Electronic Monitoring of Post-transplant Drug Regimen Compliance

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On my honor as a University student, on this assignment I have neither given nor received unauthorized aid as defined by the Honor Guidelines for Papers in TCC Courses.

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# Glossary of Terms

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<th>Term</th>
<th>Definition</th>
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<tr>
<td>Autonomy</td>
<td>A person’s ability to direct their freedom, especially their moral independence.</td>
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<tr>
<td>Hypertension</td>
<td>High blood pressure.</td>
</tr>
<tr>
<td>Medication Event</td>
<td>An event that occurs that implies a patient has consumed medication.</td>
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<tr>
<td>Non-compliance</td>
<td>Used interchangeably with non-adherence, this term describes a situation in which a patient does not take drugs as prescribed, or simply does not take them at all.</td>
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<tr>
<td>Non-response</td>
<td>The term for a situation in which a patient’s body does not respond to prescription drugs, and the drugs are thus ineffective in treating the patient’s ailment.</td>
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<tr>
<td>Paternalism</td>
<td>A system under which an authority undertakes to supply needs or regulate conduct of those under its control in matters affecting them as individuals as well as in their relations to authority.</td>
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<tr>
<td>PDA</td>
<td>Personal Digital Assistant. Handheld computers.</td>
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<tr>
<td>PHI</td>
<td>Protected Health Information. PHI refers to all individually identifiable health information that is transmitted or maintained by a healthcare organization, regardless of form. This includes oral, paper, and electronic information.</td>
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<tr>
<td>SDK</td>
<td>Software Development Kit. Development environments that allow for programming on PDAs.</td>
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Abstract

The inability to accurately monitor and assess patient compliance is a serious problem in modern healthcare. Current methods for monitoring patient compliance have proven to be grossly ineffective. This thesis project examined the potential effectiveness of an electronic compliance monitoring system for use in the field of organ transplantation. This task was accomplished through producing a prototype system, and evaluating its usefulness. Only recently have researchers begun to explore new potential methods for monitoring patient compliance. Consequently, the available body of literature that is relevant to this issue is not particularly extensive. The results of this project will ultimately add to this nascent body of literature.

Presently, the misdiagnosis of non-compliance costs the healthcare industry $125 billion annually. A reliable method for collecting accurate patient compliance data would alleviate much of this financial burden, and would also entail many other societal and ethical benefits. Electronic monitoring, EM, is a new approach that shows promise for being just such a method.

Evaluation of the prototype system produced in this project confirms that current methods for measuring patient compliance need to be replaced. The data collected points strongly towards EM as being a viable replacement. Unfortunately, the significance of this data is limited, due to the fact that the developed EM system prototype has yet to earn approval for use in clinical trials. Clinical trials would provide statistically significant data and a true gauge of this system’s potential. If this prototype system is further developed to a final, robust version that can be employed in clinical trials, it could result in an increase in the efficiency and quality of healthcare in general.
Chapter 1: Introduction

Statement of Thesis

In medicine, compliance is defined as “the extent to which a person’s behavior coincides with medical or health advice” (Bentley, 1999). Physicians generally have great difficulty monitoring patient compliance, particularly patient compliance with prescription drug regimens. Electronic compliance monitoring technology offers the potential for objective, event-based monitoring of patient compliance, but has not yet been developed in many fields of medicine. This thesis project examined the potential usability and effectiveness of an electronic compliance monitoring system for use in the field of organ transplantation, produced a prototype of such a system, and evaluated its effectiveness. This system, which is comprised of several Personal Digital Assistants that track and record patient activities, was developed for the Organ Transplant Team at the University of Virginia Hospital. A final version of this system will soon be submitted to the National Institutes of Health as part of a proposal for permission to conduct clinical trials.

Problem Definition

Context

Patient non-compliance is a major problem in modern healthcare, and there is no widely accepted approach to dealing with it. When patients exhibit an unexpected therapeutic response to a prescription drug regimen, physicians often have great difficulty discerning whether the response is due to non-response, which means that the patient’s
body is not reacting to the medication, or to non-compliance (Burnier, 2003). If a patient was not recovering from a bout of pneumonia for example, his or her physician would have to decide how to adapt his therapeutic approach. The physician may conclude that his patient is non-responsive to the medication he originally prescribed, and may thus choose to change the prescription. If the patient’s enduring pneumonia symptoms were actually due to non-compliance as opposed to non-response, this adaptation of the prescription would be unnecessary and could potentially present a higher risk of side effects, among other possible consequences. Either way, as exemplified, it is extremely difficult for a physician to distinguish between non-response and non-compliance. As a result, patient responses due to non-compliance are often misinterpreted and attributed to non-response. This frequently leads to misdiagnosis. Misdiagnosis of non-compliance costs the healthcare system billons of dollars annually, as it results in physicians either unnecessarily adapting their prescriptions or calling for avoidable treatments and procedures.

Electronic monitoring, which was introduced in 1986, is a relatively new methodology that has been championed by some medical experts as a promising solution to the problem of non-compliance (Claxton, 2001). Electronic monitoring uses computer technology, in place of the pencil and paper approach many physicians currently employ, to monitor and measure patient compliance.

**Produced Electronic Monitoring System**

The prototype electronic monitoring system developed in this project uses PDAs to remind post-transplant patients when and how to take their medications. At the hospital, nurses enter a patient’s prescription drug regimen into a PDA, and launch the
patient portion of the system. The PDA, running the patient program, is then leased to
the patient for the rehabilitation period immediately following his or her transplant.
Throughout the rehabilitation period, whenever it is time for the patient to take any
medication, the program running on the PDA beeps to alert the patient. A picture of the
particular medication is displayed, along with administration directions. Upon taking the
medication, the patient is prompted to record this activity by tapping “Comply” on the
screen of the PDA, thus storing an electronic record of his or her compliance.

When the patient returns to the hospital for a follow-up visit, nurses can exit the
patient mode and review the patient’s stored compliance record. In this way, reliable
compliance data is immediately available to the hospital staff in a clear, understandable
format.

**Scope**

In order for this project to be feasible, the scope of the research and development
had to be limited to a particular field of medicine. The field of organ transplantation is an
excellent candidate for the application of electronic compliance monitoring technology
because post-transplant drug regimens are typically very complex, with the average
transplant recipient often being prescribed upwards of a dozen medications (Pruett,
2003). The field of organ transplantation also boasts a promising patient population
through which to explore the benefits of electronic monitoring technology, as transplant
patients tend to be more highly motivated than other patient populations.

Ideally, the system developed in this project will give physicians an effective way
to monitor transplant patient compliance and thus help them tailor their therapeutic
approach to the true condition and behavior of their patients. If adopted for clinical use,
this system could increase the efficiency of post-transplant follow-up appointments, lead to a reduction in healthcare costs, and impact the typical compliance behavior demonstrated by patients after receiving their transplants.

**Overview of the Technical Report**

The remainder of this report will discuss the development of the University of Virginia Organ Transplant Team’s post-transplant patient compliance monitoring system, as well as all of the potential ramifications of the production of this new technology. A review of the literature relevant to this project will be conducted, as well as an analysis of the potential social and ethical impacts of the produced system. The methodology employed in the production of the final system will be overviewed, followed by a discussion of the results of the project. Finally, conclusions will be drawn and both interpretations and recommendations for further research and work will be given.
Chapter 2: Literature Review

Through reviewing relevant literature, this chapter will present how compliance has traditionally been measured and contrast the traditional methodologies with the newly emerging ones that are steadily gaining acceptance.

Current State – Traditional Methodologies

In a study on the application of electronic monitoring in the field of dermatology, it was published that, “reliable distinction between non-adherence and non-response is a new issue for medicine, the pharmaceutical industry and its regulators” (Koehler, 2001). Due to it being a relatively new issue, the body of literature relevant to this topic is rather young, and not particularly extensive. Only recently, as in the past decade, have researchers conducted studies to analyze the problem of patient non-compliance at large and to explore the potential methods available for monitoring patient compliance.

A recent study, conducted by a panel of German physicians, concluded that “incomplete compliance remains largely unrecognized and falsely interpreted as treatment resistance, because it is difficult to confirm or exclude objectively” (Favrat, 2001). This difficulty is due to the lack of reliable methods for collecting accurate, objective data on patient activities. Traditional methods include patient interviews, questionnaires, pill counts, and prescription refill surveys. Self-report, which is a compliance monitoring approach that gives the patient the responsibility to maintain a record of their adherence to their prescriptions, is currently one of the more frequently used methods. Despite its widespread use, most researchers agree that data from self-
report usually does not accurately represent patient compliance behavior (Rohay, 1998). Self-report and most traditional methods for measuring patient compliance fail to provide reliable data consistently because they are almost completely dependent upon the subjective reporting of patients (“Electronic”, 1998).

**New Relevant Literature – A Newer Methodology**

Electronic monitoring, known simply as EM, uses electronic devices to monitor patient activities for what is known as a medication event. A medication event is an event that implies that medication has been taken as prescribed. For example, one particular implementation of an EM system, used to monitor the compliance of patients with type-2 diabetes, utilizes “a pressure-activated microprocessor,” located in the caps of drug containers, to record each opening of a container (Winkler, 2002). This system operates on the assumption that the opening of a container, the medication event, implies that the patient actually consumes the drug within as prescribed. EM systems like this are slowly being adopted across many fields of medicine as the new standard for assessing patient compliance. EM systems usually provide more reliable, objective patient compliance data than traditional methods, and can even provide data regarding dose frequency, interval, and time, which are details that traditional methods typically cannot accurately provide (Koehler, 2001).

EM is by no means infallible though, in that, it still depends on the honesty and reliability of the patient. This dependence is fundamental to the assumption that medication events actually result in the patient properly taking their medication. However, patients are less likely to consciously manipulate an EM system than they are
to forget details about their activities when self-reporting. This fact makes the EM methodology inherently more reliable than other traditional methods of assessing patient compliance (Pruett, 2003).

There is some experimental evidence that EM may even cause improved patient compliance. Experiments with EM technology have been conducted in several fields of medicine with varying degrees of success. Unfortunately, presently available results and conclusions from different fields of medicine often contradict one another. For example, EM has been used extensively to monitor patient compliance in cases of resistant hypertension and has often been found to increase compliance, when compared to traditionally accepted percentages (Burnier, 2003). On the other hand, experiments that compare EM against self-report diaries, when monitoring the compliance of adult patients with asthma, have found that the self-reported compliance is continually higher (Rohay, 1998). Such contradictions emphasize the necessity of further research into EM. There still remain many fields of medicine in which EM has not been widely experimented with, so there is much room for further exploration.

**Relevance of the Field of Organ Transplantation**

One field in particular, which lacks any substantial body of literature pertaining to EM, is that of organ transplantation. Many studies have been conducted on patient compliance in the field of organ transplantation, but not much of this research has been focused on the effects of EM on the monitoring and assessment of post-transplant patient compliance.
Studies across all fields of medicine have repeatedly shown that with prescription medication, “the prescribed number of doses per day is inversely related to compliance” (Claxton, 2001). Compliance then, is a particularly serious problem in organ transplantation because, even as early as in 1993, the average transplant recipient was prescribed nine daily immunosuppressive medications (Siegal, 1995). Since then, the number has gone up, with each medication having increasingly complicated daily dosage requirements. Post-transplant drug regimens have thus become amazingly complex, which makes monitoring post-transplant patient compliance an especially challenging problem. Fortunately, transplant patients typically have a significant vested interest in complying with their prescriptions. This makes them an excellent patient population to use in research on the efficacy of EM. The results of this project will ultimately add to the body of literature that is relevant to EM, specifically pertaining to the application of EM in the field of organ transplantation.
Chapter 3: Social & Ethical Dimensions

The development of technology that facilitates the collection of reliable patient compliance data, entails many societal benefits, and also raises some meaningful ethical issues. This chapter will present some of the benefits that could be reaped through the adoption of EM technology and also discuss some of the issues that EM technology raises.

**Economic Dimensions – Reducing Healthcare Costs**

The Task Force for Compliance estimates that the compliance rate for patients with chronic conditions is only in the range of thirty to sixty percent (Gerbarg, 1998). Based on these estimates, non-compliance is projected to cost the healthcare industry $125 billion annually. This exorbitant cost comes from such sources as wasted medication, needlessly repeated doctor visits, and the ordering of avoidable treatments and medical procedures (Fleming, 1998). Non-compliance is a major financial burden on healthcare.

If patient compliance could be adequately assessed, the enormous annual cost associated with non-compliance would be greatly reduced. Physicians with accurate patient compliance data available to them would be less prone to order avoidable treatments and medical procedures than they currently are. They would also be able to isolate cases in which a drug regimen is ineffective from those in which a patient is non-compliant, and would therefore not call for as many unproductive drug regimen adaptations. This would reduce the number of unneeded repeat doctor visits as well as
the number of unnecessary hospitalizations, saving the healthcare industry great amounts of money.

The savings afforded to the healthcare industry would drive down the costs of healthcare in general (Burnier, 2003). This would be extremely beneficial to society at large, in that, it could make many medical procedures, which were once cost-prohibitive, available to a broader population of patients. Lower healthcare costs could themselves drive patient compliance rates higher, as it has been observed that approximately 1.3 million adults with disabilities do not take their medications as prescribed because of cost alone (Kennedy, 2002). This number would undoubtedly be starkly larger if the general population were to be considered, and thus it is reasonable to conclude that a reduction in healthcare costs would lead to greater patient compliance overall. Ultimately, accurate monitoring of patient compliance would save the healthcare industry great amounts of money, and drive compliance rates higher in the process.

**Ethical Dimensions – Understanding**

*The Doctor-Patient Relationship*

Beyond the financial benefits, electronic monitoring of patient compliance will provide physicians greater insight into the habits of their patients, and allow further research into the plethora of different factors that ultimately affect a patient’s decision to comply. In the field of organ transplantation, researchers have already begun to explore how patients think and feel about their transplants, and how this affects their compliance (Siegal, 1995). A greater understanding of the factors that influence a patient’s activity will allow physicians to make better informed decisions regarding the care of particular
patients, and will profoundly impact the doctor-patient relationship. A negative aspect of this enhanced understanding is that it could potentially cause an ethical conflict between what physicians believe is in the best interest of their patient and what the patient wants or decides to do for themselves.

**Patient Autonomy**

“It is sometimes suggested that the physician should offer the patient ‘just the facts,’ preferably in a ‘value-free manner,’ explain the different options, and then leave it to the patient to make the choice” (Wulff, 1995). Patients could potentially perceive the collection of detailed patient compliance information as an impediment to their autonomy. This could lead to conflict between physicians’ motivations behind collecting compliance data and patients’ notions of their own freedom of choice and action. Generally, such conflict would not be the norm, as research has shown “that clinical practice presupposes a mutual trust between physician and patient” (Wulff, 1995). If a conflict were to arise though, the patient would always retain the right to not participate in the compliance monitoring measures, so this remains as a potential limitation of the technology’s ability.

**Patient Privacy**

One of the most significant ethical issues that pertain to this project is the issue of the privacy of digitized patient records that are being created and stored by EM systems. Patient information is extremely confidential and the digitization of such information always raises the issue of security.
In April 2003, the Health Insurance Portability and Accountability Act, HIPAA, went into effect (Leydig, 2003). The privacy provision of the HIPAA places extremely rigid restrictions on the handling of Personal Health Information, known as PHI. The provision states that PHI may not be disclosed unless permitted by the patient or specifically allowed under the restrictions of the HIPAA legislation (eServices Group, Inc., 2001). The HIPAA gives patients significantly more power than before to control access to their PHI, and enacts severe penalties against any healthcare organizations that violate its privacy policies (Leydig, 2003). Electronic compliance monitoring technology stores and delivers information that is considered protected under the HIPAA legislation. Care must be taken to ensure that the data collected by any EM system is protected, and that any access to the stored data for a patient is authorized and monitored. The system developed in this project will ultimately include components that ensure data security, and system compliance with HIPAA legislation. These components will be completed by the time the system will be presented to the NIH.

The reliable monitoring of patient compliance has many societal and ethical implications. The development of an EM system, directly affects the physicians that will employ the system and their patients. There is an inherent security risk associated with capturing and storing patients’ PHI, but if such risk can be adequately assessed and handled, the development of a robust EM system could offer amazing benefits to both physicians and their patients. The potential large-scale implementation of such a system could offer great benefits to the healthcare industry, and consequently society at large.
Chapter 4: Materials & Methods

This chapter will present an overview of the materials used in the development of the prototype EM system as well as the development methodology that was adhered to, and a description of the development process as it was carried out.

Materials – The Devices and Software Used

Implementing the EM system for the Organ Transplant Team required the use of various pieces of hardware and software. All of the programming was completed using Microsoft’s Visual Studio.NET, along with the appropriate Software Development Kits. An HP Ipaq 5550, running the Windows CE operating system, was used for development and testing. This PDA model will most likely be too expensive for use in the final version of the system, as it currently sells at a price of about $750. The decision as to what type of PDAs will ultimately be used will be dictated by the budget allocated to the project if it merits approval to be deployed in clinical trials.

Methodology – Developing the EM System

The System and Its Components

The EM system has three main components: the Data Entry component, The Patient-Side component, and the Data Retrieval and Analysis component. Each separate component had particular design requirements, and was developed to meet certain unique needs and to provide particular functionalities. The components were developed
separately as per the development timeline of the project, and then were integrated to form the prototype software product.

**Typical Software Development, with some problems**

This project was developed following some of the typical guidelines of software project management. The goals of the project were first established through correspondence with the customers, namely the staff of the Organ Transplant Team. When sufficient detail was obtained from the customers, proposals were drafted for the different project components, and these proposals were reviewed and revised in more meetings with the customers. Once this initial planning and drafting phase was completed, the programming phase was initiated.

Initially, the programming phase was scheduled to be completed between mid-December and mid-January, the month during which students were on winter break. Programmer health problems, among other issues, caused a significant delay to be introduced into the project timeline. Despite complications in the schedule, a first prototype with demos of future functionality was successfully produced.

The production of the initial prototype of the system signaled the beginning of the testing phase of development. The initial prototype was run through all potential sequences of use, and given a battery of different input sets so as to test its performance in the various situations it may be used in. After sufficient testing, the prototype was accepted as the milestone artifact that would be used for this report. It represents the completion of the whole first phase of development of the project, which will continue beyond the scope of this report.
Chapter 5: Results

This chapter will present a detailed overview of the prototype EM system that is the result of this project to date, along with a run-through of the typical use of the system including screenshots of the major parts. This chapter will also review the data that was collected from the nursing staff of the Organ Transplant Team and its patients.

Current Status of the EM System

Work on this project to date has resulted in the production of a prototype EM system for monitoring post-transplant patient compliance. This prototype is comprised of the three components named in the Materials and Methods chapter of this report. The prototype is compilable and executable, with all of its components capable of being run on PDAs. Each component of the software is described in detail in this chapter.

Data Entry Component

The Data Entry Component will be used by the staff of the Organ Transplant Team to enter patient drug regimens prior to leasing the PDAs to the patient. This component of the software had to be user-friendly, intuitive, require user authentication through use of a password-user name combination, and prompt the user for the necessary information to adequately describe prescription medications. This information was defined by the customer to include the name of the medication, the dosage, the route of administration, the frequency, and the starting date and time of the prescription.
A member of the staff of the Organ Transplant Team first uses the Data Entry Component by selecting the “Staff Options” button on the main screen of the application. This brings up a sign-in screen that prompts the staff member for his or her user name and password.

Upon successfully authenticating themselves, the staff member is brought to a screen at which he or she has to enter in his or her patient’s name and unique identifier, so that the regimen he or she is about to prescribe is bound to the identity of the patient. This screen is shown on the following page.
Figure 5.3. The Patient Info. Screen requires that the staff member enter in the patient name and unique identifier so that the regimen to be entered will be bound to the identity of the patient.

After providing a patient identity to which the regimen is to be bound, the staff member is then prompted to select how many drugs the regimen is to include.

Figure 5.4. The Drug Entry screen requires the staff member to select how many drugs he or she is about to prescribe to the patient.
For every drug in the regimen, the staff member is prompted to enter the necessary medication information. The medication name and dosage lists are populated with options that are present in databases that are locally stored on the PDA. The dosage list is populated according to what medication is selected, and for both categories manual entry is an option. The Medication Info. Screen allows the user to continue on to the next medicine by pressing the done button after they have entered in all necessary information for a particular medicine. Upon entering the information for the final medicine in the regimen, the user is prompted to review and confirm the regimen as entered, and then launch the Patient-Side Component of the program.

Figure 5.5. The Medicine Info. Screen prompts the staff member for the information necessary to adequately describe a medication. The above example shows a screen prescribing that the patient take 200mg of Advil.
**Patient-Side Component**

The Patient-Side Component will be used by transplant patients to review and record their compliance activities. This component of the software had to be user-friendly, intuitive, and it had to prevent inappropriate use. To prevent such use, this component disables almost all typical Windows control functions; it cannot be closed, minimized, exited, or modified by the patient.

Patients using this component have the option of either reviewing their prescribed regimen or editing the dosages of particular medications in their regimen, assuming they have the necessary authorization information. To date, the editing functionality has not been completed, but the rest of this component is fully functional. Normally, the Patient-Side Component simply stays in Idle Mode, until it is time for the patient to be reminded that a medication needs to be taken.

![The main screen of the Patient Interface allows the patient to review their regimen by clicking on the prescription symbol, or seek help by pressing the question mark. As noted in the center label, the screen remains as such until it is time to alert the patient of a medication that needs to be taken. An Editing option will soon be added.]

**Figure 5.6.** The main screen of the Patient Interface allows the patient to review their regimen by clicking on the prescription symbol, or seek help by pressing the question mark. As noted in the center label, the screen remains as such until it is time to alert the patient of a medication that needs to be taken. An Editing option will soon be added.
If a patient chooses to review his or her regimen, he or she enters Review Mode, which includes screens that are essentially identical to the screens that were presented to the Organ Transplant Team staff when they were asked to review and confirm the patient’s regimen as entered.

Figures 5.7 & 5.8. The initial screen of the Review Mode of the Patient Interface (left) identifies the patient and the number of prescribed medications in his or her regimen. The patient can use the navigation arrows to review individual medications. The individual medication screen (right) provides detailed information about the medication that is currently selected.

When time comes for the patient to be reminded to take a particular drug, he or she is presented with the screen shown on the following page. Upon his or her assumed compliance, the medication event is recorded, and the Patient-Side Component returns to its main screen and to Idle Mode.
The Med. Alert Screen of the Patient Interface is loaded when it is time for the patient to take a medication. A picture of the medication is displayed, along with administration instructions. The patient is given the option to either comply or skip. An option to skip with authorization will soon be added.

The Patient-Side Component runs until it is exited by an authorized staff member. This is done by pressing a “hidden” exit button and providing the necessary authentication information.

**Data Retrieval and Analysis Component**

The Data Retrieval and Analysis Component will be used by the staff of the Organ Transplant Team to retrieve stored patient compliance records. This component of the software had to be user-friendly, intuitive, require user authentication through use of a password-user name combination, and provide the staff member with patient compliance data in a clear, understandable format.

After authenticating themselves and selecting the “Data Retrieval” button on the Staff Menu Screen (Figure 5.2), an authorized staff member is presented with the
following screen, which provides them options for how they wish to view their patient’s stored compliance data.

Figure 5.10. The staff data retrieval menu allows the staff member to choose between a summary or detailed review of the stored patient compliance data. An even further detailed, medication event review, option will be added in the future.

Currently, the staff member can only view a summarized or detailed view of the regimen they have entered for their patient. Eventually, they will have the ability to browse through each medication event that was either missed or complied with by the patient in question. This functionality is not complete yet, but it will be implemented in the future development of the system. If the staff member chooses a Summary Review of the patient’s data, he or she is presented with an accurate summary medication list of the patient’s regimen. If he or she chooses a More Detailed Review, he or she is presented with a medication-level breakdown of the patient’s regimen. As per the Organ Transplant Team’s request, the soon to be added Medication Event Review will present
the staff member with an accurate medication list for the patient that includes a tally of missed medication events for each medication in the regimen.

**As A Whole**

Although the initial prototype does not encapsulate all of the functionality that the finalized system will eventually possess, it is a sufficient artifact to be used in gauging the ultimate effectiveness of the refined EM system that is to be the final product of this project. The initial prototype of the EM system was presented to members of the Organ Transplant Team for the purposes of data collection for this report. The prototype system was also presented to some patients, although not in any official manner.

**Staff and Patient Reactions and Responses**

Strict laws and regulations govern all experiments that are conducted in medicine, particularly those that directly involve patients. Experiments that alter patient treatment in any way require explicit government authorization to be considered legal. Collecting quantitative data for this report would have required a departure from the usual methods of patient treatment at the Organ Transplant clinic of UVa. Transplant patients would have to have actually used the developed prototype EM system throughout their rehabilitation periods to produce any relevant quantitative data. Since this project has not yet been submitted for approval to the necessary authorities, data collection had to be qualitative.

The nurses of the Organ Transplant Team and a choice group of their available patients were given a demo of the prototype EM system and were then asked to fill out simple questionnaires. The questionnaires asked about the current methods of monitoring
patient compliance, what impact this project could potentially have on the measurement of patient compliance, and how this project could be further enhanced to better serve its purpose. Examples of the questionnaires are provided in Appendix A and the results are summarized below.

**Organ Transplant Team Staff Responses**

The nursing staff of the Organ Transplant Team overwhelmingly responded that the methods that are currently used to measure patient compliance are grossly inefficient. As a group, they gave mixed responses when asked about the accuracy of the current methods. Some rated the accuracy as mediocre, and some as low, while none rated the accuracy as being high or even good. Every single member of the nursing staff of the Organ Transplant Team responded that nurses would benefit from EM technology, and that immediately available patient compliance information would make their jobs easier. The nursing staff suggested a whole plethora of improvements and potential additional features for the system, some of which will be reviewed in the Recommendations section of the Conclusions chapter of this report.

**Patient Responses**

Patients of the Organ Transplant Team provided varying responses when asked whether it was currently easy for them to keep track of when they had to take their medications, and whether it was easy for them to record their medication events. Still, patients overwhelmingly responded that they would benefit from a device that would both remind them of when to take their medications and handle the event data recording for them. The patients responded kindly to the interface of the prototype EM system, but
for the most part they responded that they were not completely comfortable with computer technology in general. The patients also provided suggestions for how this project could be improved, which will be reviewed along with the staff suggestions.

The data collected from the Organ Transplant Team and their patients, along with the results of the few other studies relevant to the topic were used to extrapolate the conclusions for this report. The data collected in this project is necessarily very limited, due to the restrictions in place that prevent any significant interaction with patients for the purposes of research that has not received approval from the appropriate authorities. The data collected to date will be used in drafting a proposal for approval to conduct further research, particularly clinical trials.
Chapter 6: Conclusions

Summary of Results

The results of surveying the staff of the Organ Transplant Team and its patients correlate with those of other research studies that have been conducted on compliance. The results show that many of the systems that are currently used for monitoring and measuring patient compliance should be replaced. The current methods suffer from problems on both the healthcare staff and patient sides that contribute to their inaccuracy and inefficiency. The staff of the Organ Transplant Team unanimously held the opinion that the system that they currently use is grossly inefficient. The patients surveyed in this project almost unanimously responded that they believed that they would benefit from the adoption of EM technology. The results definitely show a strong trend towards a particular solution to the problem of assessing patient compliance, that being the employment of EM technology.

Interpretation of Results

The prototype EM system developed in this project did well in achieving its original goals. The system, and the response it received from both the nurses on the Organ Transplant Team and their patients, showed that the development of EM technology for the field of organ transplantation is not only possible, but that it could even prove to be very useful. These results could be further generalized to form the basis of an argument that the use of EM technology should be explored across all fields of medicine.
Even though the results from surveying the Organ Transplant Team and their patients are very helpful in supporting the aims of this project, it must be taken into account that the groups from which data was collected in this project were very small. Also, the data collected to date has been limited to only qualitative data, which is inevitably highly subjective. These characteristics of the results are important, in that, in order for them to ultimately be considered as statistically significant many more people would have to get involved in the project and quantitative data would have to be collected.

The small size of the subject population of this project is not necessarily an insurmountable obstacle, nor is the lack of quantitative data. The size of the subject population could grow to be very large if the prototype EM system were to be further refined and developed to the point where it could actually be tested in a true clinical environment with a random sampling of patients. Such clinical testing would provide an avenue through which solid quantitative data could be collected in parallel with qualitative data.

Another limitation of the produced prototype system is that it currently only addresses a very linear sequence of events with regards to the activities of the patients it is supposed to monitor. Unfortunately, in reality there is very little about medicine that is truly linear or predictable. The system currently operates under the simple event model of a nurse entering in a prescribed regimen, the patient taking their medications over a period of time, and then the patient returning to the nurse for a follow-up appointment sometime thereafter. Often, many other events crop up during the time between when the patient leaves the hospital and when they return for their follow-up. For example,
patients are regularly instructed to change their dosage requirements, and they sometimes
even go to different doctors to get additional drugs prescribed. These and other possible
events need to be accounted for if the system is to truly have its intended positive impact.

Beyond all others, the major limitation for this prototype EM system remains to
be that it is not yet developed to the point where it can earn the necessary approval to be
used in clinical trials. Clinical trials would provide results that would allow the further
enhancement of the system to accommodate situations and circumstances that have yet to
be considered. Clinical trials could also provide a true gauge of the usefulness of this
particular application of EM technology, and provide the foundation for a solid argument
for or against the widespread development and adoption of EM technology.

**Recommendation for Further Work**

Some modifications, enhancements and additions must be made to the prototype
EM system in order to develop it into being a viable candidate for receiving approval to
be used in clinical trials. Significant amounts of work have to be done on the security of
the system’s stored data in order for it to meet some of the strict standards set by
legislation such as the HIPAA. This is an absolute necessity for the system to receive
approval for use in clinical trials.

In addition to data security, the staff and patients of the Organ Transplant Team
suggested many improvements to the system that would enhance its ultimate impact.
These include such necessary modifications as building in the ability for patients, to edit
the dosages of medications in their regimens as instructed by their nurses, to go back and
review the medications that were recorded as being skipped, to allow other physicians to
modify the regimen that was originally prescribed by the nurse at the hospital, and so on. Developing responses for such irregular events that may occur after a patient leaves the hospital and before they return for their follow-up will result in a more robust system and thus a more effective solution to the problem of accurately assessing patient compliance.

The potential impact of a final, robust version of the prototype system developed in this project is colossal. Today, practical computing technology that could revolutionize the way patient compliance is assessed is widely used in seemingly all walks of life outside of healthcare. The prototype system developed in this project is only the first step in the healthcare application of such practical computing technology. If this project is carried out to some greater level of completion, as is planned, providing healthcare to patients in need could be made more efficient and ultimately more effective in general. As a result, more people could avail themselves of previously cost-prohibitive medical treatments, and the general welfare of patients could be improved across the board.


Appendix A

The following are copies of the questionnaires that were given to the staff of the Organ Transplant Team and its patients so as to assess their reaction to the prototype EM system developed for this project.

**Nurse Questionnaire?**

1. How would you rate the efficiency of current methods for assessing patient adherence?
   
   **Low** ------------------------------------------ **High**

2. How would you rate the accuracy of current methods?
   
   **Low** ------------------------------------------ **High**

3. Do you feel that nurses and patients may benefit from technology that would allow the digital tracking of patient adherence information?

   **Yes** _________ **No** _________

4. What information would you like immediately available to you when you have to meet a patient for a follow-up visit?

   [Blank space]

5. Would immediately available Medication lists, and Adherence statistics make your job easier?

   **Yes** _________ **No** _________

6. Please use the back of this form to make any suggestions for features that would be helpful to you. This program is still being actively developed, and obviously has many more features that will ultimately be added. Any information that you could provide will help me make a better final product, and would be much appreciated.
Patient Questionnaire?

1. How easy is it for you to keep track of when you have to take your medicine?
   
   Easy ------------------------------- Hard

2. How easy is it for you to record each time you take your medicine?
   
   Easy ------------------------------- Hard

3. Do you feel that you could benefit from a device that would remind you when to take your medicine?
   
   Yes ________ No ________

   What about a device that would do this, and do the record keeping for you?
   
   Yes ________ No ________

4. How comfortable do you feel with computer technology? (Like a PDA)
   
   Not Much ------------------------------- Very

5. How understandable (simple) is the interface that you were shown?
   
   Not Much ------------------------------- Very

6. What changes would make the program better for you? (Continue on back)