added for her own notes. She also suggested creating a list of doctors, their offices, and telephone numbers, so that if she were running late for an appointment she could easily contact their office.

As with Patient One, the second patient we interviewed had also completed her research trial and had been on a follow-up schedule since September, 2001. Patient Two was one of the

three patients we interviewed who had worked in the medical field and therefore found the transition into her research trial reasonably easy.

Even though Patient Two knew the "ins and outs" of her calendar, she found it very practical to have her appointments mapped out for her. She would give copies to her family members, employers, and child caregivers; this way they knew where she had to be and when, and they could easily schedule appointments and activities around her trial appointments. Patient Two did find that it would have been useful to have a list of doctors, their offices, and phone numbers to refer to if necessary.

Patient Three, our second interviewee that day, was halfway through her research trial and like Patient Two, worked in the medical field. When she was first introduced to the treatment calendar, she found it to be very accurate and straightforward in the information that it was intended to display and therefore, very useful She also found her calendar to be a helpful way to quickly glance at what she had coming up. After utilizing her treatment calendar, the one suggestion she had for us was to make any variations more noticeable, maybe by use of color coding or highlighting. For example, there was an asterisk placed next to her appointment, but she wasn't sure what it meant. After asking her research coordinator, she found that it was explained at the bottom of her calendar, but she had not noticed that.

Our next interviewee, Patient Four, was unclear on where she stood in her research trial because of medical complications. Even though she was unclear of her trial situation, Patient Four did find her calendar to be laid out well and to present her appointments in a straightforward manner. However, unlike other patients, Patient Four did not have a medical background and would have found it helpful for the abbreviations in the comments column to be spelled out. She would have also found it effective to include the approximate length of time that each appointment would be. Patient Four also found that she was adding other appointments with her surgeon and cardiologist and would have found it useful if there were another column in which she had the extra space to do so. She preferred the setup of the current calendar as opposed to a monthly one.

The last patient we interviewed was in her second to last week of treatment, which would be followed by surgery and another cycle of chemotherapy treatments. Patient Five had previously worked at MGH, among other hospitals, creating schedules and was therefore familiar with the scheduling aspect of her research trial. She found the calendars to be a comprehensive way to provide everything in one place (e.g. the blood work needed, tubes needed for blood work, as well as her appointments). Patient Five also felt that a monthly format might be helpful as there was not enough room to make notes or place reminders. However, she said that if another column were added to the list format, and it created ample space, then that would have the same benefit as a monthly calendar. Even though she had worked in hospitals, she was unclear what the last column represented, as there were only abbreviations. She would have found the comments useful if they were spelled out or explained to her. Similar to other patients, Patient Five was in favor of color coding any changes or variations to the calendar to make them more apparent.

In concluding what the five patients suggested for improvements, it is important to note that there was not always a consensus and that we had to determine an appropriate compromise. Below, in Figure 4.1, each patient's suggestions are laid out.

Putting together the various needs of each patient, and assuming these are the general needs of clinical research patients within the Gillette Center, there are five major considerations: 1) format, 2) color coding or highlighting, 3) additional column or room for patient notes, 4) a key or explanation of the current "comments" column, and 5) a list of doctors within medical oncology with their offices and phone numbers. Considerations two through five were either an agreement by all patients, or no patient was opposed to them and would therefore be found useful if implemented based on this consensus.

Suggestions					
	Format	**Color Coding**	**Additional Room/Column**	**Key/Explanation**	**List of Doctors**
Patient One	Calendar	Yes	Yes (if not calendar)	N/A*	Yes
Patient Two	List	N/A*	N/A*	N/A*	Yes
Patient Three	List	Yes	N/A*	Yes	N/A*
Patient Four	List	Yes	Yes	Yes	N/A*
Patient Five	Calendar/List	Yes	Yes (if not calendar)	Yes	N/A*

*NOTE: "N/A" refers to the patient not mentioning or discussing the suggestion.

Figure 4.1: Patient Suggestions

However, for the first suggestion, that of the format, there was not a consensus. If the current program, Microsoft Word, is to be used again, then it would take research coordinators additional time to create another calendar. Unless another program is implemented in which different formats can automatically be created using the same information, then we have decided that the list format would be best for most patients and the best option for the research coordinators who create them. In keeping the list format, we recommend that another column or additional space be created for notes and other information patients wish to put into their calendar, as all patients suggested this (assuming the list format). This is a compromise for those patients who suggested a calendar format, as their reasoning for such was to give them more space for notes. If these suggestions are carried through to production in treatment calendars, then they would satisfy all patient needs, without compromising any one need significantly.

4.3 Functional Requirements

After examining the suggestions presented in the above sections, which reflect the consensus of the five patients and the two clinical research coordinators that we interviewed, we determined a set of functional requirements. These functional requirements will ultimately influence our recommendations. In this section, we articulate what each requirement means with respect to treatment calendars. Some of the requirements are essential for any alternative to receive serious consideration, while others are desirable, but not absolutely necessary.

The core functional requirement that was first tested against each potential alternative was the *ability to save multiple calendars*, one for each patient. As each research coordinator works with over one hundred patients, a software package must have the ability to save more

than one calendar within its system. Without this essential capability the research coordinator would be required to create a new calendar from an existing one and any information that was previously saved would be deleted and lost. A software package that did not allow for multiple calendar storage within the system would be ineffective and inefficient for the treatment calendar creation process within the Gillette Center.

The next set of functional requirements is that of *additional space* and *color coding*. We have placed this set of requirements within a "strong preference" category. These functional requirements, set by both patients and research coordinators, are not required, but would be extremely helpful to both. In the printed version of treatment calendars, allowing additional room for notes was suggested by coordinators and patients so that they could add personal notes and reminders. Additional room could be provided by a software package in several ways: expansion of column or row width, availability of additional column space, or providing ample room within each day. Highlighting of locations, as seen in Figure 4.2 was suggested by patients and can be done through coding by colors or symbols. The symbol option would be most useful if the Gillette Center does not have, or does not have funds for, a color printer. By establishing a color or symbol scheme, research coordinators will be able to visually organize appointment locations, which will help patients manage their visits more easily.

TREATMENT DATE	OFFICE VISIT	PROVIDER	CHEMO	COMMENTS
Date Cycle 1	Time Test Location 1	Provider Name	Time Location 2	abc-123
Date Cycle 2	Time Test Location 1	Provider Name	Time Location 3	

Figure 4.2: Example Highlighting by Location

An additional functional requirement was automation, which was placed into the "strongly desirable" category. Although this requirement has been suggested, it is not currently in use within the Gillette Center. If a system fails to possess this suggested capability, nothing would be taken away from the process or product. Although automation could offer beneficial time saving abilities to research coordinators, a package will not be required to have such capability. There are two possible levels of automation to be considered: complete and automatic repetition of appointments. A completely automated system would take several points of data and generate a treatment calendar from them. Items such as protocol number, group number and start date of a treatment would be entered into the software. From there, the program would recognize the cycle lengths and appointments associated with these data points, as they would have been programmed into the system previously. Patients typically visit the Gillette Center for appointments on the same day of each week (e.g., every Tuesday starting after 11am) the program could also be instructed to set up appointments on that specific day of the week or time. The research coordinator would still have to schedule the appointments and fine

tune the calendar, but the dates and appointments would be mapped out for them by the program. From there the research coordinator could finalize the treatment calendar and print the product out for the patient.

The second level of automation, automatic repetition of appointments, refers to the ability to take a data point, such as a specific type of appointment, and repeat it into the appropriate places as many times as required. This function of a software package became a strong desirable when evaluating each of the alternatives. For example, in a given protocol there are cycles that need to occur within a certain amount of time. If each blood work appointment needs to occur every two weeks, then the repeat function would allow the research coordinators to enter in the first appointment, specify the repetition (which would be every two weeks), as well as enter in the number of appointments necessary according to the total number of cycles in the protocol.

A final system requirement is the ability of the software to create the calendars in the preferred format. Currently, this preferred format is that of a list type in which appointments are documented in a table. The other alternate format resembles more of a calendar in which each day of the month is displayed. Although the list format is favored, if a calendar format was the only option offered by a software package, both groups would be able adjust to it without much difficulty. When evaluating packages we kept in mind that either was workable, but aimed more at the list style because of its popularity among research coordinators and patients alike.

Other criteria that we considered, in addition to functionality, relate to the acquisition of the software package. The cost of purchase of each package was determined first. Because funds would be better spent on the clinical research trials themselves, it would not be wise for the Gillette Center to put unlimited funds into a program for creating treatment calendars. After cost, the amount of time that would be required to fully implement the system was estimated. This factor was based upon several criteria including the length of installation, ease of learning each program, and other factors such as the amount of time to program specific requirements into packages.

Finally, we provided an estimated amount of time that would be saved when creating calendars with each package. Based on our observations of the creation process performed by Ms. Malaquias, we estimated that the calendars currently require at least 20 minutes of creation time. From this we were able to approximate the amount of time that would be saved based on a comparison to the current process with Microsoft Word. For this requirement, we have divided the time saved into three categories: significant amount of time saved, some time saved, and no time saved. Those packages that fall into the significant amount of time saved category will improve efficiency of creation by more than 10 minutes; those that fall into the some time saved category will save coordinators anywhere from 1 to 10 minutes; those that fall into the no time saved category will either save no time from what is currently spent or will take more than 25 minutes to create.

5 Explorations and Development of Alternatives and Solutions

This chapter describes our assessment of alternative calendar creation processes that could potentially meet the needs of the Gillette Center. Three other clinical care providers were questioned as to their current practices when creating patient treatment schedules, in order to give us some ideas as to what types of packages to investigate. We also searched for software packages capable of meeting the functional requirements we have developed. These packages were categorized into several different groups according to the functional requirements that each did or did not meet.

5.1 Processes Used by Other Clinical Research Providers

Several other institutions that conduct clinical trials were contacted and interviewed in order to discover methods of patient treatment calendar creation that we might have overlooked. There was a broad range of levels of development that these providers spanned. On the most advanced end, one group had developed their own, homegrown system. Another group was using a software package that was designed for creating regular, monthly calendars. An additional group had not yet found a means of data management and was actually in the process of searching for a software package for doing so. The interviews with each were very valuable in helping us reach our goal of a detailed and thorough assessment.

5.1.1 Norris Cotton Cancer Center

Dartmouth College, the Dartmouth-Hitchcock Medical Center, and the Norris Cotton Cancer Center in Lebanon, New Hampshire, make up one of the foremost institutions for research, education, and treatment of cancer in New England. Established in 1972, Norris Cotton Cancer Center is one of a select group of institutions nationwide designated by the National Cancer Institute (NCI) as a Comprehensive Cancer Center. It is ranked as one of the top cancer care facilities by U.S. News & World Report (Norris Cotton Cancer Center website). We were fortunate enough to speak with the associate director of the center, Priscilla West, on the subject of patient treatment scheduling.

Norris Cotton Cancer Center was in the same position as the Gillette Center approximately one year prior to our speaking with them. They were in search of a new and better method of patient treatment scheduling. The staff of the center tried common calendar creation packages but they did not like them. The major issue was that for treatment lapses (patient rescheduling) there was no option to reformat the calendar after it had already been made. Optix, one such program, was created by a company in Canada. The base cost of this package and many others like it was $1.5 million. Many of these commercially available calendaring programs are meant for large pharmaceutical companies. In the end the staff of the Norris Cotton Cancer Center decided it would be best and most useful to create their own program.

The design of the program took a long time and much effort to create. Many people were involved with designing and creating the "home-grown" program. The data base management system software used to create it was Sybase SQL because of the web compatibility that it offers. The program is a work in progress because it involves administrative databases with detailed

study information as well. It took over a year and thousands of hours of programming to implement. It was created by a group of people that are associated with the calendars, including an employee that is the programmer for all of the clinical research at Norris Cotton, as well as the research coordinators themselves.

The technical specifications of this program were designed so that the calendars would be extremely thorough. The information in these calendars includes study outcomes as well as patient demographics. At the beginning of a new protocol the program is set up with a new template specific to that protocol. Then there are two separate sets of data entered: one for technical calendars and one for lay calendars. There is a different template for each type of calendar within each protocol. There are only two required pieces of data that are entered into each template: the start date and group number. For a technical calendar the days are numbered starting with the pre-study days as negative numbers, and Day 0 as the date of patient registration. After Day 0, when the trial actually begins, technically or medically oriented information is included within the calendar. There is room for comments about test types, dates, times, locations of procedures, etc. The patient or lay calendars are presented in a format with times, dates, and appointments all listed on the appropriate days.

According to Ms. West, the benefits of this new system are so great that it has made all of the time and effort put into it more than worthwhile. The program was not hard for the staff to learn because everyone responsible for using it was also involved in designing it, so nothing was unfamiliar when the system was finally installed. The staff using the system works throughout the Norris Cotton Cancer Center in all of the departments and accesses the system through an internal database. An additional calendar called a billing calendar is also created sometimes for treatments that are not covered by insurance. These calendars are shared with the billing department. The system also saves the staff large amounts of time when making patient treatment calendars because they no longer have to research and enter multiple points of information. Also, the patients like the calendars and find them to be helpful. A "test" calendar is usually created for a patient considering multiple trials. Test calendars are example calendars that show a patient how often she will have to come in according to different protocols. This is especially helpful for patients coming from rural areas because of the amount of travel time required. These benefits more than compensate for all of the effort and time that has been put into this system.

It has taken some time, but presently all of the "bugs" have been worked out of the system. It is now owned and copyrighted by Dartmouth College. The cost of a commercial package of the same caliber would have been substantial. Places other than the Norris Cotton Cancer Center have been able to use non-commercial packages for patient treatment scheduling as well. However, it is the belief of Ms. West that these institutions have not gone as in depth into the creation and programming of the system.

5.1.2 Boston Medical Center

Boston Medical Center is a private, non-profit, academic medical center located in Boston, Massachusetts. The hospital is the primary teaching affiliate for Boston University School of Medicine. Emphasizing community-based care, Boston Medical Center is the largest safety net hospital in New England. Extensive research and development occurs here while

students are allowed to improve their own education. Within the medical center is the Cancer Research Center, where we contacted Sally Fennessey.

The program that is currently in use for patient treatment scheduling is a program called Calendar Creator 4.0 by Softkey. The information that is to be entered into the calendar is entered into either a box or a banner. The box is an individual day or date while the banner spans across several days in the same week. The banner is helpful when the same treatment is required each day. Some of the information that is included in the calendars is daily appointment times, chemo dates, stem cell infusion dates, and other points of this nature. Also, there are usually several reminders for the patient included in the calendar. These include reminders for items that the patient must bring to the appointment such as medications and charts. There is also room for reminders to take medications on specific, non-treatment days.

Patients are left room on their calendars to write about things that they do on their own. When the patients take medications at home they are asked to write down how many pills they took, side effects felt, and any other feedback that they feel is important. Then at the end of the treatment the patient is asked to bring the calendar back to the researchers, and the data that the patient wrote down are included in the study results. According to Ms. Fennessey, this is very helpful because there is otherwise no way to track this sort of information. Also, patients take these calendars with them everywhere. If the patient has to go to the emergency room they have a perfectly documented way of reporting what treatment(s) they have received and what medication they are on. The patient and research nurse both receive a copy of the calendar, and there is also a copy included with the patient's chart. Examples of these calendars are shown in Appendix A13. There is also a "master calendar" that is created for the entire office that includes information about all of the patients.

The researchers at Boston Medical Center try to keep the calendars as simple as possible. The patients usually go to the same place every time that they have treatment so unless this changes, it is not included in the calendar. The program itself is a bit complicated to learn. It tends to be a bit confusing at first because the calendar and the events are two separate documents. Once learned, however, Ms. Fennessey believes that there are many benefits. The calendars help each patient individually with keeping track of appointments. Tracking data on a particular level for things like side effects is very beneficial to the study outcome. The patients also find that tracking data is helpful. As with anything, there are also some drawbacks. There is no room to make notes electronically on the calendars. If there is something more to be included in the print-out it must be in one of the boxes or handwritten onto the calendar. Also, when creating the calendar, it must first be saved and then the events that go into it are saved separately. Then, both must be saved as something called a "workbook". This makes keeping track of many things a bit more complicated. Although there are problems, Ms. Fennessey thinks the benefits more than outweigh them.

5.1.3 University of Massachusetts Medical School

University of Massachusetts Memorial Health Care is the clinical partner of the University of Massachusetts Medical School and the largest health care system in Central and Western Massachusetts (Umass Medical School website). This nonprofit system encompasses a complete health care continuum, with a multi-campus academic medical center, member and affiliated community hospitals, freestanding physician practices, ambulatory clinics, long-term

care facilities, home health agencies, hospice programs, and rehabilitation and behavioral health services. Sheila Noone, the director of the Umass Medical School's department of clinical research, is in the process of searching for an automated way of tracking patient-related data.

While currently there is no centralized data recording or tracking system, the staff of the center is considering several options. The way that data and patient treatments are currently being tracked is by using templates that are supplied by the pharmaceutical company sponsors that Umass is doing research for. This is problematic because they are forced to rely upon what the sponsor company gives them. Additionally, there is a template in use that was designed by a consultant to keep track of the trials that do not have large, corporate funding, but these types of trials are rare.

Although the staff of the Umass Medical School does not have a program yet, they have identified several of the key criteria that a program must meet. A web-based program that will track and monitor all clinical research data and will also work well in a state institution that runs large volume trials are examples of some of the specifications. The program must also offer a common format for all study-related data in an efficient and consistent way. Additionally, the program must be from a well established software company because if a large amount of money is to be invested the system must work without any flaws. Some examples of the systems being researched are Study Manager, Siteworks Solutions, and Integra. There are also companies called Contract Research Organizations (CRO's) that will come in and manage a research organization's data for them. These organizations can be very helpful but are also very expensive. The Umass Medical School is still in the process of deciding upon and researching an answer to the data management issue.

5.2 Software Packages Research

After determining the functional requirements for a system to generate treatment calendars, we examined alternative software packages. We searched through many scheduling and calendaring software packages, as well as data management programs, and gauged each package's ability to meet our pre-determined standards. Some of the packages that we looked at were found through the use of the internet search engine "Google," while others were suggested by or are currently being used by clinical researchers from facilities other than the Gillette Center that we interviewed. After researching many alternatives, we were able to split them up into three separate groups based on how close each came to meeting the functional requirements: candidates not satisfying core requirements, candidates satisfying core requirements, and candidates designed for clinical research. Within each category, we have described each of the packages so that the least useful is discussed first and the most useful last.

5.2.1 Candidates Not Satisfying Core Requirements

The three packages outlined in this "non-contender" section do not meet the one functional requirement that is necessary to this project. The ability to create and save multiple calendars is essential to the Gillette Center (as well as MGH, DFCI, and other affiliates of Partners HealthCare), as they admit anywhere from 350 to 400 new clinical research trial patients per month. The efficiency of research coordinators will be increased if parts of the treatment calendar creation process are made more efficient. In the case of these non-contenders,

the efficiency of research coordinators would be decreased, and would therefore create a lengthier process than what is currently being done to generate treatment calendars. Although some of these packages may look promising in other unique aspects, the flaw of not meeting the one functional requirement that is vital is the common downfall.

COSMI, manufacturer of the calendar creation software Amazing Calendar Creator, (http://www.cosmi.com/html/software_productivity.htm) offers its package starting at $6.95 through Amazon.com. Amazing Calendar Creator has the features of highlighting appointment locations through color coding and symbols as well as creating calendar format printouts. This software also allows the user to add special events and daily, recurring events to a calendar. Unfortunately, once an event is added through the "Events Database," it is also added to any calendar saved previously. Although this software can produce multiple formats of calendars, it lacks the ability to save calendars without automatically updating information to a calendar in which it doesn't belong. This feature would be more harmful that useful to clinical research coordinators at the Gillette Center.

Franklin Covey Planning Software 8.0 (http://www.franklincovey.com/) has the ability to create handheld and web compatible calendars for only $79.95. Although FC Planning Software has the features of automatic repeat appointments and a calendar format, it does not have the essential element of creating multiple calendars. This software also does not have the capacity to allow additional space for comments or the addition of color or symbols to code appointments in printed versions.

Plan Plus (http://www.franklincovey.com/planplus/features.html) for Microsoft Outlook is an add-on that could help research coordinators become more efficient in their daily tasks. Through prioritizing what matters most by day or week, users of Plan Plus can set goals and be sure to accomplish those that matter most. This software, priced at $74.99, also has the ability to highlight appointment locations through color coding, provide a calendar format, allow for some additional comment space, as well as automate information generation with a repeat function. However, again, Plan Plus does not provide the user the ability to create and save multiple calendars.

5.2.2 Candidates Satisfying Core Requirements

The packages in this section meet at least the multiple calendar requirement as well as some other functional requirements. In general each package will meet the basic functional needs of the Gillette Center, but is not geared towards clinical research. Each also has interesting characteristics that could be useful to the Gillette Center.

Complete Calendar Kit (http://www.databecker.com/) from Data Becker has the ability to produce and save multiple calendars, provides some additional space for notes, and has the format of a calendar for the cost of $29.95. However, as these are the only functional requirements that this software meets, this would not be a package for the Gillette Center to compare further against their future needs. The major drawback to this package is that it does not include a repeat appointment function which is strongly desirable.

Another planning product from Franklin Covey is Forms Wizard 2.0 (http://shopping.franklincovey.com/html/ibeCCtpSctDspRte.jsp?section=16886&item=6555). This package allows for additional space and highlighting of appointment locations through color coding, in a

calendar format, for $29.95. Forms Wizard 2.0 does not have a repeat function to automate any process of scheduling. With Forms Wizard 2.0, the user can personalize one of the over 60 templates provided to create multiple calendars. The main feature of this product is not scheduling, but its ability to create forms ranging from personal to business and childcare to automotive. This focus, which is contrary to that of the Gillette Center, does not make Forms Wizard 2.0 a major competitor for implementation.

A package that is designed for project management, Microsoft Project 2002 (http://www.microsoft.com/office/project/evaluation/default.asp), can be of use when managing several schedules. Multiple calendars or projects can be created through the interactive Project Guide, as well as highlighting through color coding, printouts in both list and calendar format, and additional space for extra comments. Each patient, in the case of the Gillette Center, could be thought of as an individual project. Although it does offer a calendar feature, it is not designed to schedule appointments which is what the Gillette Center needs. The main purpose of this software, which costs $566.99, is to provide general timelines for activities that run in parallel.

Task Manager 2003 (http://orbisoft.com/) is a software package that assists the user in managing and tracking individual or team-oriented tasks, jobs, and products. This program, which is priced at $495.00, is designed to be used in the workplace and allows for tasks to be entered and then edited or changed if necessary. With Task Manager 2003, the user creates a "task" which can be any number of appointments or jobs. Task Manager also has a repeat function for recurring events, highlighting ability for locations through color coding and symbols, and a list format. However, the disadvantages of Task Manager 2003 is that it does not provide any additional space in which research coordinators or patients can put notes or comments.

Calendar Creator 4.0 (http://www.micro-wiz.com/calcreate4.html), which is currently in use at the Boston Medical Center for patient treatment scheduling, by Softkey is a calendaring program that allows the user to choose from 11 different calendar layouts for the price of $29.95. Unlike other calendaring programs, Calendar Creator 4.0 not only allows the user additional space for notes, it also offers the ability to resize rows and columns to allow for ideal additional comment space. This software does not have a repeat function which will not allow Calendar Creator 4.0 to automate any of the treatment calendar creation process.

A Broderbund calendaring program that could be promising for the Gillette Center is Calendar Creator Deluxe 9 (http://www.broderbund.com/SubCategory.asp?CID =109). For $49.99, the user has the ability to create multiple calendars in list, calendar, or an original design format, and highlight appointment locations through color coding and symbols. Calendar Creator Deluxe 9 also has a repeat function as well as a "drag & drop" feature that allows for easy rescheduling of appointments. Although the software allows for additional comment space, it is limited. Also, based on aesthetics, this software was not professional enough as it is geared towards personal applications.

Microsoft Outlook (http://www.microsoft.com/office/outlook/default.asp) is a software program that is currently being used by the Gillette Center for e-mail purposes. It has the ability to save multiple calendars both by template and by calendar. Outlook's ability to create calendars is not being used currently because the default view does not allow ample room for research coordinators to enter in the required treatment calendar appointment information. However, this is not the only calendar view that Outlook offers which is why we have researched

this package. One view in particular that we researched, as we felt it could be useful to the Gillette Center, was that called "active appointments." Through this view, the research coordinators can enter appointment information, as well as additional comments, in a list format and use a repeat function to organize recurring appointments. Since a patient will come in on the same day each week (or according to the necessary timetable) it would be easy to tell Outlook to recur a chemotherapy appointment every two weeks. The first time would be specified, but each subsequent appointment could be adjusted according to provider availability by going into each appointment and changing the start and end times.

Excel by Microsoft (http://www.microsoft.com/office/excel/default.asp) is a program that is primarily used for creating spreadsheets, and analyzing and managing data. Excel offers the ability to color code cells, save multiple documents, produce a list type format, as well as allow for additional comment space. With regards to automation, Excel can be used effectively to allow for the repeat function and this can be added to the treatment calendar creation process. It is possible to set up a spreadsheet that will automatically fill in the dates of required appointments by simply entering the date of the first appointment into the appropriate cell or cells. The best method for using Excel would be to set up a template at the start of each protocol and use this template for each calendar created within that protocol.

5.2.3 Candidates Designed for Clinical Research

With any system implemented by the Gillette Center, it is important to think about the management of data. Because the value of clinical research depends on the quality of data collected, managing data efficiently and accurately should be a main concern of the Gillette Center. If in the future there are plans to rework the organization of clinical research data within the Gillette Center, we have come across several options that will help in the management and analysis of trial data as well as the current scheduling issues.

Clinical Software Solutions is a premiere medical software company. The most relevant package to this project among the several offered by Clinical Software Solutions is Clinical Software Solutions Scheduling (www.clinsoft.com/ CSSCHED.htm). It is designed specifically for managing patient, physician, and technologist's schedules in one system. Data for a large number of patients, physicians, or departments can be stored within CSS Scheduling. Although this program has the ability to create multiple calendars and has a "drag and drop" feature, which would be useful for recurring appointments, it is geared more towards managing schedules rather than creating them. This program also only has the ability to print daily schedules, which would not be ideal for patients.

Study Manager (http://www.acs-world.com/html/solutions_study_manager.asp), from Advanced Clinical Software, incorporates a large range of features including web-compatibility, patient recruiting, and study budgeting. This package offers security and patient confidentiality and is designed to be Oracle and Sybase SQL compatible. Other features of Study Manager include graphical scheduling, patient and contact databases, as well as document tracking. This package would not be considered for use as a scheduling system because the appearance and format of the graphical schedule would not be useful to patients or research coordinators within the Gillette Center.

Another data management technique that is becoming more common is to use an outside source to manage clinical research data. About 60% of institutions that perform clinical research studies used the aid of clinical research organizations (CRO) in 1997 (http://www.acrpnet.org/whitepaper2/html/ii._contract_research_organizations.html). A CRO, such as Parexel, Quintiles, or Boston BioStatics, might help to improve the efficiency of a given clinical study based on their knowledge of the market, specifically previously attempted data management systems. The main feature of a CRO is to provide clinical institutions, such as the Gillette Center, with a useful way to manage and analyze clinical research data. However, the cost for such a service would be ongoing and end only when the service provided by the clinical research associate (CRA), the consult from a CRO, has ended.

One way for the Gillette Center to achieve an ideal process and product in regard to treatment calendars would be to create and implement a proprietary or homegrown system. Such a system can be built on any database foundation and can be developed to meet the exact needs of the Gillette Center. If created, the system should be able to create multiple calendars, provide extra comment space, highlight locations through color coding or symbols, automate the process completely, provide both list and calendar formats for research coordinators and patients, as well as include other requirements beyond that of appointment scheduling such as data management.

It is important to mention that when using a database, such as Oracle or Sybase SQL, the Gillette Center would have to fund the very time-consuming creation of a proprietary system. Several employees within the Norris Cotton Cancer Center, an institution which created a homegrown system based on Sybase SQL, spent more than a year creating and implementing their system. While unwilling to divulge actual costs, they most likely spent in excess of one hundred thousand dollars. However, the associate director of the center, Priscilla West, feels that the ideal system that was created was well worth the effort and they are completely satisfied with the results.

5.3 Microsoft Outlook and Excel Program Details

In this section, we provide in depth research into formulating treatment calendars with the Microsoft software packages Outlook and Excel. As stated in the previous section, each of these programs offers unique features that could be of use to the Gillette Center. Below are in-depth steps that would be required in order for the Gillette Center to create treatment calendars using these packages.

5.3.1 Microsoft Outlook

The steps to create a calendar in the active appointments view are outlined below.

1. Open *Microsoft Outlook*
2. Open *Calendar* Icon in *Outlook Shortcuts* toolbar (or in *Folder List* toolbar)
3. In the *View* menu, click on *Current View*
4. In *Current View,* click on *Active Appointments*
5. Double click on an empty cell or click *New* (under the *File* menu) to enter appointment information

6. New dialog box opens as *Untitled - Appointment*
7. Enter *Subject* information (type of appointment; i.e. chemo)
8. Enter *Location* information (location of appointment; i.e. Gray 2nd Floor)
9. Click on *Recurrence* to enter repeat appointments
10. New dialog box opens as *Appointment Recurrence*
11. Enter *Start* time (i.e. 11:00am)
12. Enter *End* time (i.e 12:00pm)
13. *Duration* of appointment will automatically update (i.e. 1hr.)
14. Enter *Recurrence Pattern* of appointment (i.e. Recur every 2 weeks on Tuesdays)
15. Enter *Range of Recurrence* (i.e. Start date, number of occurrences, and end date)
16. Click *Ok*
17. Enter provider contact information under *Contacts* (i.e. Dr. Jones, 123.456.7890)

In order to save calendars, the user of Outlook would need to go to the *File* menu and click on *Save As*. Although these are not the only options, the calendar can be saved as either a *Rich Text Format* (the default *save as type*), or as an *Outlook Template*. A new calendar will need to be created for each new patient either by using a template or by entering an existing calendar and deleting the information and saving it under a different patient name.

For printing of calendars the *Print Styles* can be modified if the Gillette Center wishes to alter the appearance of the default views. This alteration can be done by following these steps:

1. Click the *File* menu and select *Print*
2. From the print dialog box, select *Define Styles*
3. Select the *Print Style* that the new style will be based off of and select *Copy*
4. Enter a name to the new style into the *Style Name* box
5. Select the options for the print style that are desired and click *Ok*
6. Close out of the *Define Print Styles* dialog box
7. Click *Ok* to print from the *Print* dialog box (in the style desired)

The concern with Outlook is in the appearance of the calendar itself. Outlook provides the opportunity to print using color labels, however, in the active appointments view, this is not an option. The active appointments view, which was reviewed above, also does not list all appointments. When recurring appointments are entered, each is not listed; every appointment repetitively scheduled only shows up in certain views (e.g. in a monthly calendar format). These views, however, do not allow enough room for the required data points of the appointments, and are therefore not useful to the Gillette Center. However, if the calendar is exported into an Excel file, any recurring appointment made will appear in an Excel cell as shown in Figure 5.1. The steps to do so are:

1. Go to the *File* menu and select *Import and Export...*

2. An Import and Export Wizards dialog box will appear

3. Select *Export to another file* and click *Next*

4. Choose *Microsoft Excel* from the list and click *Next*

5. Export from the *Calendar* file located under *Personal Folders* (should be highlighted already) and click *Next*

6. Name the export file with an appropriate title and click *Next*

7. Open the program *Microsoft Excel* and under the *File* menu, choose *Open*

8. Select the file under the title name chosen and click *Open*

9. All appointments are now in an Excel file

Subject	Start Date	Start Time	End Date	End Time	Meeting Organizer	Location
Blood Work	3/12/2003	11:30:00 AM	3/12/2003	12:00:00 PM	Crystal Lee Caron	Gray 2nd Floor
Blood Work	3/26/2003	11:30:00 AM	3/26/2003	12:00:00 PM	Crystal Lee Caron	Gray 2nd Floor
Blood Work	4/9/2003	11:30:00 AM	4/9/2003	12:00:00 PM	Crystal Lee Caron	Gray 2nd Floor
Blood Work	4/23/2003	11:30:00 AM	4/23/2003	12:00:00 PM	Crystal Lee Caron	Gray 2nd Floor
Blood Work	5/7/2003	11:30:00 AM	5/7/2003	12:00:00 PM	Crystal Lee Caron	Gray 2nd Floor
Blood Work	5/21/2003	11:30:00 AM	5/21/2003	12:00:00 PM	Crystal Lee Caron	Gray 2nd Floor
Blood Work	6/4/2003	11:30:00 AM	6/4/2003	12:00:00 PM	Crystal Lee Caron	Gray 2nd Floor
Blood Work	6/18/2003	11:30:00 AM	6/18/2003	12:00:00 PM	Crystal Lee Caron	Gray 2nd Floor
Chemo	4/2/2003	1:30:00 PM	4/2/2003	2:00:00 PM		Cox 1st Floor
Chemo	4/23/2003	1:30:00 PM	4/23/2003	2:00:00 PM		Cox 1st Floor
Chemo	5/14/2003	1:30:00 PM	5/14/2003	2:00:00 PM		Cox 1st Floor
Chemo	6/4/2003	1:30:00 PM	6/4/2003	2:00:00 PM		Cox 1st Floor
Chemo	6/25/2003	1:30:00 PM	6/25/2003	2:00:00 PM		Cox 1st Floor

Figure 5.1: Exported Outlook File Viewed in Excel

Through exporting the file, the user now has the ability to print in color by filling the text boxes. However, if the file or calendar created in Outlook is exported to Excel and changes are still required once it is an Excel document, we decided to further research the capabilities of Microsoft Excel.

5.3.2 Microsoft Excel

The process for setting up an Excel template is as follows:

1. Open Excel
2. Under File select *Save As*
3. In *Save as type:* field select *Template*
4. Name the file appropriately and save
5. In row 3 enter the appropriate column headings (Date, Office Visit, Provider, Chemo, Comments) across the spreadsheet columns, rows 1 and 2 are left blank

	A	B	C	D	E
1					
2					
3	**Treatment Date**	**Office Visit**	**Provider**	**Chemo**	**Comments**

Figure 5.2: Screen shot after step 5

6. Select cell A4 and then under the *Insert* pull down menu select *Function*
7. Change the *Category* of the function to *Date and Time* and select the *DATE* function
8. A function arguments window will appear, in this window enter the following:
    a. Year = C1
    b. Month = A1
    c. Day = B1
9. Click *Ok*, a "#NUM!" message will appear in the cells but this changes when actual values are entered into the calendar.

	A	B	C	D	E
1					
2					
3	**Treatment Date**	**Office Visit**	**Provider**	**Chemo**	**Comments**
4	#NUM!				

Figure 5.3: Screen shot after step 9

10. Repeat steps 6-9 in the cells below A4 as many times as necessary (5 weeks cycles = 5 rows), but in each consecutive row adjust the day by starting with 7 and adding 14, 21, etc. to each row. To do so simply enter A1 + 7 in the Day field of the function arguments window.
11. Now that the functions are set adjustments to the layout and appearance can be made by highlighting the cells and selecting the correct functions from the format pulldown menu. The column width, row height, cell border, font type, footer, and print area should all be adjusted.
    a. Column width: A = 20.00 (145 pixels)
    B = 22.00 (159 pixels)
    C = 22.00 (159 pixels)
    D = 22.00 (159 pixels)
    E = 30.00 (215 pixels)

b. Row height: Rows 1-3 = 15.00 (20 pixels)
Rows 5-end = 79.50 (106 pixels)

c. Cell borders Outline and Inside should be selected

d. Font Type: According to preference, it is possible to bold the column headings and leave the appointment cells as regular font

e. Footer can be adjusted by selecting "Header and Footer" from the View pulldown menu

f. Print area is set by highlighting the cells to be printed, clicking "Print Area" and then selecting "Set Print Area" in the File pulldown menu. The page setup should be fixed once this is complete so that the page's scale is to 1 pages wide by one pages tall.

12. Now that the template is set up it should be saved in the templates folder. Each time a calendar is to be made for the protocol the template is opened and saved as an individual calendar.

This process should be repeated for each protocol at the beginning of the study. The template is the starting point for each patient's treatment calendar but is just saved differently. Once the template is stored, in order to use it properly the research coordinator would create a new Excel document from an existing template and start from there. It should only take 15 to 20 minutes to create each new template and once this has been done the calendars should take less than five minutes to create. The process for use of a template is as follows:

1. Open Excel
2. Under File select *Open*
3. Open the correct template from the templates folder. The templates folder can be found by opening the hard drive (usually C), open the *Documents and Settings* folder, open the *Application Data* folder, then open the M*icrosoft* folder, and finally in the *Templates* folder will be the appropriate protocol template.
4. In *Save as type:* field select *Microsoft Excel Workbook*
5. Name the file appropriately and save.
6. Now enter the correct start date in cells A2-C2
    a. A1 = Month number (eg. January = 1, February = 2, etc.)
    b. B1 = Day number
    c. C1 = Year (Enter all four digits of year, eg. 2003)
7. The appropriate date information should now be entered into the cells down the column and the additional information can be added in later.

When information occurs repeatedly down a column there is an option that is also available with Excel. This option allows the research coordinator to enter the information without having to type and retype it each time. In order to use the "fill formatting" option the user must type the information into the first cell that it is supposed to go in. Then, using the mouse, place the pointer on the lower right-hand corner to the cell where the information was

just typed. After the mouse pointer turns into a black plus sign hold the left click button and pull down the text to the cell where there needs to be information.

Additionally, there are many other helpful options that are available when Excel is used as the template. There is a way to add comments to certain cells that will not be shown in the printout. Such comments might be helpful for the research coordinators to create reminders for themselves that are not important to patients. In order to add a comment highlight the cell where it is needed and then select *Comment* form the Insert pulldown menu. The comment appears as a text box that when not highlighted appears as a red triangle in the upper right hand corner of the cell. If preferred, these comments can also be displayed after a clear copy has been printed up. The header and footer can also be adjusted to display the information that is currently displayed with the Microsoft Word calendars. This is done in the same way with Excel as it is with Word. Select *Header and Footer* from the View pulldown menu and edit each appropriately. If text that is entered into a cell is too long and extends beyond the cell there is a way to format the text so that it all fits. After the text has been entered click the format pulldown menu and select *Cells* option. Next under the *Alignment* tab check the box next to the *WrapText* option and then click *Ok*. This will adjust the text so that it fits one line under the next as shown in the "Comments" column of Figure 5.4. Lastly, the option of color coding is available with Excel simply by highlighting the correct cell and then clicking the format pulldown menu and select *Cells* option again. This time select the *Patterns* tab rather than *Alignment* and just choose the color to fill the cell with.

In order to make the calendars meet the needs of both stakeholder groups it would also be useful to include additional information to the reverse side of the paper or as part of the footer. Some examples of additional information are things like location codes (eg. COX-2), any acronyms or abbreviations that might be used, or a color code key. Additionally, it was suggested to include information pertaining to provider details such as office location, phone number, etc. Any information of this type and purpose can be put together and then printed on a blank sheet. Then, when it comes time to print out the treatment calendar just use the reverse side of the additional information. The information for the footer can be included simply by selecting the *Header and Footer* option from the View pulldown menu again and adding the needed facts.

Treatment Date	Office Visit	Provider	Chemo	Comments
3/30/2003	11am	Kuter/Diane	2:30p	**Bloodwork Needed:**WBC, ANC, HgB, PLT
4/6/2003	10:30am	Kuter	11:30am	**Bloodwork Needed:** WBC, ANC, HgB, PLT
4/13/2003	10:30am	Diane	11:30am	**Bloodwork Needed:** WBC, ANC, HgB, PLT
4/20/2003	10:30am	Kuter	11:30am	**Bloodwork Needed:** WBC, ANC, HgB, PLT
4/27/2003	10:30am	Diane	11:30am	**Bloodwork Needed:** WBC, ANC, HgB, PLT

Figure 5.4: Example Treatment Calendar Created With Excel

6 Conclusions and Recommendations

After collecting and analyzing all of the necessary data, we were able to bring about multiple conclusions that the Gillette Center may desire to implement into their current clinical research program. First, we present a summary of the packages that we considered and evaluated. Then, we provide the final recommendations from these findings and assessments that we felt to be promising. From this, the Gillette Center will know the options that are available and will be able to decide which one is best for improving the organization of their current and future needs.

6.1 Summary Assessment of Software Solutions

Figure 6.1 displays each of the 14 software packages that we researched and displays an assessment of the ability of each to meet the functional requirements that we previously developed. We have also evaluated them on the basis of an estimation of time saved, time for implementation, and cost. Each and every package was thoroughly examined prior to the creation of this table in order to develop a sound, overall evaluation and recommendation. Our recommendations of software packages will be based on the ability of each to fulfill not only the functional requirements but to also be efficient enough to make the implementation worthwhile for the Gillette Center.

The first column gives the name of the product, company, or suggested package. The next column assesses the ability of the product to generate multiple calendars, whether for the patient and the research coordinator or for more than one patient. Additionally, the ability of a package to create room for extra notes was examined in the adjacent column. "Color" is whether or not the package is capable of creating color-coded schedules. In order to do so, the software must have the ability to produce color print-outs. The next functional requirement that these packages were tested for was the ability to create treatment schedules automatically with the entry of only one or two data points. The suggestion of creating calendars in a monthly style, as opposed to the list style which is currently in use, was made; the third column shows whether or not the package has the ability to do so. After the assessment of the functional requirements of each software package was determined we investigated three additional key points.

These three key points were an estimation of time that will be saved from use of the software, an estimation of the time that it will take to be fully implemented and learned, and the price of each. In order to assess the amount of time that would be required to create a treatment calendar, we sampled each of the packages and used them to try and create treatment calendars as if we were research coordinators. When compared with the actual time that a clinical research coordinator spends on creating a calendar (approx. 20-25 minutes) each package varied in its own way. The column entitled, "Est. Implement Time," was for the predicted amount of time that would be required to install, learn, and finally use each package. Some of the packages would require well over 1000 hours to be fully implemented because they involve a great deal of programming.

Software Package	Functional Requirements					Time Saved	Est. Time Implement (hour)	Est. Cost
	Multiple	Add Info	Color	Auto	Format			
Current System (MS Word)	Y	Y	Y	N	List	NA	NA	NA
Amazing Calendar Creator	N	Y	Y	N	Cal	None	+2	6.95
Franklin Covey Planner	N	Y	Y	N	Cal	Some	+1	$79.95
Plan Plus	N	Y	Y	N	List	None	+1	74.99
Complete Calendar Kit	Y	N	Y	N	Cal	Some	+1	29.99
Forms Wizard	Y	Y	Y	N	Cal, List	None	+1	29.95
Microsoft Project 2002	Y	Y	Y	N	Cal, List	None	+1	566.99
Task Manager	Y	N	N	N	List	Some	+2	495.00
Calendar Creator 4.0	Y	Y	Y	N	Cal	None	+3	356.48
Calendar Creator 9	Y	N	Y	N	Cal	None	+2	69.99
MS Outlook	Y	Y	Sometimes	R	Cal, List	Some	+1	NA
MS Excel	Y	Y	Y	R*	List	Some	+1	NA
Clinical Software Solutions	Y	Y	N	N	Cal	None	+50	V
Study Manager	Y	Y	Y	N	Cal, List	None	+50	V
Proprietary "Home-grown"	Y	Y	Y	C	Cal, List	Significant	+1000	V

Figure 6.1: Analysis of Alternative Packages

Quick Reference Key	
Symbol:	**Meaning:**
NA	Not applicable
N	Does not meet condition
Y	Meets condition
V	Price varies
Cal	Calendar format (monthly, yearly, etc.)
List	List format, current format used by Gillette Center
R	Repeat automation
R*	Repeats dates through a template formula
C	Complete automation
Time:	Significant: More than 10 minutes per calendar
	Some: 1-10 minutes per calendar
	None: No time saved or more than 20 minutes per calendar

Lastly, the price of the software or service was assessed. Some packages would be less costly if only a "bare" or basic version of the software were purchased; if any additional features were added, the price would increase accordingly. Additionally, many of the packages would require training from a consultant or an employee of the company which produces these products. In these instances, the package's price would increase as would the time of implementation.

6.2 Recommendations

An objective of the project was to identify functional requirements for treatment calendar creation software and then to identify such a package that would be capable of handling each of the functional requirements found through our research. The core functional requirement that was the focus of this project was the ability of the software to create multiple files, or in the case of the Gillette Center, multiple treatment calendars. Another functional requirement was that of a package with the ability to automatically generate a treatment calendar from entering as little information as possible into the program. Additionally, we wanted to find something that would be helpful to the patients as well as the research coordinators; which was the purpose of the color coding, the list format, and the additional comment space functional requirements. With the results that we gathered throughout this project, the Gillette Center should be able to make an informed decision as to which approach to take now. Which solution is most appropriate depends on the time and money that the Gillette Center is willing to spend on implementation. With these points kept in mind the group has come up with the following recommendations.

For a relatively simple, low-cost way to create treatment calendars through automation, we recommend that the clinical research coordinators change from Microsoft Word to Microsoft Excel. The Excel spreadsheet offers the template functionality that is needed to create a calendar more efficiently by entering only a few points and ending up with a calendar. This program meets all of the functional requirements that we identified in our research. If each template is set up properly it could save as much as 10 minutes of creation time per calendar. It would be possible to learn and use this alternative within hours of starting. Detailed instructions are provided in section 5.3. Also, since it is already available on the computers at the Gillette Center no money is required to be spent on implementation of the Excel program. Furthermore, the Excel spreadsheet can be used to provide the space and color that the patients recommended without adding significant amounts of time to the process. A table of medical oncology doctors (their names, office locations, and telephone numbers) can also be created in Excel and saved in its own file. Located within this file could also be an explicatory table or legend of the appropriate abbreviations; those which are currently in the comments column. When a treatment calendar is printed, this file can also be printed on the back to provide useful tools for patients.

However, if the Gillette Center is looking to make changes that will affect their clinical research process as a whole, they should consider either implementing one of the study management programs or build their own proprietary system. A study manager program will not only allow for efficiently creating treatment calendars but also help in managing data. A proprietary system would meet the requirements of the Gillette Center exactly, for the calendars and for data management. This alternative is able to meet all of the functional requirements as well as provide many additional advantages such as detailed data management, complete automation, or increased security. The benefits of such a system could be as tremendous as they

have been for the Norris Cotton Cancer Center. Choosing this route would be a greater time commitment and larger financial investment, but could result in larger improvements in efficiency.

Appendix

A1 Karleen Habin, September 2002 Telephone Interview Protocol

Introduction:

- Introduce ourselves again: name, year, major.
- Let her tell us a bit about herself, the Gillette Center, and the project.

Questions and Answer:What is the scope of the available treatments that the Gillette Center offers? Number of patients, funding, etc.

1. We noticed that the Gillette Center itself was not listed as being a participant in any clinical trials under the Dana Farber Cancer Institute Webpage, but we did notice that Dana Farber itself was listed as a center. Does this mean that the Gillette Center is sometimes just categorized as Dana Farber?
2. What are the responsibilities of the R.N. or the doctors within a clinical trial setting?
3. What is the program that is currently being used for creating calendars? Would it be possible for us to use it or access it to make some initial evaluations?
4. What problems are there with the current system? How are medicine calendars prepared? Who prepares them? Where are they made?
5. How long does it take for one person to prepare a calendar?
6. Should we focus on just clinical research medications, or the other treatments that are using medication calendars?
7. What medications are currently being used with the clinical trials?
8. How can we use the Gillette Center itself as a resource? Patients, nurses, doctors, etc? If not are there online resources that we can access?
9. What are the best times/days to come in and speak with patients? Staff?
10. Who else can we be contacting? Is there anyone that is under you?
11. Are there any patient feedback forums or questionnaires that deal specifically with patients involved in clinical trials that we can access? If not, would it be at all possible for us to develop a survey to distribute to these patients? Focus groups?

A2 Karleen Habin, September 2002 Interview Protocol

Itinerary for Meeting

12:45pm Friday (09/06)

12:45pm **Progress Report**

Review of what we accomplished this past week

Information gathered (i.e. glossary of terms, clinical trials and references)

Future Plans

Interview with Karleen (questions planned and any input advisors have)

1-2pm **Conference Call with Karleen**

(details above)

A3 Sarah Malaquias, October 2002 Interview Protocol 1

1. First introduce ourselves and make sure that each of them has a pretty clear understanding of what exactly our project consists of and what exactly the purpose and goal of the project is.
    a. Define that we will not make a program, but we will (hopefully) find one, assess the feasibility of one, and be able to make a recommendation.
2. Have them walk us threw the fax that Karleen had sent to us and also if what she sent was not exactly their treatment calendar then have them walk us through the steps they would use to create one.
    a. What template is being used for the calendars currently?
    b. Determine the average time that is spent creating treatment calendars
    c. Estimate how much time they think they could save with it being automated.
    d. Maybe we could get our hands on some actual calendars, blank or filled out.
    e. What are the "Data points" that are entered into the calendars?
        i. Time points?
        ii. Types of treatments?
        iii. Timing factors?
    f. Find out how patients are trained or taught to understand their calendars.
3. Ask them if they have tried any form of automated calendars before, if so why are they not using them, not exactly what they wanted? Did it not work?
    a. Programs, templates, etc.?
4. Ask them if there has been any other company that they know of that have either tried or successfully are using an automated calendar.

A4 Sarah Malaquias, November 2002 Interview Protocol 1

From today's observations and questioning, we hope to view the program used for calendar creation and see how it is used. We would also like to view the current template for the treatment calendars as well as the steps taken in the complete formulation of a treatment calendar. Through these steps, we hope to view the creation process in its entirety from a blank template to a complete patient treatment calendar. Along the way, please feel free to highlight the specific steps, as well as any problems or nuisances that you may have. Such problems can be with aesthetics, the program itself, layout, etc. We will also be asking you questions throughout the process, unless you would like to complete the process and then answer questions.

Sarah's response...cater interview to her without compromising our needs

Now that you know what we hope to accomplish from this meeting, could you please outline the steps verbally so we know what to expect. Would you also please tell us how long each step would usually take you to complete.

Sarah highlights steps and time spans

1. Are these the steps that would be taken for every calendar (in this particular protocol)?
    a. *If yes:* So they are all made with a blank template, correct?
    b. *If no:* If all are not made from scratch, are preceding calendars based off of the first one created within that protocol or is there another way?
2. Now could you please walk us through the process using the steps you highlighted for us. Please feel free to express problems or concerns.
    a. *If she states problems, we will ask her to express them more in depth.*
    b. *If she states no problems, we will ask her if there are any problems with this step and ask her to be specific.*
    c. *Follow the above step until the calendar is completed, making sure that questions are raised if they come up (like if we don't understand something she may take for granted or assume we know). We will also be sure to raise questions of problems she may have and probe deeper into their causes.*

Follow up creation process with several questions:

3. What features of the process you just showed us do you think can be improved?
4. How do you think such improvements could benefit you?
5. In dealing with patients, have you heard anything from them about the calendars themselves concerning aesthetics or the layout?
    a. *If yes:* Do they have any likes or dislikes?
6. Also, have you heard anything from providers working with treatment calendars about problems concerning the same (layout and aesthetics)?
    a. *If yes:* Do they have any likes or dislikes?
7. Is there anything else that you have concerns with that we have not covered today?

A5 Project Description Submitted to Patients

As students at WPI, our degree requirements consist of three projects, one of which combines the use of technology with a societal problem. During this project, we will be working with the Massachusetts General Hospital to assess the process of patient calendar developments and the use of such for patients enrolled in Breast Cancer Clinical Research Trials. By means of this evaluation project, we hope to provide recommendations for the development, improvement, and possible implementation that will make treatment calendars easier to formulate and understand. We will be asking patients for comments and suggestions as we go through this assessment process. It is important for us to mention that although we will be taking notes, your confidentiality will be maintained. The information learned today will not include names, addresses, or key information that will be able to identify you; we are merely noting aspects of the process. We also hope that you will be willing to share your impressions of treatment calendars as well as offer suggestions on hew these may be improved or made to be more helpful.

We would be delighted to answer any questions you may have. Also, please feel free to contact Karleen Habin, RN, BCCS MPHc, and Breast Cancer Clinical Research Nursing Manager if you have any further questions or comments. Thank you for allowing us to meet with you today.

Sincerely,

Cassie Fisher, Crystal Caron, and Sarah Rogers

Contact Information: Karleen R. Habin, 617-726-1922

A6 Patient 1, November 2002 Interview Protocol

Previously, she will have been given the paragraph and a copy of the questions we will ask. Hopefully she will have the chance to review these between appointments, or whenever she has free time.

1. Did you get a chance to look over the questions planned as well as the paragraph explaining what it is we are doing?
    a. *If yes:* Ok, great. Do you have any questions or concerns about why I am talking with you today?
    b. *If no:* Ok, that's fine. *Review it with her, if she doesn't have the copy she received earlier then give her another so she can keep it for possible future use.*

What we hope to accomplish through meeting with you, and other patients, is a connection to someone who directly uses treatment calendars. As a patient enrolled in a clinical research trial, you are the main source clinical research coordinators create treatment calendars for. Our main objective for today's interview is to gain your perspective on such calendars, as you are someone that deals with them. Through this project, we hope to generate new treatment calendars that are better suited to the patients who use them, which is why we feel it is important to gain your perspective regarding these.

2. Before we get started, do you have any questions for me?
3. At what point are you in your treatment?
4. When you first began your clinical trial, what were the steps taken to inform you about the clinical trial process? (*make sure to include: who, time intervals, format presented)*
5. Are you familiar with the treatment calendars that are created by the clinical research coordinators?
6. When you were first introduced to these calendars, what were the questions you had, if any? (*were they aesthetic, layout, content?)*
    a. *If yes:* Do you still find these to be _____? *(use whatever they said...i.e. confusing)*
    b. *If no:* Where you ever given the chance to give your input about the nature of the parts you had questions on?
7. What aspects of the calendars did you need to be explained to you? *(were they aesthetic, layout, content)*
8. What do you find useful about the calendars? *(good way to keep track of appointments, manage your time)*
9. Is there anything that you find to be ineffective about the calendars?
    a. *If yes:* What in particular do you find least useful?
10. What changes would you suggest that could make the calendars more useful?
11. Have you found that you need to add things to the calendar or make notes of some sort in the margins?

a. *If yes:* What sorts of things?

12. Have you ever had to alter the calendar because of a scheduling change? *(i.e. if you've had to miss an appointment)*

    a. *If yes:* Did this require that a new calendar be created?

13. Do you have any suggestions for possible appearance related changes for the calendar? *(i.e. would you change columns, set the calendar up differently, add color to emphasize things, etc.)*

14. Is there anything else you feel I have not covered and would like to discuss?

A7 Patients 2-5, December 2002 Interview Protocol

Before we get started, do you have any questions for me?

Begin Interview:

1. At what point are you in your treatment?
2. When you first began your clinical trial, what were the steps taken to inform you about the clinical trial process? *(make sure to include: who, time intervals, format presented)*
3. Are you familiar with the patient appointment calendars that are created by the clinical research coordinators?
4. When you were first introduced to these calendars, what were the questions you had, if any? *(were they aesthetic, layout, content?)*
    a. *If yes:* Do you still find these to be _____? *(use whatever they said...i.e. confusing)*
    b. *If yes:* Were you ever given the chance to give your input about the nature of the parts you had questions on?
5. What aspects of the calendars did you need to be explained to you? *(were they aesthetic, layout, content)*
6. What do you find useful about the calendars? *(good way to keep track of appointments, manage your time)*
7. Is there anything that you find to be ineffective about the calendars?
    a. *If yes:* What in particular do you find least useful?
8. What changes would you suggest that could make the calendars more useful?
9. Have you found that you need to add things to the calendar or make notes of some sort in the margins?
    a. *If yes:* What sorts of things?
10. Have you ever had to alter the calendar because of a scheduling change? *(i.e. if you've had to miss an appointment)*
    a. *If yes:* Did this require that a new calendar be created?
11. Do you have any suggestions for possible appearance related changes for the calendar? *(i.e. would you change columns, set the calendar up differently, add color to emphasize things, etc.)*
12. Is there anything else you feel I have not covered and would like to discuss?

Thank her for taking the time to meet with you.

A8 Inquiry Sent to Other Providers of Clinical Care

To Whom It May Concern:

I am a student from Worcester Polytechnic Institute (WPI) in my junior year. Part of WPI's degree requirements is that each student completes an Interactive Qualifying Project (IQP) to solve a societal problem. The topic of the IQP which I am currently working on has to do with Clinical Research at the Gillette Center for Women's Cancers in Boston, MA. Each patient participating in a clinical trial receives a "treatment calendar" that is made by a Clinical Research Coordinator to keep track of their individual treatment appointments. These calendars pose several problems on two separate levels: (1) The process for creating the calendars is often too long and involved; (2) The final appearance of the calendar is often confusing to the patient.

In order to make a valid assessment of possible alterations to these calendars and the processes for making them, a comparison of what methods other groups conducting clinical research use will be made. This is where your group or company comes in. I was wondering if there was any way that I would be able to ask a few questions, whether via e-mail or telephone, about what method is currently being used to track patient treatment dates by your institution. If treatment calendars are not what are being used, how do you keep track of patient appointments, if at all? If the calendars are utilized, what is the method of creation and what template is employed? I would appreciate any feedback that you or someone from your institution could offer. Thank you for your time.

Sincerely,

Sarah Rogers

sarahm@wpi.edu

A9 Priscilla West, Norris Cotton Cancer Center Interview Protocol

Hello Priscilla,

I would like to thank you for your speedy responses to the e-mails that I have sent within the past week. I hope that what the Norris Cotton Cancer Center has done in way of patient treatment calendars can help us with our own project affiliated with the Gillette Center for Women's Cancers. Just so you have a better knowledge of what we are trying to do, I will give you a brief description of our project.

First off, an IQP or interactive qualifying project is one of the many degree requirements of WPI. What it entails is that a group of students, usually 2-3, solves a societal problem having to do with technology. Myself, along with my two other project partners, Cassie and Crystal, have been working with the Gillette Center to improve upon their treatment calendar process, as well as the calendar produced. The Gillette Center is located within MGH and specializes in Women's cancers. In order to keep track of each patients' appointments, clinical research coordinators make a treatment calendar. Making the calendar often involves a lengthy process of cross checking protocol information and scheduling the right appointments.

What they are doing now to do this is using old calendars created in Microsoft Word as a template. From there the CRC looks at the protocol to check for #'s of cycles, cycle lengths, and needed appointments (ie. Chemo, bloodwork). Our project goal is to find some kind of template or program that can determine the appropriate calendar information and generate it from only a few points of data. We, like the Norris Cotton Cancer Center, are finding that the production of two calendars, one technical for providers and research coordinators and one lay calendar for patients will most likely be the best option.

Right now we're in the phase of research where we are trying to identify some possible alternatives. From your first e-mail response it seemed like you have done exactly what we are trying to do.

1. Do you have any questions so far?
    a. *If yes: try and answer them to the best of your ability.*
    b. *Some to think of:*
        i. *With whom: Gillette Center for Women's Cancers: Dana Farber Cancer Institute Treatment Center*
        ii. *Who are you closely contacted with: Clinical Research Coordinator (keep in mind they may not call them this)*
            - *Schedules patient appointments according to a particular protocol*
            - *Actively involved in the patient intake process for clinical research within the Gillette Center*
        iii. *If no: Is it ok if I ask you some questions about the program you currently use and how you came about designing it?*

If she cannot answer these following questions, ask for a contact person that you could speak with about the technical aspects of creating such a system

2. You mentioned in your e-mail that you tried other commercial packages, but they failed, what were some of these packages?
3. How was this program created? Who created it?
4. What are some of the technical specifications of this program?
    a. *In your first e-mail, you stated that the patients receive a regular calendar with all days of the week included, and not just the dates of their treatments, correct? Is this general information also included in the technical version?*
    b. *If the same:* What are the specific data points that are included? *(i.e. protocol #, treatment date, provider, office visit)*
    c. *If different:* What are the specific data points that are included in the technical version? *(i.e. protocol #, treatment date, provider, office visit)*
    d. What are the specific data points that are included in the lay version for patients? *(i.e. protocol #, treatment date, provider, office visit)*
5. How long did it take for this program to be fully implemented and in use?
6. Was it hard or complicated to learn?
7. Who creates these patient treatment calendars? *(i.e. her, or someone else...be sure to get their position title, name and possible contact information)*
8. Who else uses these calendars? *(i.e. providers, administrators)*
9. What were some of the benefits of this system?
    a. Save time?
    b. Patient Feedback?
10. Are there any problems that you have encountered with the process since your "home-grown" system was created?
    a. *If yes:* Are there any changes that you would recommend be made?
    b. *If no:* So, they are just minor then.
        i. *If yes:* What kinds of changes would you recommend?
11. Are there any problems that you have with the current layout?
    a. *If no:* Would you correct them for future use, or recommend that they be fixed, or are they just minor?
    b. *If yes:* What kinds of problems specifically? *(i.e. content, format)*
12. Have you heard of any problems that other users have? *(i.e. patients, providers, administrators)*
    a. *If yes:* What kinds of problems specifically? *(i.e. content, format)*
    b. Would you recommend these be corrected for future use?
13. Is this program something that owned or copyrighted by Dartmouth?

14. Would it be possible to obtain a copy of the program itself or some of the design parameters for use at the Gillette Center?
15. Could you fax us some examples of a finished product?
16. Would it be at all possible to visit and observe the process for calendar creation?

A10 Sally Fennessey, Boston Medical Center Interview Protocol

Hello Salli,

I would like to thank you for your speedy responses to the e-mails that I have sent within the past week. I hope that what the Boston Medical Center has done in way of patient treatment calendars can help us with our own project affiliated with the Gillette Center for Women's Cancers. Just so you have a better knowledge of what we are trying to do, I will give you a brief description of our project.

First off, an IQP or interactive qualifying project is one of the many degree requirements of WPI. What it entails is that a group of students, usually 2-3, solves a societal problem having to do with technology. Myself, along with my two other project partners, Cassie and Crystal, have been working with the Gillette Center to improve upon their treatment calendar process, as well as the calendar produced. The Gillette Center is located within MGH and specializes in Women's cancers. In order to keep track of each patients' appointments, clinical research coordinators make a treatment calendar. Making the calendar often involves a lengthy process of cross checking protocol information and scheduling the right appointments.

What they are doing now to do this is using old calendars created in Microsoft Word as a template. From there the CRC looks at the protocol to check for #'s of cycles, cycle lengths, and needed appointments (ie. Chemo, bloodwork). Our project goal is to find some kind of template or program that can determine the appropriate calendar information and generate it from only a few points of data. We, like the Norris Cotton Cancer Center, are finding that the production of two calendars, one technical for providers and research coordinators and one lay calendar for patients will most likely be the best option.

Right now we're in the phase of research where we are trying to identify some possible alternatives. From your first e-mail response it seemed like you have done exactly what we are trying to do.

1. Do you have any questions so far?
    a. *If yes: try and answer them to the best of your ability.*
    b. *Some to think of:*
        iv. *With whom: Gillette Center for Women's Cancers: Dana Farber Cancer Institute Treatment Center*
        v. *Who are you closely contacted with: Clinical Research Coordinator (keep in mind they may not call them this)*
            - *Schedules patient appointments according to a particular protocol*
            - *Actively involved in the patient intake process for clinical research within the Gillette Center*
        vi. *If no: Is it ok if I ask you some questions about the program you currently use and how you came about designing it?*

If she cannot answer these following questions, ask for a contact person that you could speak with about the technical aspects of creating such a system

2. You mentioned in your e-mail that you are currently using Softkey Calendar creator 4.0, what are some of the technical specifications of this program?
    a. What are the specific data points that are entered into the program? *(i.e. protocol #, treatment date, provider, office visit)*
    b. What are the specific data points that formulated from these? *(i.e. protocol #, treatment date, provider, office visit)*
3. How long did it take for this program to be fully implemented and in use?
4. Was it hard or complicated to learn?
5. Who creates these patient treatment calendars? *(i.e. her, or someone else...be sure to get their position title, name and possible contact information)*
6. Who else uses these calendars? *(i.e. providers, administrators)*
    a. Is there a separate calendar for the patients and research coordinators?
7. What were some of the benefits of this system?
    a. Save time?
    b. Patient Feedback?
8. Are there any problems that you have encountered with this program?
    a. *If yes:* Are there any changes that you would recommend be made?
    b. *If no:* So, they are just minor then.
        i. *If yes:* What kinds of changes would you recommend?
9. Are there any problems that you have with the current layout?
    a. *If no:* Would you correct them for future use, or recommend that they be fixed, or are they just minor?
    b. *If yes:* What kinds of problems specifically? *(i.e. content, format)*
10. Have you heard of any problems that other users have? *(i.e. patients, providers, administrators)*
    a. *If yes:* What kinds of problems specifically? *(i.e. content, format)*
    b. Would you recommend these be corrected for future use?
11. Could you fax us some examples of a finished product?
12. Would it be at all possible to visit and observe the process for calendar creation?

A11 Sheila Noone, UMass Medical School Interview Protocol

Hello Sheila

I would like to thank you for your speedy responses to the e-mails that I have sent within the past week. I hope that what the Umass Medical School has done in way of patient treatment calendars can help us with our own project affiliated with the Gillette Center for Women's Cancers. Just so you have a better knowledge of what we are trying to do, I will give you a brief description of our project.

First off, an IQP or interactive qualifying project is one of the many degree requirements of WPI. What it entails is that a group of students, usually 2-3, solves a societal problem having to do with technology. Myself, along with my two other project partners, Cassie and Crystal, have been working with the Gillette Center to improve upon their treatment calendar process, as well as the calendar produced. The Gillette Center is located within MGH and specializes in Women's cancers. In order to keep track of each patients' appointments, clinical research coordinators make a treatment calendar. Making the calendar often involves a lengthy process of cross checking protocol information and scheduling the right appointments.

What they are doing now to do this is using old calendars created in Microsoft Word as a template. From there the CRC looks at the protocol to check for #'s of cycles, cycle lengths, and needed appointments (ie. Chemo, bloodwork). Our project goal is to find some kind of template or program that can determine the appropriate calendar information and generate it from only a few points of data. We, like the Norris Cotton Cancer Center, are finding that the production of two calendars, one technical for providers and research coordinators and one lay calendar for patients will most likely be the best option.

Right now we're in the phase of research where we are trying to identify some possible alternatives. From your first e-mail response it seemed like you have done exactly what we are trying to do.

1. Do you have any questions so far?
    a. *If yes: try and answer them to the best of your ability.*
    b. *Some to think of:*
        vii. *With whom: Gillette Center for Women's Cancers: Dana Farber Cancer Institute Treatment Center*
        viii. *Who are you closely contacted with: Clinical Research Coordinator (keep in mind they may not call them this)*
            - *Schedules patient appointments according to a particular protocol*
            - *Actively involved in the patient intake process for clinical research within the Gillette Center*
        ix. *If no: Is it ok if I ask you some questions about the program you currently use and how you came about designing it?*

If she cannot answer these following questions, ask for a contact person that you could speak with about the technical aspects of creating such a system

2. You mentioned in your e-mail that your are exploring "web-based clinical trials management programs," what are some of the other programs you have tried?
3. You did mention study manager as one of the programs, what are some of the technical specifications of this program?
    a. What are the specific data points that are entered into the calendar? *(i.e. protocol #, treatment date, provider, office visit)*
4. How long has there been research into this program?
    a. *If it is currently implemented:* How long did it take to be fully implemented and in use?
    b. *If yes:* Was it hard or complicated to learn?
5. Who creates these patient treatment calendars? *(i.e. her, or someone else...be sure to get their position title, name and possible contact information)*
6. Who uses these calendars? *(i.e. providers, administrators)*
    a. Is there a separate calendar that is made for the patient?
7. What were some of the benefits of this system?
    a. Save time?
    b. Patient Feedback?
8. Are there any problems that you have encountered with the new program?
    a. *If yes:* Are there any changes that you would recommend be made?
    b. *If no:* So, they are just minor then.
        ii. *If yes:* What kinds of changes would you recommend?
9. Are there any problems that you have with the current layout?
    a. *If no:* Would you correct them for future use, or recommend that they be fixed, or are they just minor?
    b. *If yes:* What kinds of problems specifically? *(i.e. content, format)*
10. Have you heard of any problems that other users have? *(i.e. patients, providers, administrators)*
    a. *If yes:* What kinds of problems specifically? *(i.e. content, format)*
    b. Would you recommend these be corrected for future use?
11. Could you fax us some examples of a finished product?
12. Would it be at all possible to visit and observe the process for calendar creation?

A12 Example Calendar Used by the Gillette Center

Cycle	Treatment Date	Office Visit	Provider	Chemo	Comments
AC-1	7/18/2001	11am	Kuter/Diane	2:30pm	BloodWork Needed: WBC, ANC, HgB, PLT
		Port Placement @ 1PM			
AC-2	8/9/2001	10:30am	Kuter	11:30am	BloodWork Needed: WBC, ANC, HgB, PLT
AC-3	8/30/2001	10:30am	Diane	11:30am	BloodWork Needed: WBC, ANC, HgB, PLT
AC-4	9/20/2001	10:30am	Kuter	11:30am	BloodWork Needed: WBC, ANC, HgB, PLT
PLEASE SCHEDULE ECHO/MUGA FOR 3 WKS AFTER LAST AC DOSE					
Projected ECHO/MUGA Date: 10/11/01				ACTUAL DATE:	

A13 Example Calendars Used by the Boston Medical Center

Patient Name: _____ Patient Signature: _____ Date: _____

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
February S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28		April S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30		1 __ 50mg <drug name> Capsules Taken List Symptoms:	2 __ 50mg <drug name> Capsules Taken List Symptoms:	3 __ 50mg <drug name> Capsules Taken List Symptoms:
4 __ 50mg <drug name> Capsules Taken List Symptoms:	5 __ 50mg <drug name> Capsules Taken List Symptoms: Week 10	6 __ 50mg <drug name> Capsules Taken List Symptoms:	7 __ 50mg <drug name> Capsules Taken List Symptoms:	8 __ 50mg <drug name> Capsules Taken List Symptoms:	9 __ 50mg <drug name> Capsules Taken List Symptoms:	10 __ 50mg <drug name> Capsules Taken List Symptoms:
11 __ 50mg <drug name> Capsules Taken List Symptoms: Dr. visit this week	12 __ 50mg <drug name> Capsules Taken List Symptoms:	13 __ 50mg <drug name> Capsules Taken List Symptoms:	14 __ 50mg <drug name> Capsules Taken List Symptoms:	15 __ 50mg <drug name> Capsules Taken List Symptoms:	16 __ 50mg <drug name> Capsules Taken List Symptoms:	17 __ 50mg <drug name> Capsules Taken List Symptoms:
18 __ 50mg <drug name> Capsules Taken List Symptoms:	19 __ 50mg <drug name> Capsules Taken List Symptoms: Week 12	20 __ 50mg <drug name> Capsules Taken List Symptoms:	21 __ 50mg <drug name> Capsules Taken List Symptoms:	22 __ 50mg <drug name> Capsules Taken List Symptoms:	23 __ 50mg <drug name> Capsules Taken List Symptoms:	24 __ 50mg <drug name> Capsules Taken List Symptoms:
25 __ 50mg <drug name> Capsules Taken List Symptoms:	26 __ 50mg <drug name> Capsules Taken List Symptoms:	27 __ 50mg <drug name> Capsules Taken List Symptoms:	28 __ 50mg <drug name> Capsules Taken List Symptoms:	29 __ 50mg <drug name> Capsules Taken List Symptoms:	30 __ 50mg <drug name> Capsules Taken List Symptoms:	31 __ 50mg <drug name> Capsules Taken List Symptoms:
	3 Month Evaluation @ BMC					

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