Self-Medication Practices of Adults with Sickle Cell Disease: Design and Methodology

Courtney Marie Beyers
University of Connecticut - Storrs, courtneymbeyers@gmail.com

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Courtney M. Beyers
University of Connecticut

Author Note
Courtney M. Beyers, School of Nursing, University of Connecticut, Storrs, CT.
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Advisors were School of Nursing Professor Patricia J. Neafsey, PhD, RD, ActualMeds™ Corp.
Principal Scientist, and Principal Investigator Victoria O. Odesina, DNP, APRN, University of
Connecticut Health Center Medication Adherence Programs. The author wishes to acknowledge
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Abstract

Adults with Sickle Cell Disease (SCD) are a significant population to study when considering self-medication behaviors, as they utilize multiple prescription drugs for management of symptoms related to their disease. Adults living with SCD will demonstrate adverse self-medication practices as recorded on the ActualMeds™ Medication Management System via use of Apple iPad® digital mobile device during a single interview, in order to identify the self-medication practices of adults with SCD. To demonstrate the ability of the ActualMeds™ program to conduct automated medication reconciliation on the Apple iPad®, it is necessary to tailor the program design for compatibility use with this device. ActualMeds™ is a team-based health care information technology program focused on providing web-based medication management and reconciliation (ActualMeds™, 2013). The ActualMeds™ program enables health care teams to conduct cost-effective medication reconciliation for high-risk patients, such as among adults living with SCD. The purpose of this study was to conduct usability testing by the student researcher with ActualMeds™ Medication Management System using the Apple iPad® digital mobile device, prior to conducting the investigation “Self-Medication Practices of Adults with SCD” at the University of Connecticut Health Center. The technology was originally developed and validated in an NIH sponsored randomized, controlled trial in the School of Nursing at the University of Connecticut, where the intervention demonstrated it could improve patient outcomes and lower health care costs (Neafsey et al., 2010). Results from usability testing were used 1) to systematically modify and tailor the ActualMeds™ program design compatibility for use via Apple iPad® and 2) to create the touchscreen computer tablet release version of the ActualMeds™ program for a large-scale use
in clinical care (on the Apple iPad® and other tablet devices). The usability-testing processes used in this feasibility study ensured an interface design adapted to the student researcher needs and preferences to allow her to effectively use the ActualMeds™ technology in a clinical setting among adults with SCD. This is the first report of a feasibility study of ActualMeds™ Medication Management System usability, targeting high-risk patients, on an Apple iPad® digital mobile device.

Keywords: usability testing, healthcare informatics, sickle cell disease, self-medication practices
Statement of Research Problem

Sickle cell disease (SCD) represents a group of serious inherited blood disorders associated with acute and chronic morbidity, recurrent unpredictable and unrelenting episodes of pain, increased risk of infection, stroke, organ damage and other debilitating complications (Ballas, 2010; 1995; Jacob, 2001; NIH, 2002; Platt, et al., 1994). As a result, adults with SCD are prescribed different medications to treat complications of SCD and other comorbidities (Odesina et al., 2010). In addition to the side effects (drowsiness) of the pain medications, such as opioids that they take for pain relief, it has been documented that many adults with SCD have cognitive deficiencies from ischemia to the brain (Vinchisky et al., 2010). It is unclear how these factors affect their understanding of treatment plan, follow up instructions and medication adherence. Furthermore, these are potential contributing factors to adverse self-medication practices. Because individuals with SCD are now outgrowing the specialty care of pediatricians, they often find themselves left to manage multiple medications and self-care interventions. Without understanding the self-medication practices of adults with SCD, we are not able to identify and begin to adequately meet their needs.

Neafsey et al. (2010) has demonstrated the potential for adverse self-medication practices in adults with hypertension, a chronic condition such as SCD, that lends itself to polypharmacy. The ActualMeds™ program enables health care teams to conduct cost-effective medication reconciliation for high-risk patients, such as among adults living with SCD. The usability of ActualMeds™ program via Apple iPad® must first be verified in a training environment, 1) to guide the design of system information architecture, 2) to test the software interface, and 3) to gather feedback information prior to conducting the feasibility study, “Self-Medication Practices of Adults with SCD,” at the University of Connecticut Health Center.
Review of Literature

Prevalence of Sickle Cell Disease

Sickle cell disease (SCD) is an inherited autosomal recessive genetic disorder. SCD occurs most commonly, but is not limited to, families with a known ethnic heritage from India and Saudi Arabia, Africa, South and Central America, the Caribbean, and the Mediterranean region.

In the United States, SCD affects an estimated 70,000–100,000 people, primarily in the African American population; SCD occurs in about 1 out of every 500 African American births. SCD also affects Hispanic Americans, occurring in more than 1 out of every 36,000 Hispanic American births (NIH 2013). Life expectancy for persons with SCD has recently increased from age fourteen in 1973 to the mid to late forties in 2004, transforming SCD into a long-term chronic illness. This chronic disorder may result in a lifetime of pain experiences and frequent hospitalizations (Jenerette, C.M., & Lauderdale, G., 2008). Because adults with SCD are living longer today, and are outgrowing the care of pediatricians and left to manage on their own, there is a need to identify self-medication practices in order to meet the needs of this vulnerable population.

Hospital Readmissions

According to the U.S. Agency for Healthcare Research and Quality, SCD was named the condition with the highest readmission rates in the year 2010, in a national study of healthcare cost and utilization. The study found 31.9% of patients with SCD were readmitted and this exceeded all other conditions, including heart failure, hepatitis, HIV, chronic renal failure, and others. This percentage may be better understood as over one in every four patients with SCD were readmitted. Costs for hospital stays due to complications of SCD were estimated at $488
million in 2004 (AHRQ, 2010). It is the intention of the research staff to survey self-medication practices in order to reduce adverse medication behaviors; Changes to medication regimen of study participants by their providers, such as reducing adverse medication behaviors in individuals, has the potential to reduce the hospital readmission rate of the adults with SCD interviewed in this feasibility study.

Reducing adverse medication behaviors and promoting self-care are primary concerns to the efforts of nursing. The Institute of Medicine has cited medication adherence as of critical importance (Institute of Medicine, 2010). It is through this study that the student researcher hopes to gain experience with use of ActualMeds™ Medication Management System in the population of adults living with SCD. Ultimately, the student researcher will strive to improve the quality of life in this population. Future studies will extend data collection of self-medication practices, in order to inform an educational intervention that is community-based and culturally appropriate.

**Issues of Self-Medication**

Adults with SCD are a significant population to study when considering self-medication behaviors, as they utilize multiple prescription drugs for management of symptoms related to their disease. Studies have shown that mixed pain (chronic and acute) and the use of opioids prescribed by healthcare providers have negative effects on the functional status of adults with SCD, specifically in the physical and social domains (Ballas, 1995; McClish, et al., 2005). Neurologically intact adults with SCD with apparently normal intelligence and language capacities have been reported to show neurocognitive deficiencies due to the negative effects of pain experience and use of opioids to manage pain. This negatively affects the ability to plan, take control of self-management activities, and participate in vocational and social functions for
adults with SCD (Vinchinsky, et al., 2010; Wills, et al., 2010). Adults with SCD often lack self-efficacy, positive coping responses, self-care management skills, and the ability to adhere to treatment regimen, or skills required for independent and/or supportive living related to such neurocognitive deficiencies (Jenerette, & Brewer, 2010; Jenerette, & Valrie, 2010; Jenerette, & Murdaugh, 2008; Jenerette, & Lauderdale, 2008; Jenerette, & Phillips, 2006). Because individuals with SCD are living longer and transition from pediatric to adult care, there is a need to identify self-medication practices in order to meet the needs of this vulnerable population.

**Research Questions**

1. What are the self-medication practices of prescription and commonly used over-the-counter medications and alcohol among adults with SCD?

2. What are the adverse self-medication behaviors of adults living with SCD?

In order to address these questions, the following must first be considered:

3. How is the usability of ActualMeds™ program faring via Apple iPad® use, with respect to perceived system usability, system usefulness, system-use satisfaction, and interface time?

**Theoretical Framework**

Initially derived from social cognitive theory, Self-efficacy theory attempts to explain and predict behavior (Bandura, 1977). Behavior, cognitive factors, and environmental influences are hallmark concepts of Social Cognitive Theory. These concepts form the basis of a model with the relationship of three-pronged reciprocal determinism. Not necessarily equally, the three concepts interact bidirectionally. At different times, different factors may be the force driving the behavior.

The end result of self-efficacy expectations and outcome expectations is indeed behavior
(Bandura, 1982). As the patient develops self-efficacy and expected outcomes are identified, she/he evaluates his or her own ability to successfully complete the task. Thus, in the patient’s evaluative process, there exists an element of pragmatism. Specifically, if patients believe in their ultimate success related to their therapeutic process, self-efficacy and outcome expectations are increased. In this study, self-efficacy theory provided the underlying framework to guide the examination of patient behavior.

Self-efficacy theory suggests that self-efficacy expectations change over time with experience, given the opportunity to develop skills. It is an adaptive process. If a behavior were mastered, a desired outcome would result, as proposed by outcome expectations. Propositions related to outcome expectations and self-efficacy expectations differ—a person may expect that a certain outcome will result from a certain behavior, but not have confidence in his or her own ability to complete the task.

**Conceptual Definitions of Terms**

Sickle Cell Disease (SCD) is an inherited disease and presents clinically as serious disorder in which the body produces “sickle-shaped” — also referred to as “crescent-shaped” — red blood cells. Sickle cells contain an abnormal protein structure called hemoglobin S. Sickled cells tend to block blood flow in vessels, limbs, and organs, causing pain, contributing to organ damage, and increasing risk for infection (National Heart Lung and Blood Institute, 2002).

The ActualMeds™ Medication Management System is a health care information technology, web-based system that enables team-based medication management and reconciliation at the point of care. ActualMeds™ technology was originally developed and validated in an NIH sponsored randomized, controlled trial in the School of Nursing at the University of Connecticut, where the intervention demonstrated it could improve patient
outcomes and lower health care costs (Neafsey et al., 2010). In a structured interview, clinicians use this tool to capture prescription and over-the-counter medication information, and other important patient self-medication information, such as conditions and symptoms (ActualMeds™ 2013). Prior to this study, medications for SCD were loaded into the ActualMeds™ Medication Management system.

Self-medication practices are self-reported, clinician-entered data on prescription and over-the-counter (OTC) medications and alcohol use. In a behavioral feasibility study, descriptive statistics of self-medication practices will be calculated using SPSS. Frequency distributions will be conducted and analyzed.

**Methods**

**Research Design and Setting**

Institutional Review Board approval was sought and approval granted from the UCHC with reciprocal approval granted by UConn Storrs. An exploratory descriptive study design will be used in the study. The University of Connecticut Health Center (UCHC) provides medical management to over 400 patients with SCD. The study will take place at UCHC. Patients who consent to participate in the study will be shown into a private room. The researcher will utilize a clinician-entry version of ActualMeds™ software program and enter participant self-reported information into the ActualMeds™ program. Dependent variables that will be measured include self-medication practices and adverse medication behaviors.

A convenience sample of adults with SCD that are patients of the Sickle Cell clinic will be recruited. Homogeneity will be considered as a control strategy. This will entail one sample of adults living with SCD. A study limitation is that the patients may not be representative of the general population of adults with SCD. Participants will be encouraged to be honest in the data
they will report to the researcher. When the researcher introduces the project, she will tell the participants there are no wrong answers, but that information is needed on medications patients take in their homes.

**Background of Instruments**

The ActualMeds™ *Medication Use* instrument was initially developed for the population living with hypertension with established content and construct validity (Neafsey et al., 2001; Neafsey & Shellman, 2002); however, it has been modified for use with adults with SCD. The ActualMeds™ Medication Management System is a simple, secure web-based tool to help health care providers manage complex medication regimens in older adults or other high-risk patients (ActualMeds™, 2013). It is designed for use on a tablet computer and captures patient self-reported, clinician-entered frequency and longitudinal use data on medications, supplements, and alcohol. Adherence to medication is measured from patient responses to questions related to what, when, and how they take each agent. Results from the data have been repeatedly tested in the touchscreen computer tablet formant with older adults (Lin et al., 2009; Neafsey et al., 2008; 2009; 2010).

**Sampling Plan**

The study flyers describing the study (see Appendix A), participant criteria, and contact information of the researcher will be placed in the UCHC Sickle Cell Clinic, infusion room, and AACU. Health care providers at the UCHC Sickle Cell Clinic, infusion room, and AACU will share flyers with their patients advertising the study after they are educated about the study via poster presentation by the researcher, see Appendix B; ActualMeds™ images are unavailable due to the sensitivity and nature of the Non-Disclosure Agreement (Appendix C). Staff at the
UCHC Sickle Cell Clinic will mail flyers to their patients with SCD advertising the study. Interested participants will contact the researcher. The researcher will be in a room on the days patients with SCD are seen to meet with prospective participants to answer any questions the interested patients may have and screen for eligibility. Prospective participants can also contact the researcher by phone regarding eligibility.

The prospective participants will meet with or arrange a meeting time with the student researcher to answer any questions the participant may have and obtain informed consent. The researcher will call to remind participants of the study enrollment appointment time arranged to meet with the researcher 1) to answer questions, 2) obtain informed consent. The phone call to participants will remind them to please bring a bag of their medications for the potential research study interview. The researcher will meet with the prospective participants in a private room previous to a UCHC appointment, approximately one hour in advance to a scheduled UCHC appointment with his or her health care provider. The student researcher will explain the study and obtain informed consent, after answering any questions the participant may have.

This feasibility study will include 10-20 participants. Inclusion criteria are: 1) adults 18yrs and older, 2) adults with diagnosis of SCD, 3) English speaking, and 4) any ethnic background. Patients with SCD under 18 years of age and people with sickle cell trait will be excluded.

**Threats to Internal Validity**

Patients may have a different level of understanding of their illness, based on their level of education and SES. Patients will be recruited based upon their regularly scheduled clinic appointments, May through July 2013. This selection might affect internal validity. The patients who choose to participate may be more highly motivated. The researcher will strive to recruit an
ethnically, economically and educationally diverse population. All instruments used have been previously validated.

**Threats to External Validity**

Only adults with SCD who are current patients at the University of Connecticut Health Center will have the ability to participate in the study. These patients may not be representative of the general population of adults living with SCD. For the purpose of this feasibility study, one location was used; however, future studies will include other settings. Data collection will be conducted in a private room at the Sickle Cell Clinic by the researcher, to minimize distractions.

**Instruments**

The ActualMeds™ Medication Management System (formerly PEP-NG) will be used for the *Medication Use* survey. The instrument has been used in several studies (Neafsey, Strickler, Shellman, & Chartier, 2002; Neafsey et al., 2008, 2010; Neafsey, Lutkus, Newcomb, & Anderson, 2009; Neafsey et al., 2007) investigating the self-medication practices of patients with hypertension. The instrument was used to collect self-reported data on medications prescribed and adherence, use of supplements, and alcohol intake. Adherence to the prescribed medication regime was addressed through the completion of a series of prompted questions describing what, when, and how the patients took their medications. Also, a three-item paper and pencil survey (see Appendix D) will address the participant’s hydration status with targeted hydration questions, developed by the researcher.

It has been shown to be effective in increasing knowledge and self-efficacy related to the patient’s medication regime and decrease adverse self-medication practices in older adults with hypertension, a chronic condition such as SCD that lends itself to polypharmacy (Lin, Neafsey,

Data Collection Procedure

This study will require one visit and a follow up contact by phone 2 weeks following initial visit. Only one visit is required to complete the survey for this feasibility study. The entire process during initial interview will require about 30-45 minutes. Patients who consent to participate in the study will be shown into a private room previous to a regularly scheduled UCHC appointment, approximately one hour in advance to a regularly scheduled UCHC appointment with his or her health care provider. Participants will provide their private information in an informed consent hard copy paper form only. All paper consent forms will be kept in a research notebook. The student researcher will assign each participant a four digit ID number. The ID number is randomized and stored in the ActualMeds™ user ID bank, which is a password-protected secure online server. The student researcher will code the assigned four digit ID number to each participant on the participant’s consent form. Only the student researcher and the PI will have access to the coded consent form. The ActualMeds™ online server will only have access to de-identified information stored by the participant’s assigned four digit ID number. The ActualMeds™ online server will not have access to the coded data nor the research notebook, and therefore, the information connected to four six digit ID number will be de-identified. All consent forms and the research notebook will be placed in a locked filing cabinet in the PI’s office in the Dowling North Medical Building. The principal investigator and the undergraduate nursing research student will be the only individuals with access to the raw data.

All participants will be assigned by a random ID number on the software program prior to data entry. Data collected on the ActualMeds™ program, including demographic and medication
use will be later downloaded onto a flashdrive file retained by the student researcher and PI, and downloaded to the research database via a secure server. Gender and age information (collected on the consent form) will be added to this file after download. The ActualMeds\textsuperscript{TM} server will not have the gender and age information. The secure server is password protected. The flashdrive containing electronic file will be placed in a locked filing cabinet in the PI’s office in the Dowling North building. Participants will be contacted by telephone 2 weeks after initial interview to follow-up self-care management. Participant responses during a 10 minute phone call will be documented into a research notebook as coded data with a four digit ID number. The research notebook will be placed in a locked filing cabinet in the PI’s office in the Dowling North Medical Building.

Participants will bring prescription medication and over-the-counter (OTC) medications from home to assist their self-report of behaviors regarding the use of these medications. Self-medication practices will be documented by the student researcher with regard to prescription medications, over-the-counter (OTC) medications, and current alcohol intake. This interview will not address illicit drugs; participants will not be asked about illicit drug use in this study. Each participant will be provided with a printed summary of the interview. The health care provider of each participant at the UCHC will be provided a printed summary of the interview by the student researcher before the regularly scheduled appointment that day following the research interview. This will provide an opportunity for the health care provider to review the information and make a clinical decision necessitated by the information; for example, we expect three types of summary report results and actions for health care providers to take: 1) No risk – providers will review information and continue plan of care; 2) Moderate risk – providers will make changes to participant medication regimen if necessary; 3) High risk – providers will make
changes and/or refer participants to UCHC Infusion Room or Emergency Dept for urgent care if necessary.

The researcher will contact participants 2 weeks after the initial interview visit by telephone call. The purpose of the call will be to ask follow-up questions regarding what actions were taken after obtaining the survey results (see Appendix E). The phone call will require about 10 minutes.

Data Analysis Plan

Coded data will be entered into an SPSS data file. Descriptive analyses will be conducted on all variables organized by race and age. Frequency distributions of the Adverse Self-Medication Behavior Score will be analyzed. Because this is a small feasibility study, no conclusions will be made based on race or age.

Timeline

The project proposal was written in the fall of 2012. The version I proposal was submitted to the institutional review board (IRB) at the University of Connecticut Health Center in March 2013. The version II proposal, revised per IRB chair comments (see Appendix F), was submitted to the IRB in April 2013. A letter of support was sought from the director of UCHC Sickle Cell clinic (see Appendix G). Final approval by the IRB for this expedited project was granted on May 9, 2013 (See Appendix H)

Application to Nursing

SCD is responsible for over one million hospital admissions annually and is the most common cause for hospital admission in persons over 65 years of age. Ultimately, the researcher will strive to improve the quality of life in this population. Future studies will extend data collection and compare men and women’s self-medication practices.
Usability Testing

The usability of ActualMeds™ Medication Management System via Apple iPad® was tested by the student research in three timed sessions, in a manner similar to previous usability testing by APRNS of the earlier software version, PEP-NG (Lin et al., 2010). The student researcher developed medication lists typical of adults with SCD, based upon clinical experience. The knowledge of medications that adults with SCD take was derived from personal experiences in the nursing care of adults with SCD in UCHC inpatient hematology-oncology. Using such prior knowledge, the researcher developed hypothetical medication lists distinct for each trial. The lists were created with a range of 14-17 medications total, as polypharmacy is very commonly seen in this patient population, refer to Appendix I for medication list details for all trials. Also, typical information was provided by the student researcher, based upon clinical experience, for data entry such as health status, daily living, and self-reported nonadherence behaviors. The student researcher entered such data and simulated medication reconciliation in three timed trials. In the first time trial, an Apple iPad® was used without accessories. In the second trial, an Apple iPad® was accompanied with a stylus. In the third trial, an Apple iPad® was used with stylus and portable keyboard accessories (Appendix J).

In a similar manner to Lin et al. (2010), the student researcher engaged in a “think-aloud procedure” while entering data into the ActualMeds™ Medication Management System. The interface action and think-aloud expressions were captured via digital video, as the student researcher verbalized her thoughts during system interface. Then, a PSSUQ survey was completed (see Appendix K for PSSUQ template). The digital video footage was reviewed and transcribed, recorded comments supplemented the PSSUQ survey, respectively.
The student researcher has continued to provide her opinion on the design of ActualMeds™, with respect to information architecture, graphic design, color, font, screen size preference, interactivity functions for data entry and retrieval, and ergonomic features, including use of stylus touch-screen interface and wireless keyboard.

**Results**

At this time, patients have not yet enrolled in the study “Self-Medication Practices of Adults with SCD.” The results included here are detail the student researcher’s experience with the usability testing of the ActualMeds™ program, in preparation for study interviews with participant. Usability testing is necessary to verify appropriate conduct in prospective study interviews with participants, such as with respect to time. The results of the usability testing will aid the research staff and further development of ActualMeds™ with the knowledge of effective and less effective techniques employed.

**Verification of Usability Testing**

The student researcher utilized an Apple iPad® to conduct three trials of usability testing. In the first trial, only an Apple iPad® was utilized with touchscreen features. In the second trial, the Apple iPad® use was accompanied by the use of a stylus. In the third trial, the Apple iPad was utilized with a stylus as well as a wireless keyboard accessory. The results for the modified 15 PSSUQ items are reported as follows. With regard to the usability testing, conceptual dimensions were associated with the following: (1) system usefulness (a five-item scale); (2) system usability (a six-item scale); (3) system-use satisfaction (a four-item scale).

**System Usability**
As seen in Table 2, the third usability trial was found to have significantly improved results, suggesting that the student researcher did not find using an iPad alone with touchscreen features to be usable. Results show that the student researcher demonstrated an improved usability experience with the iPad accompanied by a stylus, and an increased usability perception reported by the third trial with a stylus and accompanying keyboard accessory.

**System Usefulness**

The student researcher reported a high usefulness rating for both trials 2 and 3, indicating that both the use of Apple iPad® with stylus and/or the use of Apple iPad® and stylus with keyboard are equally useful (Table 2).

**System-Use Satisfaction**

The student researcher reported highest satisfaction with the use of Apple iPad with stylus and keyboard accessories, as seen in Trial 3 (Table 2). Results indicate a significantly low satisfaction rating for Apple iPad alone, without accessories.

**Interface Time**

There was a twelve minute reduction in interface time between the Trial 1 and Trial 2 usability testing, a ten minute reduction in interface time between Trial 2 and Trial 3 usability testing, and a 22 minute reduction in interface time between the Trial 1 and Trial 3 usability testing. This shows that the interface entry time in Trial 3 with the stylus and wireless keyboard incorporated into use was 1.6 times faster than with the iPad alone. This is necessary knowledge for the research staff prior to conducting “Self-Medication Practices of Adults with SCD.”

**Limitations**

With the student researcher’s solo usability testing in mind as precedent, it is necessary to conduct a formal usability study of the ActualMeds™ Medication Management System via the
use of a touchscreen Apple iPad®. Usability testing with Apple iPad® with prospective clinician-entry users at the Neag Comprehensive Cancer Clinic, such as RNs and advanced practice RNs (APRNs) of the ActualMeds™ Medication Management System must be conducted, in order to use ActualMeds™ in practice to capture the self-medication behaviors of adults with SCD and other vulnerable patient populations for which medication adherence and reducing adverse self-medication behaviors are concerns.

Conclusion

The student researcher has verified the usability of ActualMeds™ program via Apple iPad® use, with respect to perceived system usability, system usefulness, system-use satisfaction, and interface time. In order to promote time efficacy for use with patients in face-to-face interviews, the student researcher has determined the Apple iPad should be used with both accompanying stylus and keypad for implementing the ActualMeds™ Medication Management System in the investigation of “Self-Medication Practices of Adults with Sickle Cell Disease.” With this knowledge, the student researcher will 1) identify the self-medication practices of prescription and commonly used over-the-counter medications and alcohol among adults with SCD, and 2) identify the adverse self-medication behaviors of adults living with SCD in the SURF-funded study approved by the University of Connecticut Health Center Institutional Review Board.
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APPENDIX A
Poster to recruit adults with Sickle Cell Disease

Do you have Sickle Cell Disease and take medications?

Are you at least 18 years of age?

If you are at least 18 years old with a history of Sickle Cell Disease and take medications, then you are eligible to participate in this study, “Self Medication Practices of Adults with Sickle Cell Disease.”

You will meet with a researcher once for about 45 minutes to answer some questions. You may receive a 5-10 minute follow up phone call 2 weeks later.

You will receive a $20.00 gift card after completing the interview.

The study is being conducted by Victoria Odesina, APRN DNP and her partners at the University of Connecticut Health Center.

To find out more about this study, please contact Courtney Beyers at 860 679-3893.

UCHC IRB # _______
APPENDIX B Poster presentation by research staff

Self-Medication Practices of Adults with Sickle Cell Disease:
Study Design and Methods

Courtney Marie Beyers, Bachelor of Science in Nursing Honors ‘13
Victoria O. Odusola, DNP, APRN, University of Connecticut Health Center Medication Adherence Program
Patricia J. Heathay, PhD, NNP, Honors Advisor, University of Connecticut School of Nursing

Abstract
Adults with Sickle Cell Disease (SCD) are a significant population to study when considering self-medication behaviors, as they utilize multiple prescription drugs for management of symptoms related to their disease. Adults living with SCD may demonstrate diverse self-medication practices due to the ActavisMed™ program during a single interview and will be contacted 2 weeks after initial interview regarding care management follow-up. This will identify the self-medication practices of prescriber and commonly used over-the-counter (OTC) medications and alcohol among adults with SCD.

Introduction
SCD represents a group of serious inherited blood disorders associated with acute and chronic morbidity, recurrent unpredictable and unrelenting episodes of pain, increased risk of infection, stroke, organ damage and other debilitating complications (Ballas, 2019, NIH, 2003). As a result, adults with SCD are prescribed multiple medications to treat complications of SCD and other comorbidities (Chidena et al., 2016). In addition to the side effects (pneumocystis) of the pain medications, such as episodic that they take for pain relief, it has been documented that many adults with SCD have cognitive deficiencies from ischemia to the brain (Chidena et al., 2016). It is unclear how these factors affect their understanding of treatment plans, follow up instructions and medication adherence. These are potential contributing factors to adverse self-medication practices.

Nexhroy et al. (2016) has demonstrated the potential for adverse self-medication practices in adults with hypertension, a chronic condition such as SCD that leads itself to polypharmacy. Because individuals with SCD are now outgrowing the specialty care of pediatrics, they often find themselves left to manage multiple medications and self-care interventions on their own. Understanding the self-medication practices of those living with SCD is not only related to mortality in their quality of life.

Method
An exploratory descriptive study design was used in the study to identify the self-medication practices of prescriber and commonly used OTC medications and alcohol among adults with SCD using ActavisMed™ web-based software (Figure 1).

Procedure
The study will take place at the University of Connecticut Health Center (UCHC) Sickle Cell clinic. Health care providers at the clinic will screen patients with first patients volunteering to participate. Healthy participants will be contacted by the research assistant. Patients who consent to participate in the study will be shown into a private room.

This study will include 10-20 participants. Inclusion criteria are: 1) adults 18 and older. 2) adults with diagnosis of SCD. 3) English speaking. Patients with SCD under 18 years of age and people with sickle cell trait will be excluded.

This study will require four visits and a follow up contact by phone 2 weeks following the visit. Only one visit is required to complete the survey for this pilot study. The entire process during initial interview will require about 30-45 minutes. Patients who consent to participate in the study will be shown into a private room. Approximately one hour in advance to a regularly scheduled clinic appointment with their health care provider.

Consented participants will be given a randomized non-identifiable ID number. All participants will be asked to return a random ID number on the survey program prior to data entry. De-identified data collected on the ActavisMed™ program, including demographic and medication use survey will be downloaded to the research database via a secure server (Figure 2).

The participant and the health care provider of each participant will provide a brief summary of the interview before the inquiry schedule. UCHC Sickle Cell Clinic appointment through this research interview.

Results
An anonymized summary (Figure 3) for the health care provider’s review shows him or her to make the clinical decision associated with the information. For example, a patient finds him to be at very high risk for multiple adverse drug interactions and is instructed by patient self-report on ActavisMed™ software may be referred to the UCHC Emergency Department for immediate care. The smeared UCHC Sickle Cell Clinic appointment would be deferred at this time.

Health care providers may adjust individual medication regimens based upon the adherence and interactions revealed by the interview summary report (Figures 3 and 4).

Conclusion
Study is in progress at this time. Coded data will be entered into an SPSS Data file. Descriptive analyses will be conducted on all variables organized by race, gender, and age. Frequency distributions of the Advance Self-Medication Behavior Score will be analyzed. Because this is a small pilot study, no corrections will be made based on test period or age.

Significance
The results will be reported in a manuscript and at conferences or workshops. It is the intention of the researcher to use this data to inform the development of a future study with larger sample size, begin to appreciate the self-medication practices of adults with SCD and explore how they impact self-care and health outcomes.

Figure 1: ActavisMed™ Interface showing medication side effect risk stratification.
MUTUAL NONDISCLOSURE AGREEMENT

This Mutual Nondisclosure Agreement (the Agreement), dated as of _______ 2013, is between AdhereRx Corp., a Delaware corporation (AdhereRx), having a place of business at 222 Pilgrim St., East Hartford CT 06108, and __________, an individual having a place of business or residence at __________. To explore the possibility of a business relationship between AdhereRx and Company, each party (Discloser) may disclose sensitive information to the other (Recipient). The parties agree as follows:

1. Definition. Proprietary Information means, to the extent previously, presently or subsequently disclosed by or for Discloser to Recipient, all financial, business, legal and technical information of Discloser or any of its affiliates, suppliers, customers and employees (including information about research, development, operations, marketing, transactions, regulatory affairs, discoveries, inventions, methods, processes, articles, materials, algorithms, software, specifications, designs, drawings, data, strategies, plans, prospects, know-how and ideas, whether tangible or intangible, and including all copies, analyses and derivatives thereof), that is marked or otherwise identified as proprietary or confidential at the time of disclosure, or by which its nature would be understood by a reasonable person to be proprietary or confidential. Proprietary Information shall not include any information that (a) was rightfully known to Recipient without restriction before receipt from Discloser, (b) is rightfully disclosed to Recipient without restriction by a third party, (c) is or becomes generally known to the public without violation of this Agreement by Recipient or (d) is independently developed by Recipient or its employees without access to or reliance on such information. Discloser represents and warrants to Recipient that it is authorized to disclose any and all Proprietary Information made available to Recipient under this Agreement.

2. Restrictions. Recipient agrees (a) to use Discloser’s Proprietary Information only for its consideration internally of a business relationship or transaction between the parties, and its performance in any resulting arrangement, but not for any other purpose, (b) to maintain it as confidential, and exercise reasonable precautions to prevent unauthorized access to it, (c) not to copy Discloser’s Proprietary Information, (d) not to disclose it to any third party other than Recipient’s employees and agents who have a need to know for the permitted purpose and who are apprised of the confidential nature of the Proprietary Information and all of the restrictions in this Agreement, (e) not to decompile, disassemble or otherwise reverse engineer any Proprietary Information provided hereunder, or use any similar means to discover its underlying composition, structure, source code or trade secrets and (f) not to export or reexport any Proprietary Information or product thereof in violation of US or other export control laws or regulations. The terms and conditions of any transaction or possible transaction between the parties, the fact that disclosures, evaluations or discussions are taking place, and the status and results thereof will also be held in confidence by both parties and not disclosed to any third party. Each party shall be responsible for any breach of confidentiality by its respective employees and agents. Immediately upon Discloser’s request at any time, Recipient shall return to Discloser all originals and copies of any Proprietary Information and destroy all information, records and materials developed therefrom.

3. Compelled Disclosures. These restrictions will not prevent either party from complying with any law, regulation, court order or other legal requirement that purports to compel disclosure of any Proprietary Information. Recipient will promptly notify Discloser upon learning of any such legal requirement, and cooperate with Discloser in the exercise of its right to protect the confidentiality of the Proprietary Information before any tribunal or governmental agency.

4. No Warranties or Licenses. All Proprietary Information is provided “AS IS.” Discloser will not be liable to Recipient for damages arising from any use of the Proprietary Information, from errors, omissions or otherwise. All of Discloser’s rights in and to its Proprietary information remain the exclusive property of Discloser. Neither this Agreement, nor any disclosure of Proprietary Information hereunder (a) grants to Recipient any right or license under any copyright, patent, mask work, trade secret or other intellectual property right, except solely for the use expressly permitted herein, (b) obligates either party to disclose or receive any information, perform any work or enter into any agreement, (c) limits either party from developing, manufacturing or marketing products or services that may be competitive with those of the other except insofar as this Agreement limits the use and disclosure of Proprietary Information, (d) limits either party from assigning or reassigning its employees in any way or (e) limits either party from entering into any business relationship with third parties.

5. Termination. This Agreement will terminate as to the further exchange of Proprietary Information immediately upon the earlier of (a) receipt by one party of written notice from the other and (b) the first anniversary of this Agreement. The confidentiality obligations of this Agreement, as they apply to Proprietary Information disclosed prior to termination, will survive termination for a period of 5 years; provided, Recipient’s obligations hereunder shall survive and continue in effect thereafter with respect to any Proprietary Information that is a trade secret under applicable law. Upon termination of this Agreement, Recipient shall return to Discloser all originals and copies of any Proprietary Information and destroy all information, records and materials developed therefrom.
6. Remedies. Due to the unique nature of the Proprietary Information, the parties agree that any breach or threatened breach of this Agreement will cause not only financial harm to Discloser, but also irreparable harm for which money damages will not be an adequate remedy. Therefore, Discloser shall be entitled, in addition to any other legal or equitable remedies, to an injunction or similar equitable relief against any such breach or threatened breach without the necessity of posting any bond.

7. General. This Agreement constitutes the entire agreement, and supersedes all prior negotiations, understandings or agreements (oral or written), between the parties concerning the subject matter hereof. This Agreement may be executed in one or more counterparts, each of which is an original, but taken together constituting one and the same instrument. Execution of a facsimile copy shall have the same force and effect as execution of an original, and a facsimile signature shall be deemed an original and valid signature. No change, modification or waiver to this Agreement will be effective unless in writing and signed by the party against which enforcement is sought. The failure of either party to enforce its rights under this Agreement at any time for any period shall not be construed as a waiver of such rights. Unless expressly provided otherwise, each right and remedy in this Agreement is in addition to any other right or remedy, at law or in equity, and the exercise of one right or remedy will not be deemed a waiver of any other right or remedy. In the event that any provision of this Agreement shall be determined to be illegal or unenforceable, that provision will be limited or eliminated to the minimum extent necessary so that the Agreement shall otherwise remain in full force and effect and enforceable.

This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, USA without regard to the conflicts of laws provisions thereof. Exclusive jurisdiction and venue for any action arising under this Agreement is in the federal and state courts located in Massachusetts having jurisdiction over Adherex's principal office, and both parties hereby consent to such jurisdiction and venue for this purpose. In any action or proceeding to enforce or interpret this Agreement, the prevailing party will be entitled to recover from the other party its costs and expenses (including reasonable attorneys' fees) incurred in connection with such action or proceeding and enforcing any judgment or order obtained. Any notice hereunder will be effective upon receipt and shall be given in writing, in English and delivered to the other party at its address given herein or at such other address designated by written notice.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as a sealed instrument, effective as of the date and year first written above.

ADHEREEX CORP. COMPANY

By: ___________________________ By: ___________________________

Name: ___________________________ Name: ___________________________

Title: ___________________________ Title: ___________________________
APPENDIX D paper and pencil survey items targeted at hydration status

Interview questions to be recorded by student researcher with paper and pencil.

What is your highest level of education completed, such as some high school, completed high school, some college, completed college? (open ended response)

Tell me about the things you would drink on a regular day, such as coffee, tea, water, soda, juice?

Per response (example: juice) about how many cups of juice per day do you think you drink? Small cups or large cups?

Continues ...

*Alcohol will be asked via KnowMyMeds software program. Illicit drug use will not be asked via paper and pencil interview, will not be asked via KnowMyMeds software program.
APPENDIX E

Follow-up Phone Call Interview Questionnaire:

1) After the ActualMeds™ interview, has your health care provider made changes to your medicines?

2) What change suggestions were made to the way that you take your medicines in the last two weeks?

3) In the last two weeks, have you personally made any changes to the way that you take medications, on your own accord?

4) Do you have any thoughts or concerns at this time, related to the ActualMeds™ study, that you would like me to know?
APPENDIX F IRB Chair Comments

The following are comments from the IRB chair regarding your new study. Please let me know if you have any questions when addressing the changes.

1. Please clarify that the data collected will be coded with a subject (randomized) number and linked with a master list, the master list should be stored separate from the data. Describe how the subject (randomized) number is created. Also address who will provide (create) the code, which should be the PI and you, not the program. Clarify that only de-identified data is shared with the server/program. Describe how the subject (randomized) number is created. Also address who will provide (create) the code, which should be the PI and you, not the program. Clarify that only de-identified data is shared with the server/program.

2. Clarify that the flyers will not be mailed to SCD patients and specify where they will be posted. Describe the process for the physicians handing the recruitment information sheet to patients.

3. Decide when you will be calling the patients back after their initial visit. 2 days, 2 weeks or 30 days? Address the questions being asked to make them appropriate for the time span for the call back.

4. Clarify that the report will be given to the patients' health care provider following the interview and whether the report will be put in the medical chart. Provide a letter from the director of the SC, Dr. Biree Andemariam supporting your study.

5. Phone script should "ask" all questions regarding eligibility as described in the HIPAA Waiver #1. Are you meeting with the potential subject at the UCHC clinic prior to their scheduled clinic visit? How/where will you record the patients information (name and telephone number) if they are determined eligible for the meeting? This information should only be collected once they are eligible and agreed to meet with you.

6. ICF waiver, Item #1, indicate that the waiver is only for initial phone screen. Item #2, correct response to collect name and phone number only if the potential subject is eligible. Third sentence, correct to say "consent will be obtained...". Item #3, Please address the question being asked.

The Protocol (page 4, data collection procedures), IRB Application and Consent must be re-written to address all these issues. The chair has provided some hand written comments, please provide a fax number and I will fax them to you.
APPENDIX G

April 12, 2013

To whom it may concern,

I am writing to express my support for nursing student-initiated research, "Self-Medication Practices of Adults with Sickle Cell Disease," led by project PI Victoria Odesina, DNP, APRN. This research is important in understanding medication management, such as high-risk medication adherence behaviors, prescription drug interactions, and over-the-counter drug interactions with prescription drugs in the UCHC patient population of adults living with Sickle Cell Disease (SCD).

Patients with SCD with a health care provider at UCHC will be informed of this study via flyer advertisements posted in the UCHC Neag Comprehensive Cancer Center clinic space, infusion room, and JDH AACU. Flyer advertisements will also be mailed to the primary residence of patients with SCD and distributed into the community via SCD advocacy organizations, such as CQSCC meeting space and website.

The researcher will be in a private room on clinic days to enroll interested patients with SCD. Patients who are eligible and consented as study participants will be asked about their self-medication practices by the researcher in a private room at UCHC, which will be recorded on the Apple® iPad® AdhereTx™ KnowMyMeds™ software program during a single “brown bag” medication survey interview. This study will 1) identify the self-medication practices of prescribed and commonly used over-the-counter medications and alcohol among adults with SCD and 2) identify the adverse self-medication behaviors of adults living with SCD. For the purposes of this survey pilot research, only 10-20 participants will be enrolled in the study.

The AdhereTx™ KnowMyMeds™ software program will generate a summary report at the conclusion of the research interview. The researcher will provide a copy of the summary report to the participant’s health care provider. The research interview summary report will be included in the participant's medical chart, and has the potential to reveal documented adverse self-medication practices per the participant's self-report. Health care providers will be prepared to review the summary and act accordingly in the best interest of the study participant (patient).

We expect three types of summary report results and actions for health care providers to take:
1) No risk – providers will review information and continue plan of care;
2) Moderate risk – providers will make changes to participant medication regimen if necessary;
3) High risk – providers will make changes and/or refer participants to UCHC Infusion Room or Emergency Dept for urgent care if necessary.

Study participants will be contacted 2 weeks after initial interview by the researcher via phone contact regarding self-care management follow-up.
This area of research is critical in the care of adults with SCD and I wholeheartedly support its implementation.

Sincerely,

Biree Andemariam, M.D.
Assistant Professor of Medicine
Division of Hematology-Oncology
Director, Adult Comprehensive Sickle Cell Center
University of Connecticut Health Center
263 Farmington Avenue
Farmington, CT 06030
860-679-7590
Andemariam@uchc.edu
APPENDIX H

University of Connecticut Health Center
Human Subjects Protection Office

To: Victoria Olenska
Principal Investigator
Community Medicine & Health Care

From: UConn Health Center
IRB Office

Date: May 9, 2013

Re: Final Approval of Expedited Project
IRB Number: 13-161S-1
IRB Panel: Panel 1
Project Title: Self-Medication Practices of Adults with Sickle Cell Disease
Sponsor / Funding Agency: Principal Investigator -
Approval Investigators: Olenska, Victoria -
Consent Version: Version 1

The study referenced above has received final approval from the IRB.

The study was approved on 5/6/2013. The study was determined to qualify for expedited review in accordance with 45 CFR 46.110 under category(ies) 7. IRB approval is valid through 5/5/2014. IRB approval will lapse the following day unless the investigator submits and receives approval of a request for continuation. The IRB will send one reminder notice as a courtesy however the Principal Investigator is responsible for requesting continuation. Please note that all approved studies are also subject to audit by the Research Compliance Monitor.

If applicable to your study, copies of the IRB stamped and dated informed consent form must be used when obtaining consent. The consent form must be signed and dated by both the participant and the individual obtaining consent.

It is the responsibility of the PI to ensure that all investigators and staff associated with this study: 1) follow the approved protocol; 2) use the approved forms; 3) comply with all IRB policies including the reporting of non-compliance with the approved protocol, unanticipated problems involving risk to subjects or others, adverse events, and any suspensions or terminations of IRB approval; and 4) comply with applicable regulations and the requirements or determinations of the IRB. Policies are available from the web site, http://hspe.uche.edu/.

PI’s are also responsible for ensuring that IRB approval has been obtained and maintained at any collaborating sites involved in the research. Approval must be in place before the research can begin.

If applicable to your study, copies of the stamped and dated consent form must be used when obtaining consent and the form must be signed and dated by both the participant and individual obtaining consent.

Address all correspondence to IRB Office, MC 3326. If you have questions, call the IRB Office at 679-4849.

cc: Courtney Byers
Diane Clavette
To: IRB Office  
UConn Storrs  

From: IRB Office  
UConn Health Center  

Date: May 9, 2013  

Re: Acceptance of Role as IRB of Record  

Per the cooperative agreement in place, the Institutional Review Board of the UConn Health Center is willing to serve as the IRB of record for the study noted below. In this role the IRB of UCHC will be responsible for all continuing review, review of amendments, and review of adverse events. The UCHC IRB will keep the UConn Storrs IRB apprised of such activity.  

Title: Self-Medication Practices of Adults with Sickle Cell Disease  

UCHC Reference Number: 13-1615-1  

PI: Victoria Odesina  

Co-Investigator(s): n/a  

Via copy of this memo, the PI has been informed that he/she must submit the initial application to the UConn Storrs IRB and confirm that UConn Storrs has accepted the review of UCHC prior to starting the project.
## APPENDIX I

Table 1 Trial 1 Medication List

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage/Route/Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ativan [+]</td>
<td>1 pill / oral / 1 mg</td>
</tr>
<tr>
<td>Benadryl</td>
<td>2 pills / oral / 25 mg</td>
</tr>
<tr>
<td>Dilaudid</td>
<td>4 pills / oral / 4 mg</td>
</tr>
<tr>
<td>Excedrin</td>
<td>1 pill / oral / 250 mg</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>1 / transdermal / 25 mg/hr</td>
</tr>
<tr>
<td>Folic acid [+]</td>
<td>1 pill / oral / 1 mg</td>
</tr>
<tr>
<td>Hydrea</td>
<td>1 capsule / oral / 400 mg</td>
</tr>
<tr>
<td>Insulin lispro</td>
<td>4 spoons / subcutaneous / 100 units/mL</td>
</tr>
<tr>
<td>Insulin regular</td>
<td>16 inj / injectable / human recombinant 100 units/mL</td>
</tr>
<tr>
<td>Lovanex</td>
<td>1 inj / injectable / 100 mg/mL</td>
</tr>
<tr>
<td>Percocet 10/325</td>
<td>1 pill / oral / 325 mg-2.5 mg</td>
</tr>
<tr>
<td>Tylenol</td>
<td>1 pill / oral / 325 mg</td>
</tr>
<tr>
<td>Tylenol PM</td>
<td>1 pill / oral / 600 mg-60 mg</td>
</tr>
</tbody>
</table>
### Table 2: Trial 2 Medication List

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage/Route/Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advair Diske +</td>
<td>2 / inhalation / 260 mcg/60 mcg</td>
</tr>
<tr>
<td>Albuterol</td>
<td>1 spoon / inhalation / 1.25 mg/3 mL (0.042%)</td>
</tr>
<tr>
<td>Amoxicillin +</td>
<td>4 pills / oral / 500 mg</td>
</tr>
<tr>
<td>Ativan +</td>
<td>6 pills / oral / 2 mg</td>
</tr>
</tbody>
</table>
| bumetanide/Chloramphenicol/B 
  polymyxin B 
  ophthalmic             | 1 / ophthalmic / 400 units/10 mg - 3.5 mg/10000 units/g   |
<p>| Cadizam +                 | 1 pill / oral / 60 mg                                      |
| Celecoxib +               | 1 capsule / oral / 100 mg                                  |
| Clonazepam                | 1 pill / oral / 10 mg                                      |
| Dilaudid                  | 4 pills / oral / 8 mg                                      |
| Eloxate                   | 1 pill / oral / 250 mg                                     |
| Flovent Diskus            | 1 / inhalation / 50 mcg                                    |
| Hydra (+)                 | 1 capsule / oral / 200 mg                                  |
| Levesquim +               | 1 pill / oral / 500 mg                                     |
| Simvastatin +             | 1 pill / oral / 10 mg                                      |
| Timolol ophthalmic        | 4 spoons / ophthalmic / 0.5%                               |
| Warfarin +                | 1 pill / oral / 2 mg                                       |</p>
<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage/Route/Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability [*]</td>
<td>1 pill / oral / 30 mg</td>
</tr>
<tr>
<td>Acetaminophen/guaifenesin/phenylephrine</td>
<td>1 pill / oral / 250 mg-1100 mg</td>
</tr>
<tr>
<td>Alcohol</td>
<td>1 drink</td>
</tr>
<tr>
<td>Biafradyl</td>
<td>4 capsules / oral / 25 mg</td>
</tr>
<tr>
<td>Benepropradiol-Hydrochlorothiazide [*]</td>
<td>1 pill / oral / 10 mg-0.25 mg</td>
</tr>
<tr>
<td>CeleXA [*]</td>
<td>1 pill / oral / 40 mg</td>
</tr>
<tr>
<td>Dilaudid</td>
<td>1 / oral / 22 mg</td>
</tr>
<tr>
<td>Eladre</td>
<td>1 pill / oral / 250 mg</td>
</tr>
<tr>
<td>Femarin</td>
<td>8 / transdermal / 25 mcg/hr</td>
</tr>
<tr>
<td>Hyspa</td>
<td>1 pill / oral / 1000 mg</td>
</tr>
<tr>
<td>Jurnal FE 1.5/30</td>
<td>1 pill / oral / 35 mcg-0.5 mg</td>
</tr>
<tr>
<td>Lovenox</td>
<td>1 inj / injectable / 100 mg/mL</td>
</tr>
<tr>
<td>MyQuill Cold/Flu Relief Cherry</td>
<td>1 capsule / oral / 325 mg-15 mg</td>
</tr>
<tr>
<td>Porzocet 19236 [*]</td>
<td>1 pill / oral / 400 mg-6 mg</td>
</tr>
<tr>
<td>RilSESC CTC</td>
<td>4 / oral / 20 mg</td>
</tr>
<tr>
<td>Robitussin Allergy &amp; Cough</td>
<td>4 spoon / oral / 1 mg-5 mg-12.5 mg/mL</td>
</tr>
</tbody>
</table>
## APPENDIX J

**Table 1** Recorded interface sessions, student researcher completed data entry

<table>
<thead>
<tr>
<th>Timed Sessions</th>
<th>Trial 1 iPad with touchscreen use</th>
<th>Trial 2 iPad with stylus</th>
<th>Trial 3 iPad with stylus and wireless keyboard accessory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results in minutes</td>
<td>57</td>
<td>45</td>
<td>35</td>
</tr>
</tbody>
</table>
The Post-Study System Usability Questionnaire (PSSUQ<sup>1</sup>)

Responses reported by student researcher in usability testing

<table>
<thead>
<tr>
<th>Question</th>
<th>Trial 1 iPad, touchscreen use</th>
<th>Trial 2 iPad with stylus</th>
<th>Trial 3 iPad with stylus and wireless keyboard accessory</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Overall, I am satisfied with how easy it is to use this system.</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2. It was simple to use this system.</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3. I could effectively complete the tasks and scenarios using this system.</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>4. I was able to complete the tasks and scenarios quickly using this system.</td>
<td>7</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>5. I was able to efficiently complete the tasks and scenarios using this system.</td>
<td>5</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>6. I felt comfortable using this system.</td>
<td>5</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>7. It was easy to learn to use this system.</td>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>8. I believe I could become productive quickly using this system.</td>
<td>6</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>9. The system gave error messages that clearly told me how to fix problems.</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>10. Whenever I made a mistake using the system, I could recover easily and quickly.</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>11. The information (such as on-line help, on-screen messages and other documentation) provided with this system was clear.</td>
<td>2</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>12. It was easy to find the information I needed.</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>13. The information I provided for the system was easy to understand.</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>14. The information was effective in helping me complete the tasks and scenarios.</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>15. The organization of information on the system</td>
<td>5</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

<sup>1</sup> Likert scale range 1-7 used, number 1 as “strongly agree” to number 7 as “strongly disagree”
screens was clear.

Table 3 Usability findings--Summary of major recommendations by student researcher for improving the use of ActualMeds™ program

<table>
<thead>
<tr>
<th>Problem</th>
<th>Frequency $n^2$ (all trials)</th>
<th>Proposed solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scrolling feature attempted for use, NCD code entry</td>
<td>16</td>
<td>1) Bar scanning (to be released in 2013); 2) develop scrolling feature; 3) type exact entry to avoid scrolling</td>
</tr>
<tr>
<td>Menu selection items are limited in patient self-reported conditions, symptoms.</td>
<td>6</td>
<td>1) Allow free-text feature for items to be included; 2) develop more comprehensive list for menu items, such as itching</td>
</tr>
<tr>
<td>“Homeless” is not an available menu item for patient self-reported living situation</td>
<td>2</td>
<td>1) include “homeless” as a menu choice item, as this is seen in this particular patient population; 2) allow for a free text feature to type items into the program</td>
</tr>
</tbody>
</table>

$^2 n = \text{number of times event occurred during all trials (total) usability study.}$
Table 4 Major teaching points from formal usability study

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>ActualMeds™ has optimal visual design and usability when iPad® is used in horizontal position</td>
</tr>
<tr>
<td>2.</td>
<td>Allow more free text features, such as patient self-reported select conditions and symptoms. For example, pruritis or itching was not available to select from the menu; pruritis is commonly experienced in adults with SCD as a side effect of opioid medications for pain.</td>
</tr>
<tr>
<td>3.</td>
<td>Expand “living situation” to include lower SES population, such as “homeless” added as a menu selection choice.</td>
</tr>
</tbody>
</table>
1. Overall, I am satisfied with how easy it is to use this system.

<table>
<thead>
<tr>
<th>STRONGLY AGREE</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>STRONGLY DISAGREE</th>
</tr>
</thead>
</table>

COMMENTS:

2. It was simple to use this system.

<table>
<thead>
<tr>
<th>STRONGLY AGREE</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>STRONGLY DISAGREE</th>
</tr>
</thead>
</table>

COMMENTS:

3. I could effectively complete the tasks and scenarios using this system.

<table>
<thead>
<tr>
<th>STRONGLY AGREE</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>STRONGLY DISAGREE</th>
</tr>
</thead>
</table>

COMMENTS:

4. I was able to complete the tasks and scenarios quickly using this system.

<table>
<thead>
<tr>
<th>STRONGLY AGREE</th>
<th>1</th>
<th>2</th>
<th>3</th>
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<th>6</th>
<th>7</th>
<th>STRONGLY DISAGREE</th>
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</table>

COMMENTS:

APPENDIX K
5. I was able to efficiently complete the tasks and scenarios using this system.

<table>
<thead>
<tr>
<th>STRONGLY AGREE</th>
<th>1</th>
<th>2</th>
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6. I felt comfortable using this system.

<table>
<thead>
<tr>
<th>STRONGLY AGREE</th>
<th>1</th>
<th>2</th>
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<td>COMMENTS:</td>
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</table>

7. It was easy to learn to use this system.

<table>
<thead>
<tr>
<th>STRONGLY AGREE</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<td>COMMENTS:</td>
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</tbody>
</table>

8. I believe I could become productive quickly using this system.

<table>
<thead>
<tr>
<th>STRONGLY AGREE</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<td>COMMENTS:</td>
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</tbody>
</table>
9. The system gave error messages that clearly told me how to fix problems.

<table>
<thead>
<tr>
<th>STRONGLY AGREE</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>STRONGLY DISAGREE</th>
</tr>
</thead>
</table>

COMMENTS:

10. Whenever I made a mistake using the system, I could recover easily and quickly.

<table>
<thead>
<tr>
<th>STRONGLY AGREE</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>STRONGLY DISAGREE</th>
</tr>
</thead>
</table>

COMMENTS:

11. The information (such as on-line help, on-screen messages and other documentation) provided with this system was clear.

<table>
<thead>
<tr>
<th>STRONGLY AGREE</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>STRONGLY DISAGREE</th>
</tr>
</thead>
</table>

COMMENTS:

12. It was easy to find the information I needed.

<table>
<thead>
<tr>
<th>STRONGLY AGREE</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>STRONGLY DISAGREE</th>
</tr>
</thead>
</table>

COMMENTS:
13. The information provided for the system was easy to understand.

| STRONGLY AGREE | 1 | 2 | 3 | 4 | 5 | 6 | 7 | STRONGLY DISAGREE |

COMMENTS:

14. The information was effective in helping me complete the tasks and scenarios.

| STRONGLY AGREE | 1 | 2 | 3 | 4 | 5 | 6 | 7 | STRONGLY DISAGREE |

COMMENTS:

15. The organization of information on the system screens was clear.

| STRONGLY AGREE | 1 | 2 | 3 | 4 | 5 | 6 | 7 | STRONGLY DISAGREE |

COMMENTS:

APPENDIX H
usability study is in a non-laboratory setting. Appendix Table 1 contains the rules for calculating the CSUQ and PSSUQ scores.

<table>
<thead>
<tr>
<th>Score Name</th>
<th>Average the Responses to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>OVERALL</td>
<td>Items 1 through 19</td>
</tr>
<tr>
<td>SYSUSE</td>
<td>Items 1 through 8</td>
</tr>
<tr>
<td>INFOQUAL</td>
<td>Items 9 through 15</td>
</tr>
<tr>
<td>INTERQUAL</td>
<td>Items 16 through 18</td>
</tr>
</tbody>
</table>

Average the scores from the appropriate items to obtain the scale and subscale scores. Low scores are better than high scores due to the anchors used in the 7-point scales. If a participant does not answer an item or marks "N/A," then average the remaining item scores.