USING INFORMATICS TO FACILITATE HOSPITAL PASTORAL CARE VISITS: A PROOF OF CONCEPT STUDY

By

Sophia Norella

Thesis

Submitted to the Faculty of the

Graduate School of Vanderbilt University

in partial fulfillment of the requirements

for the degree of

MASTER OF SCIENCE

in

Biomedical Informatics

December, 2011

Nashville, Tennessee

Approved:

Professor Randolph A. Miller

Professor Nancy M Lorenzi

Professor Ellen W Clayton

Professor S Trent Rosenbloom

ACKNOWLEDGEMENTS

This work was sponsored by the National Library of Medicine through Vanderbilt Biomedical Informatics training grant, 3T15LM007450-08S1. Without their financial support, this work would not have been possible.

I am grateful to my advisor, Dr. Randolph Miller, and to my thesis committee consisting of Dr. Nancy Lorenzi, Dr. S. Trent Rosenbloom, and Dr. Ellen Clayton, for their help with this work. The other DBMI faculty, staff, and students were very helpful to me in many ways, such as listening to me while I explored ideas, giving me suggestions and input when I was stuck on various aspects of study design, and providing both direction and moral support. Joyce Green and Rischelle Jenkins were both extremely helpful with administrative tasks and providing moral support. Dr. Cynthia Gadd, and Dr. Bradley Malin also offered guidance for methodology. Dr. Dario Guise and his StarPanel team, including David Staggs, Jonathan Grande, and Karen Hughart all assisted me greatly by providing me with a "home" for my system and their help in integrating segments of my code into the StarPanel EMR system. Elizabeth Ashley Durham and Randy Carnevale supplied useful data and advice. Dr. Joshua Denny helped me to understand the hospital environment and provided several important clinical contacts for the study. Dr. Elliot Fielstein provided me with feedback regarding the IRB application process. Taneya Koonce assisted with my literature search. Glenn Gobbel and Joshua Smith both listened to my ideas and regularly offered feedback and suggestions throughout the project.

Vanderbilt University Hospital is a collegial and supportive environment in which many busy people generously gave me their time and guidance for the project. I could not have done this work without the help of hospital administrators and employees. Pam Jones, Marilyn Dubree, and Terrell Smith and the Patient and Family Advisory Council offered insight into the hospital environment and informed the development of this work. Gaye Smith, and Susan Hannasch helped me to understand the regulatory and legal frameworks involved with the study. The Department of Pastoral Care, particularly Rev. Barry Culbertson and Lisa Meyers were instrumental in gaining support both from internal chaplains as well as external (community) clergy. Dr. James Powers, Michael Jorden, and the hospital nursing staff members further assisted me with the clinical workflow aspects of this project.

Several community members were instrumental in helping me to get this project going and to gain acceptance within local religious institutions. These people were extraordinarily generous with their time, and I cannot thank them enough for having helped to turn this project from an idea into a working system. These people include: Fr. Robert Cowperthwaite; Claire Gaddis; Rev. Rus Roach; Amanda Poff; John Ross; Thomas Kleinert; Denise Mistich; Rev. Dr. Kenneth Corr; Rev. Dr. Sandra Randleman; and Rev. Dr. Michael Ripski.

Finally, I want to thank my close friends and family for giving me their love and support throughout this process and for making my adjustment to life in Nashville and as a graduate student much easier than it would have been otherwise. These people include: Robert and Rhonda Scarlata; Bea Scarlata; Carly Day; Lisa Scott; Olivia Norella; and Randy Carnevale.

TABLE OF CONTENTS

Page

ACKNOWLEDGEMENTS ii

LIST OF TABLES vi

LIST OF FIGURES vii

LIST OF ABBREVIATIONS viii

Chapter

I. INTRODUCTION TO INFORMATICS-BASED HOSPITAL PASTORAL VISIT FACILITATION SYSTEM 1

Introduction and Study Overview 1
Current Study Setting: Vanderbilt University Hospital 1
Project Team Members 2
Literature Review: Pastoral Care and Patient Engagement 3
Spiritual and Religious Care 3
The Nature and Purpose of Professional Hospital Chaplain Pastoral Care 6
Patient-Engagement and Patient-Centered Care 7
Pastoral Care and the HIPAA Privacy Rule 7
Informatics and SR Care 10
Matching Algorithm and Model Development 11
Data Security 12
Ethical Considerations 13

II. METHODS FOR INFORMATICS BASED PASTORAL VISIT FACILITATION SYSTEM STUDY 15

Overview of Complete Study Methods 15
Needs and Feasibility Assessments 15
Socio-Religious Needs Assessment Methods 15
Legal and Clinical Feasibility Assessment Methods: Interviews with Key Personnel 17
Overview Matching Algorithm Development and Validation Methods 18
Matching Algorithm and Technical Component Development: Tests Using Historical VUMC Patient Record Data 18
Matching Algorithm Validation and Threshold Determination: Tests Using Sample Record Pair Data 22
Retrospective Analysis: Tests Using Historical VUH Census Data 25
Methods: Pilot Test of the Pastoral Visit Facilitation System 25

III. RESULTS OF INFORMATICS-BASED PASTORAL VISIT FACILITATION PROJECT 32

Results: Study Enrollees and Non-Participants 32
Needs and Feasibility Assessment Results 36
Socio-Religious Needs Assessment 36
Legal and Clinical Feasibility Assessment: Interviews with Key Personnel 37
Overview Matching Algorithm Development and Validation 39
Matching Algorithm Development: Tests Using Historical VUMC Historical Patient Record Data 39
Matching Algorithm Validation and Threshold Determination: Tests Using Sample Record Pair Data 40
Retrospective Analysis: Tests Using Historical VUH Census Data 44
Results: Pilot Test of the Pastoral Visit Facilitation System 45

IV. DISCUSSION AND CONLCUSIONS 49

Overall Summary of Study 49
Discussion of Pastoral Visit Facilitation Study 50
Study Limitations 52
Future Directions: Areas for Further Study 54

Appendix

A. IRB APPLICATION DOCUMENTS 56

B. PRE-IMPLEMENTATION SURVEY FOR CLERGY 78

C. INSTRUCTIONS FOR RELIGIOUS INSTITUTION ADMINSTRATORS IN CHARGE OF MEMBERSHIP DATABASE 80

D. HIPAA-INFORMATION RELEASE AUTHORIZATION FORM 85

BIBLIOGRAPHY 87

LIST OF TABLES

Table Page

1. Study Interest and Participation by Nominated Site……34

2. Proportion of Individuals in Vanderbilt University Historical Medical Record Dataset Uniquely Identified by Character Combinations for Snippets, With and Without Date of Birth Information……...40

LIST OF FIGURES

Figure Page

1. Flow Chart Depiction of Pilot Study Processes……..30

2. Flow Chart of Religious Institutions' Study Interest, Enrollment and Dropouts……35

3. Description of Data Used for Validation and Threshold Determination…… 41

4. Recall-Precision for Matching Algorithm Validation and Threshold Determination……..42

5. ROC for Matching Algorithm Validation and Threshold Determination…….. 43

LIST OF ABBREVIATIONS

EHR.....electronic health record

DPC.....Department of Pastoral Care

VU.....Vanderbilt University

VUMC.....Vanderbilt University Medical Center

VUH.....Vanderbilt University Hospital

CHAPTER I

INTRODUCTION TO INFORMATICS-BASED HOSPITAL PASTORAL VISIT FACILITATION SYSTEM

Introduction and Study Overview

The current study sought to address the problem of facilitating pastoral care visits for patients from clergy by whom patients want to be visited. This Master's Thesis project: (1) assessed the potential utility of a model, including supporting algorithms, to facilitate inpatient pastoral care visits by patients' "home" clergy; (2) examined the ability of the model to comply with existing HIPAA regulations and general ethical principles; (3) implemented the model in a pilot trial in Middle Tennessee; and (4) evaluated the model's functionality via the pilot study, to inform and direct future model evolution. While the model is general and could in theory apply to any religious institution and any hospital, the current pilot study involved adult patients (age 18 or older) at Vanderbilt University Hospital in Nashville, TN and two Middle Tennessee religious institutions that volunteered to serve as test sites and which complied with Institutional Review Board criteria.

Current Study Setting: Vanderbilt University Hospital

The setting for the pilot study, covering May 2010-July 2011, was Vanderbilt University Hospital (VUH), an 832-bed academic medical center located in Nashville, TN. The Department of Pastoral Care (DPC) at Vanderbilt University Medical Center

(VUMC) includes a trained staff of seven full-time chaplains representing different religions and faiths. The DPC provides a number of critical services, including spiritual guidance, administration of rites and rituals, and counseling for death or crisis to help patients and their families during difficult times. Their stated mission is to be "a ministry of compassion dedicated to meeting the spiritual needs of patients and families." Their work serves an important role in VUMC's patient care processes. This project sought to expand and supplement that role.

The Medical Center has a well-developed informatics infrastructure. That infrastructure supports a large array of patients' and clinicians' information needs and includes a state-of-the-art electronic heath record system (EHR). The existence of this infrastructure enabled the study to explore ways in which an integrated patient-information framework could support the facilitation of hospital pastoral care visits.

Project Team Members

The project team for this study was led by Sophia Norella (the PI). Ms. Norella is a graduate student in the Department of Biomedical Informatics at Vanderbilt University, and this study represents her thesis work. The project team also included Randolph Miller, MD, Ms. Norella's thesis advisor and Committee Chair. Dr. Miller is a Professor of Biomedical Informatics and the Donald AB and Mary M Lindberg University Professor of Biomedical Informatics, Medicine, and Nursing. Ms. Norella and Dr. Miller will be referred to as "the study team members" unless otherwise specified.

Other members of Ms. Norella's thesis committee who contributed to the project include: Nancy Lorenzi, MLS, MA, PhD, Professor of Biomedical Informatics, Clinical

Professor in Nursing, and Assistant Vice-Chancellor for Health Affairs; S. Trent Rosenbloom, MD, MPH, Associate Professor of Biomedical Informatics, Associate Professor of Internal Medicine and Pediatrics, and Associate Professor of Nursing; and Ellen Wright Clayton, MD, JD, Craig-Weaver Professor of Pediatrics, Professor of Law, and Director of Vanderbilt University's Center for Biomedical Ethics and Society.

Additional individuals, named below, also contributed to the study.

Literature Review: Pastoral Care and Patient Engagement

Hospital care for ill and injured individuals should include appropriate patient-specific attention to spirituality and religion (SR).[1,2] Ideally, physicians and nurses should always identify when patients are in need of SR care and refer them to hospital chaplains for that care, or alternatively initiate pastoral care visits from their own "home" religious institution clergy. However, these referrals do not always happen when they should.[3,4] Reasons for shortcomings in SR care, discussed below, include: (1) complex relationships among spirituality, religion, and clinical care; (2) lack of integration of education about SR issues into clinical curricula and training; and (3) lack of information in the clinical literature addressing how one should address concerns of patients whose religions and faiths differ from one's own beliefs.

Spiritual and Religious Care

Spiritual and religious (SR) care can improve patient psychological outcomes by providing emotional comfort and a sense of meaning and hope.[5-9] It also helps to provide patients with a feeling of community and assists patients with decision-making.[10]

Previous research indicates that SR care increases happiness and life satisfaction as well as decreasing pain levels in cancer patients.[11] Cardiac surgery patients who received SR care in their preparation for and recovery from surgeries had lower levels of depression and anxiety.[12]

A previous MEDLINE review of literature from 1980-2005 using the search term "spiritual care"[13] identified two distinctly religious/spiritual categories of interventions from among other more general categories, such as counseling, emotional support, advocacy, and general support. The two SR categories were: (1) religious interventions, such as prayer and discussion of religion; and (2) spiritual interventions, including end of life care and assistance with searches for meaning and hope.

Nursing staff members provide inpatients' primary interface to and means of SR support. However, complexity and controversy surround issues of nursing-based SR care.[14,15] The nursing literature does not define SR care in a clear, meaningful way that can inform nursing practice. Nursing literature definitions are too inclusive and equate SR care to psychosocial care.[16-18] Such definitions are often difficult for nurses to implement pragmatically. Nursing SR care depends on personal factors of individual nurses (e.g. local culture).[19] While 20% of inpatient chaplain visits result from clinician referrals, studies indicated that nurses generate most referrals.[20,21] The overall paucity of chaplain referrals may reflect inadequate attention to SR issues in nursing education. A 2010 study found that an SR care training course for nurses increased pastoral care referrals and nurse sensitivity to patients' SR concerns.[22]

Nursing literature often defines spirituality and religion as distinct concepts.[23] It suggests that nurses are responsible for spiritual but not religious care. The literature

suggests conditions in which referrals to chaplains should be made, such as patient expressions of fear, abandonment, guilt, and other concomitants of spiritual distress.[24,25] It also advises healthcare professions to engage in a continuing dialogue with chaplains to improve the process nurses refer patients to chaplains and support SR care.[25]

While physicians sometimes address issues of SR care with patients, they often hesitate to have difficult SR-related discussions.[26] Physicians do not always receive ample training to help them approach SR issues with patients and families.[1,27] One study indicated that a majority of inpatients in a family practice expected physicians to consider SR needs.[28] A majority of these patients also reported that their physicians had not discussed SR issues with them. Another study found that approximately half of physicians believe that they should play a primary role in SR care, especially for patients in dire conditions.[29] Physicians who identify themselves as religious were much more likely to engage patients in SR care, while physicians who were not religious tended to wait for the patient to raise the subject.[30]

In a University of Pennsylvania outpatient study, half of patients identified themselves as religious, and of those, 90% believed that prayer could facilitate recovery from illness.[31] These patients believed that physicians should ask them about SR care. The non-religious respondents in this study preferred that physicians not ask about SR issues. Differences in opinion between religious and non-religious patients place providers in a difficult position. They might possibly offend some patients when addressing SR issues. This is a topic not thoroughly addressed in medical education.[32,33] Furthermore, the clinical literature provides little information about approaching patients from non-Christian faiths.[34]

The Nature and Purpose of Professional Hospital Chaplain Pastoral Care

Hospital chaplains share responsibility with clinical staff for identifying and caring for patients' SR needs. The Association for Clinical Pastoral Education (ACPE) certifies pastoral care providers. That multi-faith organization requires extensive training and supervised learning for certification.[35] Well-established professional guidelines for chaplains cover support of the patient during the difficult times of hospitalization.[36] Hospitals usually give departmental status to pastoral care groups. Academic medical center hospitals and religiously affiliated community hospitals generally employ more full-time chaplains in their Pastoral Care departments than others.[37]

A three-year study of Professional Chaplains in a New York hospital found that activities during pastoral visits from chaplains vary based on the patient's religious views and severity of illness.[20] For example, pre-operative pastoral visits tend to be much shorter than post-operative or treatment visits, presumably because patients need more support following treatment. Referrals to chaplains are more common for palliative care patients then for non-critical patients even though the latter may also need the support.[3,4,38]

In nearly a third of chaplain visits, the patients were not. Rather, the pastoral care served the families and friends of the patients.[20] Other studies confirm that pastoral care assists both patients and their family members.[39,40]

While patients often appreciate visits from hospital chaplains and clergy,[41,42] not all patients want to receive pastoral care visits.[43] Pastoral care visits have been likened to informed consent: that is, patients must give consent for visits to occur.[44] Correspondingly, chaplains should acknowledge when patients decline to receive visits.

Patient-Engagement and Patient-Centered Care

Patients seek information to make better decisions about their health care. Thus, much current healthcare research focuses on patient engagement.[45] Patient-centered care encompasses availability of care when needed, appropriateness and timeliness of care provided, and consideration of patient preferences with respect to care.[46] Principles of patient-centered care should also extend to SR care.

Studies have shown a strong association between patient satisfaction with SR care and patient satisfaction with the hospital experience.[6,47] The relationships include patient involvement in decision-making and hospital staff attention to patient concerns.[5] One study demonstrated a strong association between patient religiosity and patient satisfaction with hospital experiences, independent of health status.[6] Thus, enhancements to SR care can provide hospitals with an opportunity for improving patient satisfaction.

Pastoral Care and the HIPAA Privacy Rule

In 1996, the United States Congress passed the Health Information Portability and Accountability Act (HIPAA). The HIPAA legislation set a requirement for protecting health information, and gave the Department of Health and Human Services (HHS) responsibility to define appropriate standards. The HHS released the *Standards for Privacy of Individually Identifiable Health Information* ("Privacy Rule") in 2000 (with modifications in 2002).[48] The Privacy Rule has formalized the previously studied[49] need for stronger privacy and confidentiality protections. This directly affects hospital pastoral care. Hospitals need to be able to communicate with external clergy as requested by patients while protecting patient information from indiscriminate disclosure.[49]

Controversy exists surrounding the roles of hospital chaplains as members of patients' multidisciplinary healthcare teams for the purposes of accessing individually identifiable personal health information (PHI).[50] There are several models for allowing hospital chaplains to access patient information, ranging from no access to full access.[51] Many chaplains prefer the latter, in which chaplains are given unrestricted access to patient EHRs and can scan them for patients who may be in need of SR care. In institutions where chaplains are given full access to EHR systems, they are given that access because they are considered members of the "healthcare team."[50,51] Hospital chaplains provide not only SR care but other types of emotional care, so it is unclear whether they meet the HHS healthcare team requirements that exclude those whose care is strictly SR.[50] Allowing chaplains to access all patients' EHRs without explicit consent potentially violates patients' rights to privacy and confidentiality.[51] Hospitals and chaplains should develop other methods of identifying and reaching out to patients in need of SR care in a way that respects their privacy.

Pastoral visits from patients' home congregations' clergy can help inpatients by giving them familiarity, reassurance, and a sense of spiritual control over their otherwise difficult situations.[52] However**,** these clergy often depend on the patient and family for notification of congregation members' hospitalizations. In large regions, there are often multiple hospitals. The process of a clergy member physically going to each hospital to check lists of patients who gave consent for pastoral visits to identify specifically their own congregation members would take inordinate amounts of time. In the busy and stressful time surrounding hospital admissions and subsequent stays, many patients and families fail to notify home clergy.[53]

The Privacy Rule allows hospitals to disclose to clergy census lists that contain the name, location, general condition, and religious affiliation of patients. The Privacy Rule requires that patients on this list are notified and do not object before disclosing the information to internal or external (home) clergy.[54] In VUH, clergy can obtain these census lists from the hospital admitting area information desk. The clergy are required to fill out a sign-in sheeting including their names, congregations, faith groups, and the present date. The clergy are not required to show any credentials to obtain this information. This process does not fully satisfy information sharing needs for pastoral care visitations for two reasons. First, it may not adequately protect patients' private information (fact of hospitalization, location information, and condition) from indiscriminate disclosure to any clergy member (or persons posing as such) from anywhere in the world. Second, it still requires that clergy be physically present in the hospital to determine if congregation members are inpatients there. Furthermore, concerns about privacy prevent many patients from agreeing to generic disclosure of their religious affiliations even when they prefer to be visited by their home clergy.[55] One study found that, though most patients did not want to be included in denomination lists available to clergy, most patients were happy to receive visits that had resulted from such lists and contact.[55] Therefore, many patients might who refuse to be included on the denomination-based census lists for visiting clergy might still wish to receive visits from their home clergy.

Informatics and SR Care

Informatics has been applied several to areas of clinically related SR care. In 2002, before widespread accessibility to the Internet, researchers at the University of California, San Francisco, implemented a web-based information resource about HIV/AIDS for clinic patients.[56] Patients accessed this resource at an inner-city community church. Thus, the study was able to engage patients who would not otherwise have access to the web-based information. Additionally, informatics applications have made it possible to address aspects of SR care that previously were considered subjective and difficult to study.[57,58] One study suggested that EHR systems should be used to collect data about SR care and related outcomes for the development of an evidence-base.[57] Another study created an SR-related risk-assessment system that calculates, based on clinical factors and coping factors (e.g., living alone) derived from the EHR, a likelihood score for a patient needing SR care.[58]

Informatics can enhance patient-centered by improving availability of information to clinicians about patients as well as to patients about themselves.[59] In particular, an informatics-based solution might directly address the focus of this study by giving patients the opportunity to provide religious affiliation and home clergy contact information to be stored in their EHRs. However, discrepancies in patient preferences and challenges in collecting, storing, and appropriately using this information make this simple solution infeasible.[55] That task of tracking down and notifying home clergy of hospitalized patients would be a potentially prohibitively time-consuming task for nursing staff members.

Matching Algorithm and Model Development

A viable alternative to including sensitive religious affiliation information in the EHR is to develop a solution in which religious institution membership data is collected and matched with the hospital census. This approach requires the application of privacy-preserving record linkage (PPRL) techniques that allow religious institution membership databases to be shared with hospitals for matching purposes while at the same time preserving the privacy of the individuals within these membership databases. The current study developed a matching algorithm based on these concepts, discussed below, to compare these two types of data.

Privacy-preserving record linkage (PPRL) is the task of matching records from different sources that refer to the same individual while preserving the privacy of the individual records.[60-63] This task is particularly important within the field of clinical informatics because patient information is sensitive in its nature. The methods available for this task fall into several groups: (1) Equivalence Testing; (2) *n*-gram Methods; (3) Reference Space Embedding; (4) Teamwork; (5) and Phonetic Filtering.[63]

In equivalence testing, or exact matching, strings are simply encrypted and compared. This method is simple to understand and implement but does not always perform well because minor differences in plaintext strings can result in large differences in encrypted strings. In *n*-gram methods, strings are broken down into substrings of *n* length, hashed, and compared for equivalence. One such method is the Bloom Filter, which performs well but is computationally complex. Reference space embedding works by calculating a distance between a string and a reference string, encoding the difference. Strings are said to be similar if their distances are similar. Teamwork methods require

cooperation between the owners of each string to determine the similarity of the two strings. These methods are used when data cannot be shared and therefore are not appropriate for the current study. Phonetic Filtering refers to the conversion of names to a standardized form to reduce the effects of typographical errors and other errors in the data. The filtering makes it possible to match despite minor errors, but it results in a loss of discriminating power. [63] The current study's matching algorithm was developed using several of these PPRL techniques.

Probabilistic approaches have been shown to work better than deterministic (exact-match) in producing results with high sensitivity and near-perfect specificity,[64] so the current study also explored the use of using a threshold approach within the matching algorithm. Approximate string matching allows comparisons with errors in the strings and is usually performed by calculating edit distance, or the number of operations required to transform one string into the other.[65] It is analogous to comparing DNA strands by listing single nucleotide polymorphisms (SNPs). One variant of edit distance, the Hamming Distance, compares two strings of equal length and counts the number of replacements required to transform one string into the other.[65]

Data Security

The privacy protection from the PPRL methods is important for protecting the religious institution membership data from various potential forms of security breach. However, it is important to protect the data from other forms of breaches. For example, Drupal, the open-source content management system used in the current study, has incorporated important security features that are used to protect data from attack.[66] First,

Drupal allows for secure socket layer (SSL) connections, in which data is encrypted for secure transmission. Host servers storing sensitive data should be SSL-enabled.[67] Drupal also provides secure user authentication, in which users are determined to be who they say they are on the basis of something they know (e.g., a password) or something they have (e.g., a secure ID).[68] That authentication protects against common web-based security attacks such as cross-site scripting (XSS), script injection into the database, and cross-site request forgery.[66,68] Finally, Drupal provides a user-friendly and simple way to managed role-based access control, in individuals with certain roles within an organization are given access to different information within the information system based on those roles.[69] These security measures can protect data from the theoretical threat of external adversaries who might otherwise be able to access the data during its transmission or storage.

Ethical Considerations

Religious institution membership data is not usually subject to the same privacy protections as clinical data (which is mandated by the Privacy Rule of HIPAA). However, the current study explores the intersection of these two systems (religious and clinical) and therefore uses the more restrictive privacy and security policies of the Privacy Rule. Thus, if a breach occurs at any step of the process, both clinical and religious institution data will be fully protected.

The primary ethical consideration for the current study is whether an "opt-out" process could be used in place of traditional informed consent. An opt-in process is more costly and time consuming and runs the very real risk that congregants who actually

would prefer to have clergy visits may not take the time to sign up when they are well. An opt-out process is likely to include some people who would prefer not to talk with their clergy but the risk of asking them when they are a patient whether they would like to have a visit is low.

An opt-out process is superior to the current model of virtually indiscriminate sharing of patient information for the purposes of receiving pastoral care visits for several reasons. First, the process of informing individuals about sharing which religious institution they belong to with VUH so that they can choose to opt-out if they prefer gives these individuals more information than other patients at VUH receive. Thus, these patients are enabled to make decisions that more fully respect their personal preferences. Second, it is reasonable to believe that most congregants would be comfortable with having VUMC know what their church home is as long as they are given the opportunity to say no to receiving a visit during any individual hospital stay. The congregants who are not comfortable with this information being shared could opt-out and remove themselves from consideration of being identified by the current study. The opt-out process should be designed so that opting-out is simple and comfortable for individuals to do.

CHAPTER II

METHODS FOR INFORMATICS BASED PASTORAL VISIT FACILITATION SYSTEM STUDY

Overview of Complete Study Methods

The study first assessed potential need for a home-clergy pastoral visit facilitation system and the socio-religious utility thereof. Having demonstrated such need, the project developed a model for the solution, using methods from the field of privacy-preserving record linkage to privately and securely compare membership data from local religious institutions to VUH inpatient census data and look for matches. The study then implemented a small-scale pilot model focused on VUH, conducting a proof-of-concept study to inform and facilitate future model development and evolution. Description of study methods follow below in three sections: (1) Needs and Feasibility Assessments; (2) Matching Algorithm Development and Validation; and (3) Vanderbilt-based Pilot Test.

Needs and Feasibility Assessments

Socio-Religious Needs Assessment Methods

The study conducted a needs assessment, in which the PI identified a sample of religious institutions willing to participate in the study and determined their interest in such a project. These religious institutions comprised a convenience sample. Thesis Committee members asked colleagues and friends having strong ties to local Middle

Tennessee religious congregations to suggest suitable institutions to approach. Additionally, the PI met with chaplains in Vanderbilt's Department of Pastoral Care to ask for their recommendations of local religious institutions frequently involved at VUH that might be interested in participating. Furthermore, the PI met with Trudy Hawkins Stringer, Assistant Professor of the Practice, and Associate Director of Field Education at the Vanderbilt University Divinity School. Dr. Stringer also provided contact information for the clergy at one site that might have been interested in participating.

The PI attempted to contact the clergy at each nominated site via email messages and phone calls. Initial contact information included a brief introduction consisting of the background of the project, the nature of the study (study design plans mentioned that it was part of a graduate school thesis project), and a request for a face-to-face meeting to discuss how the study could best influence institutional hospital pastoral care visits.

From the meetings with clergy, project team members determined that there was sufficient justification to explore the project further. The project team applied on September 24, 2010 to Vanderbilt's Institutional Review Board for approval to conduct the study (Please see IRB application in Appendix A). The IRB approved the study on November 24, 2010 (IRB #101234). Due to the substantial delay between IRB submission and approval dates, the PI re-contacted the clergy who had initially expressed interest. The PI discussed with the religious institutions the IRB-specific project inclusion criteria. These criteria included: internet access; a membership database software system capable of producing exports of Microsoft Excel-compatible membership listings; and multiple means of contacting all congregation members to offer them the option to "opt-out."

Remaining participating clergy completed a web-based survey using the SurveyMonkey online assessment tool to more formally assess interest in and need for the system. The survey content is included in Appendix B as Pre-Implementation Survey for Clergy.

Ms. Norella and Dr. Miller met with Terrell Smith, MSN, RN, Director of VUH's Patient and Family Centered Care to discuss the relevance of the project to the VUH's patients and families. Under Ms. Smith's direction, the project team also met with the Patient and Family Advisory Council, a panel of Vanderbilt-area community members, most of whom have clinical backgrounds and/or experience as VUMC patients. The Council holds monthly meetings to provide insights and give feedback on aspects of patient care that are most relevant to the patients and families served by VUMC. Ms. Norella presented a ten-minute introduction to the project to the Council and she and Dr. Miller responded to questions and comments for another twenty minutes. The project used this feedback to further refine the research plan for the study.

Legal and Clinical Feasibility Assessment Methods: Interviews with Key Personnel

In addition to contacting clergy to gauge interest in the project, project team members also contacted several Vanderbilt University (VU) administrators to obtain feedback on the need for and feasibility of a pastoral visit facilitation tool. These administrators included: Gaye Smith, VUMC's Chief Privacy and Health Record Official; Susan Hannasch, JD, Senior Associate Counsel from VU's Office of the General Counsel; Marilyn Dubree, MSN, RN, Executive Chief Nursing Officer of VUMC; and Pam Jones, MSN, RN, Chief Nursing Officer of VUH.

The PI also met with several clinicians in the hospital, including James Powers, MD, Associate Professor of Medicine and Geriatric Fellowship Director. Dr. Powers suggested that the Palliative Care team and the charge nurses of one of the hospital units would be useful additional resources for the study. The PI presented short introductions to the project to these two teams and asked them for input from regarding how best to notify nurses and patients about pastoral care system matches without disrupting hospital workflow.

Overview Matching Algorithm Development and Validation Methods

The study used methods from the field of privacy-preserving record linkage (PPRL) to privately and securely match hospital inpatients to members of local religious institutions. Membership data was encoded collected from participating institutions and compared to VUH inpatient census data. The matching process described below includes: (1) Development of matching algorithm through analysis of VUMC's historical patient database; (2) Validation of matching algorithm and determination of threshold for probabilistic matching; and (3) Retrospective analysis comparing participating religious institution data to VUH inpatient data for the span of five months preceding the start of the pilot study.

Matching Algorithm and Technical Component Development: Tests Using Historical VUMC Patient Record Data

Many of the existing methods for PPRL are technically complicated beyond what was required for the study's small pilot test. Therefore, the study explored a variation on

exact matching known as “encode-and-compare,” in which the identifying information is encoded and then compared for matches.

The participating clergy were hesitant to share with the study their full lists even in encrypted form, however, because of concerns about security should the system have been hacked. In an effort to further alleviate their concerns, the project team members decided to take a partial-match approach in which “snippets,” or combinations of non-sequential characters derived from partial demographic data (characters from the fields “Last Name,” “First Name,” “Street Address,” “ZIP Code,” and “Date of Birth”), stored in a single string with wild card characters as space-fillers unavailable or absent information, and encoded, are extracted from the membership information databases of religious institutions and used to compare to the hospital census information. Additionally, the study’s participating clergy had noted that many religious institutions do not have complete information for all members for the date of birth field; therefore, the snippets included date of birth information when available but the ideal snippet was defined as one that was able to uniquely identify high proportions of individuals through the matching algorithm regardless of whether or not date of birth information was available.

The composition of these snippets was determined through an analysis of Vanderbilt University Hospital’s historical database, which includes approximately 1.5 million patient records. The IRB issued an exemption for the use of the historical database on August 23, 2010 (#100996). The snippet selection algorithm development began with a test of fifteen possible combinations of non-sequential characters derived from partial demographic data available at religious institutions and in VUH census data.

Each combination was tested with and without date of birth information. The optimal combination was defined as the one able to correctly uniquely identify the largest proportion of records from the data set while losing the least amount of discriminatory power when date of birth information was missing. This optimal combination of characters created the snippets used for matching through the rest of the study period.

Once the best snippet sequence was determined, Ms. Norella and Dr. Miller developed an encoding scheme based on scrambling the characters and then performing a mathematical translation of each character in the final set. The PI developed a snippet creating system in Perl. For installation at local sites on Windows machines, an executable file (snippet-creating program) was created. The locally installable program takes as input a text (tab-delimited) file created by the religious institution's database manager containing the appropriate fields and gives as output a text file of one long encoded string.

The PI scheduled installation and training meetings with the administrative staff responsible for maintaining membership databases at the participating religious institutions. During these meetings, the PI installed the snippet-creating program onto the religious institution servers and trained the administrators on the process of running the reports necessary to give input to the program. Coincidentally, all participating sites used ACS Technologies, a church management software system, as their membership database management programs. Therefore, instructions given to administrators were tailored to this particular system but could be generalized for any other program capable of producing MS Excel-compatible exports. These administrators were responsible for maintaining lists of members who had opted out of consideration for study participation.

The instructions include the creation of exclusion lists within their database management systems to account for non-participating individuals and keep data from such individuals from being encoded and sent to the study team.

The PI developed a website using Drupal, a content management system with built-in security features to protect its websites from attacks. Two SSL-secured VUMC servers were used as the host site for the transmission and storage of the membership data, which was encrypted and protected by firewall using the same protections as those used by VUMC for all EHR data. This website provided a method for transmitting encoded data from religious institutions securely to the study servers for eventual matching purposes. The administrators were given accounts on the Drupal-based site and trained to submit encoded data to the study team by uploading it onto this site. They were instructed to repeat this process as often as necessary based on membership changes and member turnover. The instructions (on report generation, snippet creation, and encoded snippet upload) given to the administrators are included in Appendix C.

Once the membership data from each religious institution was encoded and uploaded, the matching algorithm could compare it with then current VUH daily inpatient census data. For this comparison, the algorithm scans the VUH census to exclude any patients in the Children's and Psychiatric hospitals and as well as any patient who is not at least 18 years of age, as per study qualifying criteria approved by the IRB. For each individual who matches these qualifying criteria, the algorithm pulls the relevant demographics from the EMR system and encodes this data in the same way as described for the religious institution data.

From the two encoded lists, the matching algorithm checks for matches by comparing each snippet from each religious institution to each encoded string from census data. For each pair of strings, the algorithm calculates the number of replacements required to transform one into the other (Hamming Distance), or the number of characters that differ between the two. The distance is then normalized by the string length so its value is between 0 and 1. This distance score is subtracted from 1 to create a similarity score containing the likelihood that the two strings are referring to the same person.

Matching Algorithm Validation and Threshold Determination: Tests Using Sample Record Pair Data

In an ideal setting with unlimited resources, the matching algorithm would be validated by systematically testing the uniqueness of a given snippet combination with any possible combination of typographical errors and/or missing data.

Due to time constraints, the previously described ideal validation study was not feasible. Instead, the PI tested the matching algorithm on a set of actual patient records that had been constructed from patients' demographic registration data. The subset was created for testing of record linkage algorithms. This record set consisted of 30,000 patients who had more than one set of demographic identifiers in the VUMC electronic health record system. Whenever an individual arrives for clinical care at any Vanderbilt University Medical Center hospital or clinic, the individual must be registered in order to receive care. For a number of reasons, it is not always possible to find the previously existing patient record for an individual. Circumstances that might lead to this problem include, for example, when patients: (a) had changed their names (e.g., following

marriage); (b) were incapacitated and lacked identification; or (c) had difficult-to-spell names that a clerk could not easily find, so the clerk created a new registration with potentially faulty information in some fields. In such instances, new duplicate records that often contain incomplete and incorrect information are created. In order to consolidate each patient's records under a single correct identifier, the VUMC Enterprise Data Warehouse team, part of the VUMC Informatics Center, performs a semi-automated, algorithm-assisted "cleansing process" in which duplicate records within the Vanderbilt system are identified, manually reviewed, and then integrated under a single identifier with "best determination" of correct values in each demographic field. The resulting record pairs are linked by an over-arching medical record number (MRN) that consolidates all previously used MRNs for the patient.

The record set used for this study's matching algorithm validation analysis was created by randomly taking only two (even if more existed) demographic records for each individual with multiple entries (as previously described) and linking them by the overarching MRN. Thus, the data used for this analysis was chosen because it was at least in part inaccurate and incomplete (although not necessarily so for the subset of demographic fields of interest to this study). This feature of the data made it useful for testing the ability of the study matching algorithm to find matches among imperfect data; however, it placed an upper bound on the number of true matches that could possibly be found because many of the record pairs were too dissimilar (for example, sometimes patients are admitted under "alias" identities and most demographic data are altered intentionally to protect the patient's privacy during the admission; only after discharge are such records reconciled with previous non-anonymous records for that patient). The

data in the current study were further cleaned to remove any pairs of records in which the address and the last name fields were missing from one or both members of the pair. The dataset is realistic in the sense that many of the erroneous entries were made by people acting in good faith efforts to register the patients – and therefore might represent the kind of errors seen in either the VUH census data entries used in this study, or in the religious institution's membership records also used for this study.

The PI began the analysis with a characterization of the data. For each MRN in the data set, snippets were taken from each set of records (A and B). The snippets were then compared to on the basis of Hamming distance, and a histogram of similarity between snippets was graphed. The analysis then extracted snippets from all records in set A and set B and compared each snippet from each set to each snippet from the other set to look for matches.

Because the record pairs were linked through MRN, correct matches (true positives) were defined as matches identified by the system that shared a MRN. Based on this definition, the analysis then calculated sensitivity, or recall (the proportion of all matches correctly identified as matches), and positive predictive value, or precision (the proportion of matches that are correct matches).

The PI also tested a version of the snippet-extraction program that used Soundex codes to standardize names before extracting snippets to determine if such standardization would improve matching performance. The results from this version were compared with that of the previously described analysis.

Retrospective Analysis: Tests Using Historical VUH Census Data

Before starting the pilot study, the study PI obtained approximately five months of retrospective VUMC census data that included both inpatients and outpatient admits from the period from January 1, 2011 to May 25, 2011.

The administrative staff members at each religious institution uploaded their encoded membership data to the Drupal-based website, as previously described, for a pre-study analysis comparing their membership data to the census data. The purpose of this analysis was to estimate the number of matches likely during a 6-week study period.

Methods: Pilot Test of the Pastoral Visit Facilitation System

The study included two components of approval from individuals whose data were encoded and compared for the purposes of matching. Initial approval was obtained through an "opt-out" procedure similar to the Vanderbilt's BioVU project's model of informed consent.[71] Based on this model, it was considered unreasonable to expect the study team members to be able to contact and individually obtain consent from all potential study participants. Instead, the study used multiple methods of mass communication to inform relevant individuals about the study. These methods included mailed letters to congregation members, announcements during weekly religious services, website and blog postings. Individuals were informed of the study through these means and were required to contact their clergy or a member of the study team if they preferred to remove themselves from consideration of participation in the study. It is important to note that individuals who did not opt out at this stage did not consent to having their PHI shared in the event of a hospitalization. Instead, these individuals agreed

to allow themselves to be considered for participation in the study by sharing their data with the study.

The second component of individual approval was in the hospital when an individual member of one of the participating religious institutions who had not opted out of being considered for participation was hospitalized and identified as a study match. At that point, the individual was asked about his or her preferences regarding the receipt of a home clergy pastoral care visit. The individual or a surrogate was then required to sign a HIPAA-information release document required for the disclosure of their information to their home clergy.

In the first step of the pilot study, the PI again contacted the clergy involved in the needs assessment phase to obtain their approval to continue into a pilot phase. The clergy at participating religious institutions implemented this opt-out process by notifying their congregation members of their participation in the study in the following ways: (1) By sending a letter to all individuals and families that belong to the religious institution explaining the study and giving information for how to opt-out; and (2) By either making verbal announcements during weekly religious services or by making a second written announcement on either a website or a blog used for the purposes of communicating with congregation members. The study allowed the clergy to take a minimum of one month for this process to ensure that any individual congregation members who did not want to be considered for participation were given ample time to opt-out before the study began.

Together with Dario A Guise, Dr. Ing., Associate Director of the VUMC Informatics Center and creator of StarPanel, the PI developed a mechanism within StarPanel so that an uploaded HIPAA-information release form triggered the addition of

a given patient to a panel specific to the appropriate participating religious institution. The mechanism and the panels were only accessible to Ms. Norella, Dr. Miller, and the clergy and administrator in the Department of Pastoral Care (DPT). The PI trained these members of the DPT to disclose the information contained in a panel only to clergy members who had called from the religious institution represented by that panel. One potential threat to religious institution membership data in the study was that of internal hospital employees discovering religious institution affiliation information during the matching process and either consciously or unconsciously biasing behavior toward the patient as a result. The study protected against this type of threat by restricting the availability of information to the study team, the DPT, and the nurses of identified patients.

In the next stage of the pilot study, the system was turned on to match the religious institution membership lists with patients in the current, real-time Vanderbilt University Hospital census for a period of six weeks. The matching algorithm ran on the census data daily at 8:00am and 3:00pm. Once the matching process had been completed, the algorithm sent a notification email to the PI. This email included as its subject the number of matches with no additional information. When the number of matches was one or more, the PI then manually checked the output files to see which patient had been matched. If the patient matched was determined (by checking manually) to be new to the system, the PI then placed a phone call to the charge nurse of the unit where the identified patient was located and asked him or her for permission to visit the unit floor. The script for this contact is as follows:

> Hello. I'm [name] from the Department of Biomedical Informatics. We're running a research study at Vanderbilt that is testing a system to privately and securely facilitate pastoral care visits in the hospital. We've identified one of the patients on your unit as a potential match to a participating institution – something he or she would already know about. In order to complete this step of the study, I'd like to ask for 5-10 minutes of your time. The patient is [name]. Can you please let me know if there is a specific time today when you may have a few minutes?

It is important to note that this contact did not disclose the name of the matching identified religious institution.

The PI visited the charge nurse on the unit. The PI briefly explained the study to the charge nurse and asked whether the charge nurse or the patient's assigned nurse might be able to discuss the study information with the patient. Based on the charge nurse's recommendation, the PI then obtained the charge nurse's or the patient's assigned nurse's consent to participate in the study. Once the nurse's consent was obtained, the PI used a semi-structured interview to ask the nurse whether or not he or she would be comfortable approaching a patient and asking if he or she would like a visit from a specific clergy member. In the event that a member of the nursing team was not interested in participating in the study, the study team member carried out the rest of the notification process, which follows.

The nurse was given a packet of information including: a list of instructions; questions to aid the nurse in his or her discussion with the patient; and an envelope containing a piece of paper with the patient's name and the name of the matching religious institution. This envelope also contained a HIPAA information release authorization form for the patient to sign if he or she decided to request a pastoral visit.

The envelope system was designed to protect the confidentiality and to aid in patient comfort in the event of a false-positive match. The envelope containing the

matching information was not opened if the patient refused to participate in the study at the point of care. The PI remained on the unit during the notification process to collect the paperwork following the notification of the patient.

In the event that a matched patient requested a visit, the PI scanned the HIPAA information release form into the patient's EMR. This upload triggered the aforementioned process in StarPanel of adding the patient to the appropriate panel for disclosure to clergy. The PI also either called or sent an email message to the contact clergy at the patient's religious institution. Any emails sent contained no identifying information but notified the clergy that he or she had a patient in the hospital requesting a visit and that he or she should contact either the DPT or the PI to find out the name and location of that patient.

The pilot study processes are represented in flow chart form in Figure 1.

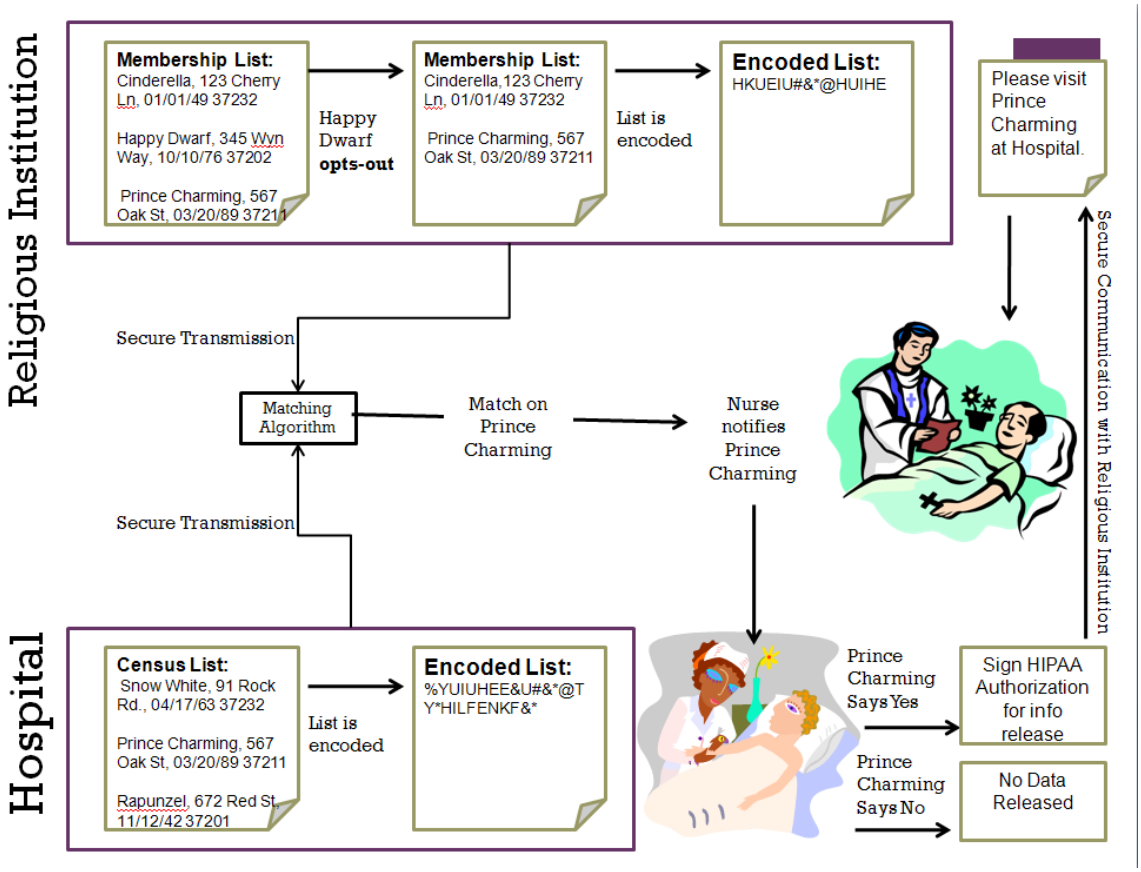


Figure 1: Flow Chart Depiction of Pilot Study Processes

The study recorded data from these encounters only in the aggregate. The data recorded for each match included whether or not a patient agreed to receive a visit and whether or not the visit was completed but did not store the patient's name or any identifying information for future use.

The PI also asked the clergy who participated in the study to complete brief post-implementation interviews following each visit. The purpose of these interviews was for them to describe the encounter with the patient and to add information for the purposes of estimating the patient's response to the study process and resulting visit. The clergy were also briefly interviewed at the conclusion of the study to assess whether they thought the system was useful enough to warrant continued use.

Charge nurses who had agreed to participate in the study by notifying an identified patient of the match were asked to complete brief post-notification interviews. During these interviews, the PI inquired into whether or not they felt comfortable having the notification discussion with the patient, whether they thought the system could be of value to patients, and how they would prefer to be notified of matches in a full working version of the system.

The PI used the data collected during the pre-implementation and pilot stages of the study to calculate and report: (1) the percentage of members from each institution who did not opt-out of receiving information regarding a potential match when hospitalized; (2) the percentage of nurses who agreed to carry out the notification of the patient, (3) the percentage of patients who requested visits following notification of a match; and (5) the percentage of participating nurses who agreed that this system was beneficial to their patients.

Participating clergy were asked to contact the study PI in the event that they learned of a congregation member's hospitalization at VUH that the study had missed. These instances were used to calculate a false positive rate for the matching algorithm.

CHAPTER III

RESULTS OF INFORMATICS-BASED PASTORAL VISIT FACILITATION PROJECT

Results: Study Enrollees and Non-Participants

Initial nominations provided the study team with a list of seventeen candidate religious institutions to contact regarding this study. The PI sent email messages and made phone calls to the clergy members each of these institutions. From these contacts, twelve clergy members responded, and efforts to contact clergy at the five remaining religious institutions, including all but one non-Christian religious institution, were unsuccessful. One of the clergy who responded expressed gratitude at having been considered but declined to be involved further, citing limited time. This left eleven candidate sites.

During initial meetings with the clergy from the eleven candidate sites, the PI explained the purposes of the study and informally asked for input regarding the potential usefulness of the system. Eight were enthusiastic and expressed interest in a potential system to facilitate pastoral care visits. They asked to be contacted as the study progressed. One of the remaining three, a deacon, explained that he thought that such a system would not be helpful for the Catholic Church because it has a strong presence in area hospitals. In his experience, that church does not have trouble locating its hospitalized patients in need of pastoral care. Another individual who declined to participate was from an Islamic mosque in the Middle Tennessee area. He expressed

enthusiasm for the project but stated that since the local socio-political climate was potentially hostile toward members of the Islamic faith, he decided that the congregation should not take any risk with respect to the disclosure of membership data. The third clergy member who declined (a priest) also cited concerns about data privacy.

A delay of two months related to time for IRB approval of the study and to algorithm development then ensued before the next contact with potential study participants. The PI approached the remaining eight clergy members seven months after the previous contact to explain the IRB requirements for participation, including the opt-out process for congregation members. Of these eight sites, two declined to participate further because the opt-out notification process would pose excessive burdens on institutional time and resources. Another clergy member was transferred to a different congregation during the interim and no longer had any authority within the Nashville-area religious institution from which he had originally shown interest. Attempts to contact a clergy member at another institution were unsuccessful. This left four remaining sites for study participation.

The remaining four clergy members participated in the pre-implementation survey. Following the pre-implementation assessment, one site dropped out of the study because the institution's board of directors refused permission to participate. An additional site declined to participate further, citing that the scope of the project had grown beyond what they had anticipated. Two institutions remained. They fully participated in the pilot study. A characterization of study enrollees and non-participants appears in Table 1 and Figure 2.

Institution	Responded to Contact Request	Agreed to Personal Interview	Expressed Interest in Participation	Consented to Participate in Study	Fully Participated in Pilot Study
A	✓	✓	✓	✓	
B	✓	✓	✓	✓	✓
C	✓	✓			
D	✓	✓	✓		
E	✓	✓	✓	✓	✓
F					
G	✓				
H	✓	✓			
I					
J					
K	✓	✓	✓		
L	✓	✓	✓	✓	
M					
N					
O	✓	✓	✓		
P	✓	✓	✓		
Q	✓	✓			
Total: 18	**12**	**11**	**8**	**4**	**2**

Table 1: Study Interest and Participation by Nominated Site

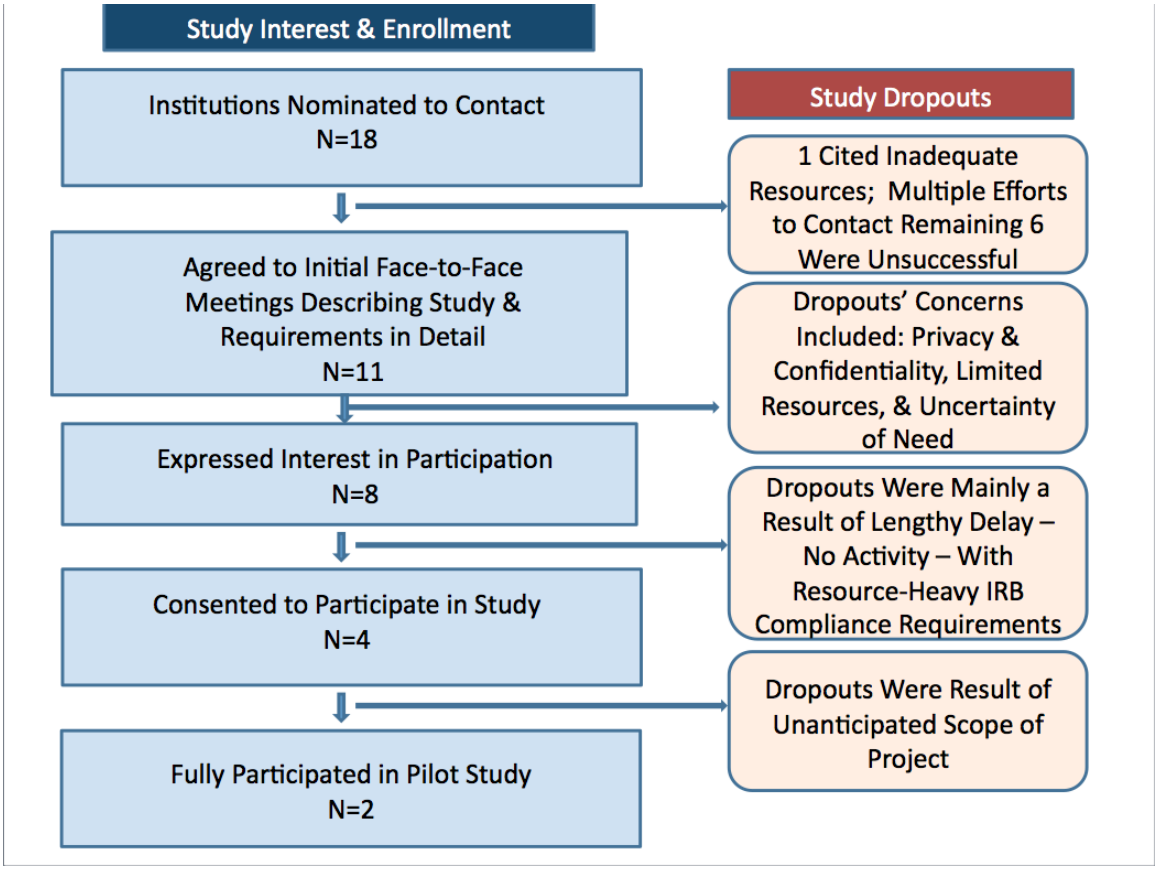


Figure 2: Flow Chart of Religious Institutions' Study Interest, Enrollment, and Dropouts

Needs and Feasibility Assessment Results

Socio-Religious Needs Assessment

The results of the pre-implementation survey for clergy indicated that potential existed for improvement in current hospital pastoral visit processes.

Three of the four clergy surveyed responded. All three held senior positions within their religious institutions and each of them had at least 30 years of experience with pastoral care. The average amount of time spent at their current religious institutions varied from 3 to 23 years, and they reported spending approximately 20-30% of their job in activities related to pastoral care visits. All of the respondents reported having had instances in which they had learned of a congregant's hospitalization after the fact, when it was too late to visit the congregant and provide for him or her in the hospital. Two of the three clergy agreed with the statement: "The current process of notification for pastoral care visits mostly works well, but we've had a couple of incidents where patients did not receive visits as they desired." One of the three clergy agreed with the statement: "It's a struggle to find out when patients are in need of a visit, and we would like a better system."

The clergy surveyed provided comments in an open-ended text box on the survey webpage. They were asked to share relevant anecdotal stories relating to the process of pastoral care visits. Their comments included:

> Some [hospital procedures are to] ask, "Do you want to be visited by clergy?" Most of my [congregation] members respond to that kind of question with a "no," […] because they do not want to be visited by people they do not

know. If the question was phrased, "do you want your own clergy to know that you are a patient?" I think many more would answer, "yes."

> There are often times when a [class] or small group will know about a congregant's hospital stay, but not the ministerial staff. The class members are then surprised that the ministerial staff did not respond and assumed that [they] ought to [have responded].

> Usually members themselves or those who know of their hospitalization will inform us. On those occasions when we do not hear of a member's hospitalization, it is usually [due] to their being on the periphery of the congregation's life. They lack the support network that accompanies [usual] participation in the [religious institution].

The Director of Patient and Family Centered Care was also enthusiastic during a private meeting and as a result scheduled a meeting for the project team with the VUMC Patient and Family Advisory Council. The Council offered input during the study team's meeting with them; they commented on the need for a system. They expressed initial skepticism concerning patient privacy issues and the need for the system (i.e., "everyone contacts their clergy on admission"). However, during the discussion, several Council members cited instances where they realized that such a system might have helped someone they knew. The Council concluded that it seemed to be of little harm to try to improve the current system through the proof-of-concept study and voted to endorse moving forward with the study.

Legal and Clinical Feasibility Assessment: Interviews with Key Personnel

The VUMC Chief Privacy and Health Record Official, Gaye Smith, and Office of General Counsel, represented by Susan Hannasch, supported the study design as meeting VUH and HIPAA requirements with the following caveats: (1) Individuals must be notified at their home religious institutions of their potential consideration for

participation in the study and be given the opportunity before the study begins to opt-out of that consideration; (2) Individuals must again be notified at the point of care (as inpatients) if matched for the study, and they must consent to have a pastoral care visit and then sign a form that gives the hospital permission to release HIPAA-protected information that they are patients and their location. Gaye Smith provided a VUH existing standard consent form for this purpose, and that form can be found in Appendix D.

The Chief Nursing Officers were enthusiastic about the project as a means to expand VUH patient engagement within the hospital. These administrators stressed how busy and overworked nursing staff has become, with a growing trend to place more responsibilities upon these individuals. The hospital executives explained that any system to facilitate pastoral care visits developed by the study could improve its chances of success by minimally burdening the nursing staff.

The Palliative Care team offered insight into future issues that the system could address. In particular, they noted that there are faith-related challenges associated with hospital patients who are not from the local area. They suggested that the study could explore the possibility of matching non-local patients to local clergy in future work on this system. Also, like other groups, they stressed the importance of including "local minority" religious institutions, such as Muslim mosques, Hindu temples, and Jewish synagogues.

Overview Matching Algorithm Development and Validation

As previously described, the study used methods from the field of Privacy-Preserving Record Linkage to privately and securely match hospital inpatients to members of local religious institutions. The results of the technical matching development process described below includes: (1) Development of a matching algorithm through analysis of VUMC's historical patient database; (2) Validation of the matching algorithm and determination of threshold for probabilistic matching; and (3) Retrospective analysis comparing participating religious institution data to VUH inpatient data for the span of five months preceding the start of the pilot study.

Matching Algorithm Development: Tests Using Historical VUMC Historical Patient Record Data

Snippets of data to be used for the study were determined through an analysis of Vanderbilt's historical patient record database. As defined previously, snippets are combinations of non-sequential characters derived from partial demographic data (characters from the fields "Last Name," "First Name," "Street Address," "ZIP Code," and "Date of Birth"), stored in a single string with wild card characters as space-fillers unavailable or absent information, and encoded. The analysis tested character combinations to form the basis of these snippets. Each character combination was tested with or without date of birth information.

The proportion of records uniquely identified by each snippet combination tested varied from 0.0018% for the first two letters of the first name to approximately 98% for a more robust combination of letters from the name, address, and zip code fields. The

percentage of individuals uniquely identified by each combination with and without the use of date of birth information is described in Table 2. The algorithm that was able to identify 98% of patients in the historical census was chosen as the final matching algorithm for use in the rest of the study.

Unique Character Combination for Snippet Development	Proportion of Individuals Uniquely Identified	
	With DOB Info	Without DOB Info
A	0.981	0.626
B	0.980	0.255
C	0.980	0.891
D	0.979	0.511
E	0.979	0.511
F	0.956	0.626
G	0.919	0.255
H	0.873	0.873
I	0.863	0.863
J	0.855	0.561
K	0.821	0.511
L	0.812	0.255
M	0.586	0.255
N	0.259	0.255
O	0.123	0.119

Table 2: Proportion of Individuals in Vanderbilt University Historical Medical Record Dataset Uniquely Identified by Character Combinations for Snippets, With and Without Date of Birth Information

Matching Algorithm Validation and Threshold Determination: Tests Using Sample Record Pair Data

The final matching algorithm was then tested on sample record pair data for validation. Removal of records missing last name or address field data left 18,799 record pairs for comparison. A histogram showing the proportion of total record pairs that

shared each similarity score between pairs of one record appears in Figure 3. A large proportion (39%) of the records pairs had perfect (1.00 similarity) matches between records within the pair. Missing or incomplete data for these pairs did not come from snippet-containing character positions. Approximately 55% of record pairs had similarities of at least 0.85. Less than 1% of the total record pairs had zero or one character in common between the two sets of the pair. These records most likely contained the previously described "alias" records within the sets.

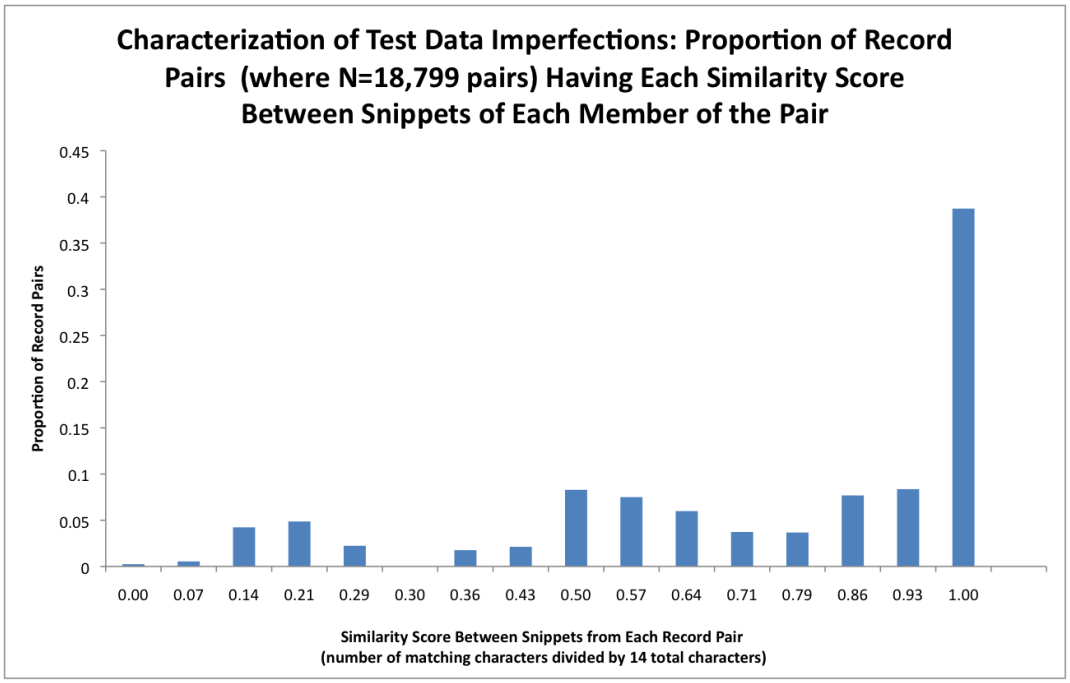


Figure 3: Description of Data Used for Validation and Threshold Determination

The analysis of record pairs was linked through MRN and correct matches (true positives), defined as matches identified by the system that shared a MRN, were calculated. Sensitivity, or recall (the proportion of all matches correctly identified as

matches), and positive predictive value, or precision (the proportion of matches that are correct matches) are plotted below in Figure 4. The area under the curve is 0.66.

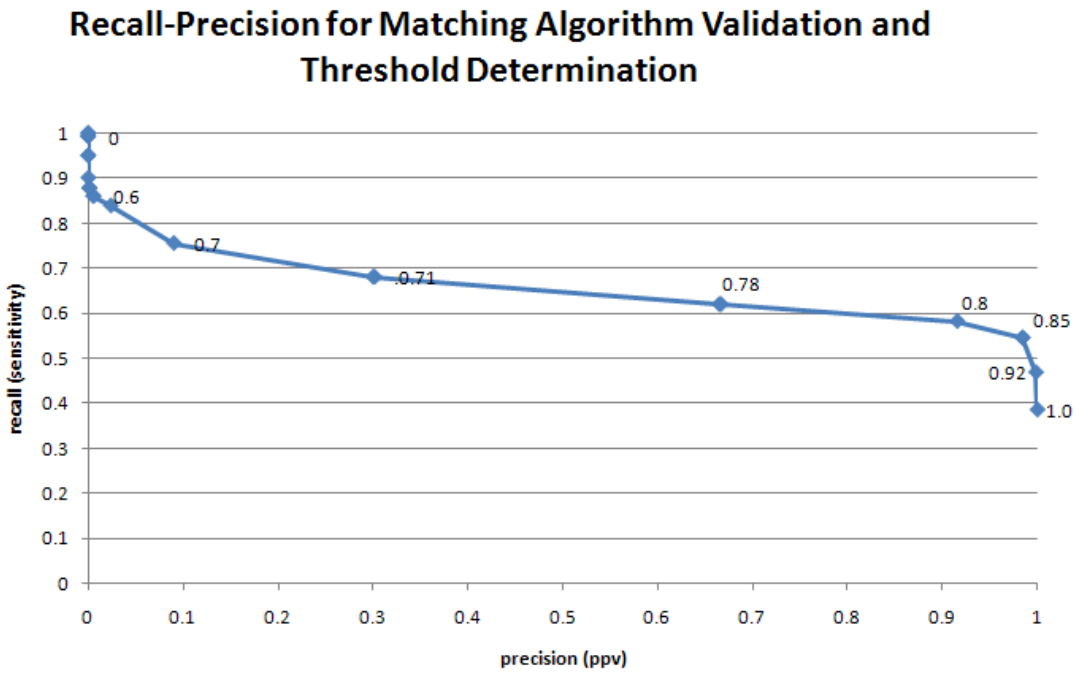


Figure 4: Recall-Precision for Matching Algorithm Validation. AUC: 0.66

The validation of the matching algorithm focused on precision in an effort to limit false positives. The matching algorithm was able to use a threshold levels below 100% while maintaining very high precision (>98%). From this graph, one can see that the lowest threshold one can choose that maintains very high precision is 85%. Therefore, the similiary metric threshold for determining whether two strings are a match for the purposes of this study was set to 85%. That threshold of 0.85 maintained high precision while allowing the matching algorithm to capture over 54% of true matches (recall). Further lowering the threshold would result in large drops in precision without much gain

in recall. The PI also calculated specificity. An ROC curve is plotted below in Figure 5. The area under the curve is 0.97.

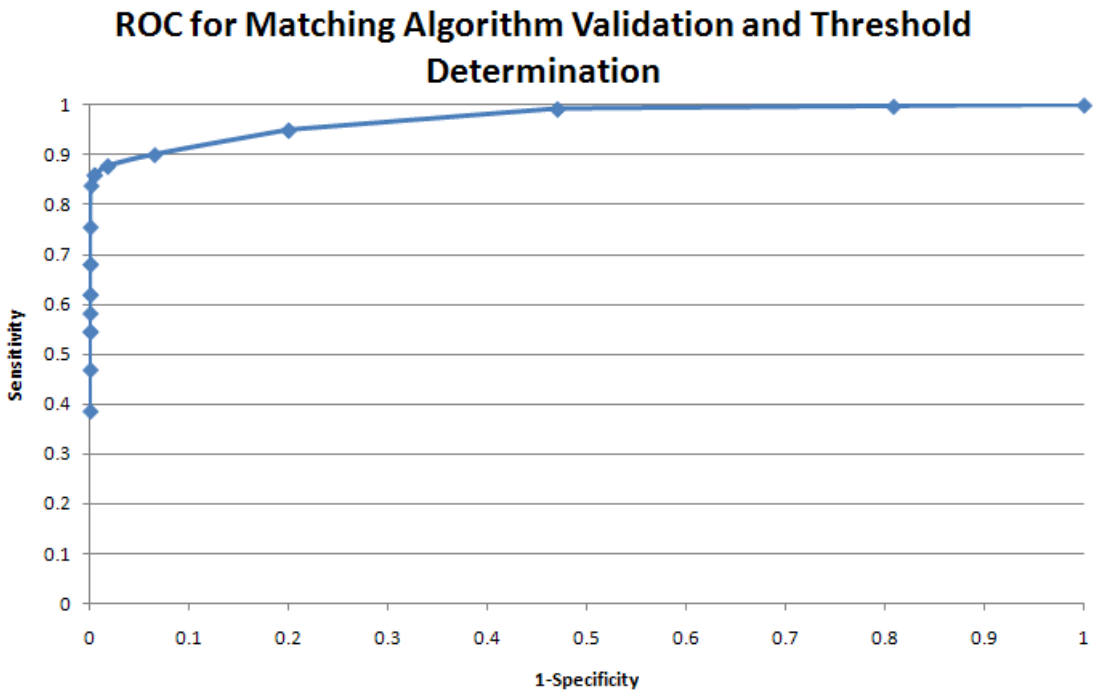


Figure 5: ROC curve for matching algorithm validation. AUC: 0.97

The validation of the matching algorithm when it had been modified to include name standardization through Soundex codes produced a recall-precision curve with an AUC of 0.55 and an ROC curve with an AUC of 0.92. In this case, setting a threshold below 100% results in significant drops in precision. The entire matching algorithm performed slightly worse when it included data standardization, as evidenced by the differences in area under the curves for the non-standardized and standardized for both

the recall-precision and the ROC curves (0.6584 and 0.5548 for recall-precision and 0.9724 and 0.9209 for ROC). There was no further consideration of using Soundex.

The validation of the matching algorithm took several days to run because the Hamming distance is an n^2 computation that compares each character in each string to each character in the other string.

Retrospective Analysis: Tests Using Historical VUH Census Data

A retrospective analysis comparing the membership data from the two sites who participated in the pilot study to the inpatient and outpatient census data for the five months prior found a total of 42 matches meeting the 0.85 matching threshold. When the analysis was restricted to include only inpatients, it found a total of 35 matches. One religious instituion's data resulted in 19 inpatient matches meeting the 0.85 matching threshold, with 10 of these 19 matching perfectly at 100% and the remaining 9 matching at above 0.85. From the second religious institution's data, there were a total of 16 inpatient matches meeting the 0.85 matching threshold. Of these 16 matches, 2 matched perfectly, one matched at 93%, and the remaining 13 matched at above 0.85. The time period for the analysis covered approximately 20 weeks. Therefore, the study expected to find 1.75 matches per week for an approximate total of 12 matches during a pilot test period of 7 weeks.

Results: Pilot Test of the Pastoral Visit Facilitation System

The pilot study began on May 26, 2011, and data was collected through July 15, 2011. Two religious institution sites participated in the pilot study. One individual at one site and no individuals at the other site opted-out of consideration for participation in the study.

The matching algorithm took 2-3 minutes to run each day. Over the course of the 7-week study period, four matches were identified by the system. The patient was notified and requested a home clergy pastoral visit in two of these matches. In one match, the patient was not notified because his hospital unit required visitors to "scrub-in" before entering the floor, so it was not feasible for the study team to approach him. In the final match, the patient was in the trauma unit and his nurse did not have time approach him between medical procedures to notify him of the study before he left the hospital.

The system identified a match on Tuesday, May 31, 2011, and the PI contacted the charge nurse on the patient's unit floor. The charge nurse declined to consent to participate in the study and asked the PI to notify the patient. The PI entered the patient's room, where the patient was accompanied by his wife and a nurse. The nurse told the PI that she was in the process of moving the patient to another unit but gave permission to talk with him. Ms. Norella introduced herself and explained the purposes of the study as outlined in the patient-contact IRB protocol (Appendix A). She asked the patient if he would like to know the name of the matching institution. The patient agreed, and Ms. Norella opened the envelope and disclosed the name of the religious institution and clergy. The patient confirmed that this information was correct and that he would like to receive a pastoral care visit from this clergy. He clarified, however, that he would like to

receive that visit once he had returned home from the hospital. When asked to sign the HIPAA information release authorization, the patient struggled a bit due to lack of mobility in his hands, so his wife signed it for him.

The study did not place the patient in the panel for the matched religious institution because of his request to receive a visit at home. The PI instead contacted the clergy directly by phone and explained the situation to him, asking him to follow-up with the patient once he had returned home from the hospital. During the follow-up interview, the clergy noted that he had visited the patient and that both the patient and his family were very happy to have received the visit. He added that the patient had been in and out of hospitals for years and rarely contacts his religious institution; however, he really appreciates visits when he receives them.

The system identified another match on Friday, June 3, 2011, but the patient matched was located in a scrub-in only unit within the hospital. The PI and Dr. Miller decided that it was not feasible for such a patient to be visited by non-hospital personnel, so they decided to wait to contact the patient until she was moved to a different unit. The patient was released from the hospital the following day without having been moved to a different unit.

Several weeks passed without any matches being identified by the system, so the PI contacted the clergy at each of the participating institutions to ask if they knew of any hospitalizations that had occurred without the study's knowledge. Both clergy responded that there had not been any patients hospitalized at Vanderbilt during that time frame.

On Friday, June 24, 2011, the system identified another match. Ms. Norella contacted the charge nurse on the unit and was invited to come to the unit floor. Upon

arriving, the charge nurse told the PI that the patient had been temporarily moved from the floor for testing purposes and to try again several hours later. When the PI returned, the nurse consented to participate in the study and agreed to notify the patient of the match. The patient was aware of the study and affirmed that the information was correct. He also signed the information-release document and requested a visit from his clergy. During the post-notification interview, the nurse reported that she felt comfortable notifying the patient, that she thought the system could be beneficial to patients, and that she would prefer notification in a working system to occur through the Overview of Patient Care, a form used by VUH nurses with a summary of patient care information.

The PI uploaded this document into StarPanel, which put the patient's information into the appropriate panel. Because this notification occurred after business hours on a Friday, Ms. Norella also called and sent an email message to the patient's clergy in an effort to contact them before the weekend. The PI was unable to contact the clergy until the following Monday morning, at which point the patient had already been released from the hospital. The patient's home clergy member later gave additional contact information to the PI to prevent future lapses in communication.

On Wednesday, July 6, 2011, the system identified a match in the trauma unit of the hospital. Ms. Norella contacted the charge nurse on the unit, who told her that she was welcome to come to the floor but warned her that the unit's nurses might be too busy to get to the study. Ms. Norella explained the study to the charge nurse and requested that he or the patient's assigned nurse notify the patient of the match. The charge nurse again expressed concerns about time, so the PI left her contact information and asked the nurse to let her know when she should come back to collect the completed patient

questionnaire. She followed up with the charge nurse at 24-hour intervals, but each time, the patient had been occupied with intensive medical care and had not yet been notified. The patient was released from the hospital six days later without having been notified of the system match.

CHAPTER IV

DISCUSSION AND CONLCUSIONS

Overall Summary of Study

Spiritual and religious (SR) care for hospitalized patients provides patients with comfort, reassurance, and a sense of meaning during times of distress. The study explored a method of facilitating SR care in the form of pastoral care visits from patients' "home" clergy – those with whom they have an existing relationship. From meetings with key stakeholders in the study, including patients and families, clergy, hospital administrators and nursing staff, the study team found that most stakeholders were enthusiastic about the prospect of improving the pastoral visit facilitation process while protecting the privacy and confidentiality of patients.

The study team developed a method of privately and securely extracting, encoding, and comparing membership data from religious institution membership lists to VUH daily census data. The method was tested through a pilot study involving two local religious institutions, in which it was discovered that integration into the clinical workflow is a necessary component of the pastoral visit facilitation system. The study results were promising, but the scale was small so more research is necessary before conclusions can be drawn about the system's effectiveness.

Discussion of Pastoral Visit Facilitation Study

The results of the needs assessments indicate a system for facilitating pastoral care visits within VUH might be beneficial. Participating clergy were enthusiastic about the project. The study did not survey patients directly so they inferred patient interest from the meeting with the Patient and Family Advisory Council, who also expressed interest. It is unclear whether this finding might generalize to the entire VUH patient population, but preliminary results suggest that matched patients responded positively to the study.

The study was able to develop a snippet composition that could uniquely identify a large proportion of hospital patients. The work of Grannis et al. suggests that a non-snippet approach with full fields of data (and stronger encryption methods) could produce better matching results.[64] However, for the purposes of the current study, it was important to use the snippet approach to provide an additional privacy protection for the religious institutions' membership databases.

The matching algorithm validation was performed on a set of data that had been created because it was incorrect (i.e., through the process of combining multiple records for the same patient). Even though the data were imperfect, however, the matching algorithm performed very well, with a precision of 98% and a recall of 54%, when the matching threshold was set to allow three unmatched characters between strings (a threshold of 85%).

The matching algorithm took several days to run because of its complexity (and determined by the time required to compare each string to every other string). However, this was a single analysis and not part of regular use of the study, so the time required for

this step did not affect the overall study. Individual runs of the matching algorithm on daily census data took 2-3 minutes with data from the two participating religious institutions. Growth of the system could potentially expand the time required for this analysis and render the system useless. Potential suggestions for reducing computational time in future work will be discussed below.

During the pilot study, the system found 4 hits over the 7-week study period instead of the anticipated 12. It's likely that difference was the result of random chance, but more matches would have given the study more data from which to possibly generalize about the pilot study's results.

For the first patient matched by the system, the notification processes went as planned with the charge nurse on the unit offering to speak with the patient directly and receiving a positive response from the patient. For another one of the matches, the charge nurse requested that the PI notify the patient herself. The notification went well, but the study could not collect any data on the nurse's preferences when she refused to participate. These issues might have been resolved through prior training and automatic notification of nursing staff in the event of a match, but it's not possible to generalize from the results of the study.

Both patients who were notified as a result of the system responded positively. The two patients expressed familiarity with the study, which suggests that the opt-out process worked well for informing members of participating religious institutions about the study. Additionally, both patients requested visits from their clergy. However, these visits were not carried out during the patients' hospital stays but after they had left the hospital. The process of getting from a match identified in the system to an authorization

by the patient to contact his or her clergy was too long for the system to be able to benefit patients much while in the hospital. The study would need to be run for a longer period of time to collect more data before anything else could be said more conclusively.

One nursing staff member was available for a post-notification interview. She gave a positive response to the system, but it is not possible to generalize from her response about the experience of all clinical staff members who might interact with the system if it were put into regular use.

Study Limitations

There are several important limitations that should be addressed in future work. Ideally, the study would have run for a longer period of time to collect more data that could better inform future system development.

As discussed previously, the institutions nominated for participation comprised a convenience sample and were not necessarily representative of all religious institutions for which the project sought to explore the facilitation of pastoral care visits. The study lacked participation from religious institutions of non-Christian faiths. Thus, the results of the study may not necessarily generalize to situations in which religious institutions of other faiths are involved. The study sought to include places of worship from the Islamic, Hindu, and Jewish traditions, but none of the clergy contacted were able to participate. This limitation is substantial because there exists a need for hospital care that is sensitive to the health concerns of patients from local-minority religious backgrounds.[73] For example, Laird et al. have described healthcare disparities for Muslim patients in the US and the UK, a problem that could be addressed by incorporating experts of the Muslim

faith into the SR care of the patient.[74] Additionally, the high rates of dropouts may have resulted from this convenience sample. Had the study team known in advance that the IRB-related requirements for participating religious institutions were going to be as time consuming as they were, the study team could have better communicated these time requirements and the project scope to clergy from the beginning, limiting the number of dropouts along the way.

The study's matching algorithm could not discriminate well among family members living in the same household. That is, when the differences between demographic data among a group of individuals (e.g., family members living at the same address) were small and limited to a single field, the matching algorithm might identify all members of that group as matching with one of the group members.

One of the matches identified by the system was to a patient on the trauma unit. That patient spent several days being moved from the unit to other parts of the hospital for emergency care procedures. Thus, the nursing staff did not have the opportunity to approach him. In this case, the system was unable to facilitate a pastoral visit. The PI speculates that she may have been able to better facilitate the notification process if she had a better understanding of clinical workflow in the trauma unit.

The study was conducted at a single hospital, VUH. Vanderbilt is a unique environment in which administrators and staff were enthusiastic about the project idea. The PI speculates that hospitals that do not focus on research might not be as receptive to the development of their own pastoral care notification systems. Additionally, the system may not be necessary in many hospitals and regions with well-developed methods of communication between hospital staff and the community.

Future Directions: Areas for Further Study

There are several areas of exploration on which future work could expand. It would be helpful to rerun the study with the inclusion of religious institutions that are from non-Christian faiths as well as those whose congregations contain non-English speakers. This study was unable to recruit participants in either of these categories, but both of these groups may benefit from such a system.

Future work should explore other privacy-preserving record linkage techniques than the encode-and-compare approach used here. Such techniques could potentially improve matching while still protecting the privacy and security of the religious institution membership data.

If the study were to expand, the computational aspects would likely need to be re-addressed to become more efficient. For example, one could use a blocking process to identify snippets most likely to be matches and then calculating the Hamming distance only for those strings.[60,61] Another approach to reducing computational time for large data sets is the use of parallel processing.[75,76] These steps would reduce the time required for the matching analysis and make it possible for the system to include membership data from a much larger number of religious institutions.

There are several components of this system that relied on manual work done by the PI. These components, which would need to be addressed for the system to expand beyond its current size, include: going to the hospital to discuss the match with the charge nurse on the unit and then waiting to receive paperwork once the nurse has spoken with the patient; scanning and uploading the HIPAA-information release authorization form into the StarPanel electronic medical record; and notifying the home clergy of

congregants in the hospital and asking them to contact the Department of Pastoral Care to find out the names and locations of those congregants. Future work should explore the possibility of housing the system in pastoral care departments.

It might be possible to consider building a complementary system that brings in local clergy for non-local individuals who have identified a religious preference that the Department of Pastoral Care cannot fill.

APPENDIX A

IRB APPLICATION DOCUMENTS

Vanderbilt University Institutional Review Board
Application for Human Research – Expedited
Behavioral and Social Sciences

1. Study Type Information

Indicate the category of minimal risk expedited review requested. From the categories presented below, check "**Yes"** for the categories that you believe describe your proposed research and "**No"** for all others. If none of the categories apply, complete an application for standard IRB review or contact the IRB staff for instructions.

Note: If you wish to request exemption status, submit ONLY the Request for Exemption.

YOU MUST CHECK "YES" OR "NO" FOR ALL OF THE FOLLOWING:

45 CFR 46.110(f)(1):

☐ Yes ☒ No

Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

45 CFR 46.110(f)(2):

☐ Yes ☒ No

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

45 CFR 46.110(f)(3):

☐ Yes ☒ No

Prospective collection of biological specimens for research purposes by noninvasive means.

Examples:

- hair and nail clippings in a nondisfiguring manner;
- deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- permanent teeth if routine patient care indicates a need for extraction;
- excreta and external secretions (including sweat);
- uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

- placenta removed at delivery;
- amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- sputum collected after saline mist nebulization.

45 CFR 46.110(f)(4):
☐ Yes ☒ No

Colle

ction of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:
- physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
- weighing or testing sensory acuity;
- magnetic resonance imaging;
- electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

45 CFR 46.110(f)(5):
☐ Yes ☒ No
Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). ***NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects: 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.***

45 CFR 46.110(f)(6):
☐ Yes ☒ No
Collection of data from voice, video, digital, or image recordings made for research purposes.

45 CFR 46.110(f)(7):
☒ Yes ☐ No
Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. ***(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects: 45 CFR 46.101(b)(2) except for children when the Investigators participate in the activities and (b)(3). This listing refers only to research that is not exempt.)***

2. Is this proposal related/associated with any other VU IRB approved studies?
➡

☐ No

☒ Yes

If "Yes," please list IRB #(s):100996

3. Location of Research

A. Is this a multi-center research project in which Vanderbilt will function as the coordinating center/lead institution? (A multi-center study is one where different PIs at different institutions are conducting the same study.)

☒ No

☐ Yes ***Note: If "Yes," please indicate the total number of participants to be consented at ALL sites, including VU, in item 11.B.***

B. List all Performance Sites "engaged in research" *(insert additional rows if needed)*.
An institution or performance site is "engaged in research" when its employees or agents (i) intervene or interact with living individuals for research purposes; (ii) obtain individually identifiable private information for research purposes; or (iii) if the institution receives a direct federal award to support such research. Please refer to the instructions for examples of what may be considered "engaged in research." ***This may apply when a VU investigator collaborates with a non-VU investigator or institution, or when VU serves as a Coordinating Center. Please check all that apply and add additional sites. Each will require a letter of IRB approval. See IRB Policy I.C.***

Check all that apply	Name of Performance Site (list all participating sites below)	FWA Holding Institution	IRB of Record	IRB Approval
☒	Vanderbilt University (indicate where at VU): VUH		☒ VU ☐ Other	☐ Attached ☒ Pending
☐	Vanderbilt Stallworth Rehabilitation Hospital		☐ VU ☐ Other	☐ Attached ☐ Pending
☐	University Community Health Services (Vine Hill Clinic)		☐ VU ☐ Other	☐ Attached ☐ Pending
☐	International Epidemiology Institute		☐ VU ☐ Other	☐ Attached ☐ Pending
☐	Faith Family Medical Clinic		☐ VU ☐ Other	☐ Attached ☐ Pending
☐	Other, specify:		☐ VU ☐ Other	☐ Attached ☐ Pending
☐			☐ VU ☐ Other	☐ Attached ☐ Pending
☐			☐ VU ☐ Other	☐ Attached ☐ Pending

C. List all Performance Site(s) "***not*** engaged in research" *(insert additional rows if needed)*. ☐ NA
An institution or performance site is considered "not engaged in research" when its employees or agents **do not** (i) intervene or interact with living individuals for research purposes; or (ii) **does not** obtain individually identifiable private information for research purposes; or (iii) if the institution **does not** receive a direct federal award to support such research. ***This applies if a VU investigator will be conducting research at a non-VU site or institution (e.g., when collecting***

specimens or information). Please refer to the instructions for examples of what may be considered "not engaged in research." *See IRB Policy I.C.*

Name of Performance Site	If the Performance Site has an IRB, a copy of the IRB approval letter is required.	If the Performance Site does not have an IRB, a letter of cooperation is required.
Belmont Baptist Church	☐ Attached ☐ Pending	☐ Attached ☒ Pending
Brentwood Baptist Church	☐ Attached ☐ Pending	☐ Attached ☒ Pending
First Baptist Church	☐ Attached ☐ Pending	☐ Attached ☒ Pending
West End United Methodist Church	☐ Attached ☐ Pending	☐ Attached ☒ Pending
St. Paul's Episcopal Church	☐ Attached ☐ Pending	☐ Attached ☒ Pending
First Presbyterian Church	☐ Attached ☐ Pending	☐ Attached ☒ Pending
Brentwood United Methodist Church		☐ Attached ☒ Pending
Belle Meade United Methodist Church		☐ Attached ☒ Pending
The Temple of Nashville		☐ Attached ☒ Pending

4. Additional VU Committee Approvals (check all that apply): ☒

NA

☐ Scientific Review Committee (SRC)

Approval Date:

5. Funding Information

A. ☒ Internal Funding (check all that apply):

☒ Departmental Funds ☐ No cost study ☐ Personal Funds
☐ Various Donors/Gifts ☐ Other, specify:

B. ☒ External Funding (list all that apply and insert additional rows if needed):

Agency/Sponsor	Funding Mechanism
NLM Training Grant #3T15LM007450-08S1	☒ Grant ☐ Contract

Note: The IRB has a copy of this grant through IRB# 080422 "Vanderbilt Biomedical Informatics Training Program". It is being used to fund the training (tuition and stipends) of Sophia Norella, the study contact.

C. Is this study Industry-Supported? (If so, it is expected that the sponsor will pay the IRB new study fee of $2250 for initial review.)
☒ No
☐ Yes
If "Yes", please indicate method of payment below.

For VU/VUMC (if Industry-Supported):
☐ Please charge my account as follows:
Center Number:

Account Number:

☐ Center and Account Number Pending—I will forward to the IRB when established.

☐ Request for Waiver of IRB Fees attached—see application instructions.

For VSRH, IEI or other non-Vanderbilt sites, payment is required as specified in the signed MOU:
☐ I have attached a check payable to the "VU IRB" in the amount of $2250.

☐ Check Requested—I will forward to the IRB when received.

6. Study Abstract

The proposed project will develop and evaluate an informatics-based model for facilitating pastoral care visits in hospitals. Pastoral visits from patients' "home" religious congregations can help inpatients by giving them familiarity, reassurance, and a sense of spiritual control over their otherwise difficult situations. However, patients' "home" clergy often have no way of knowing when one of their members has been hospitalized, because the HIPAA law prevents direct hospital disclosure of patient lists to visiting clergy. Patients and their families may fail to notify "home" clergy due to the stress and urgency that occur surrounding hospital admissions. We will develop HIPAA compliant, pragmatic algorithms to match congregations' membership lists with hospital census lists to determine when there is a likely match between a new inpatient and a participating institution's membership roster. The study will determine minimally confrontational means to ask patients and their families who appear to match a religious institution whether the patient (or their representative) would like for Vanderbilt to help arrange a pastoral visit from that site.

The proposed study will enroll 8-10 willing institutions in Nashville for a pilot study of the above approach, and individuals at each institution will have the opportunity to opt-out of being considered for participation. We will build a computer program that integrates into the electronic medical record system at Vanderbilt and which facilitates identification of patients suitable for pastoral care visits by matching encrypted abstracts of religious institutions' membership data with Vanderbilt University Hospital patient census lists for adult patients (age 18 or older). We will evaluate the success of the tool in identifying opportunities for pastoral care -- in terms of willingness of nurses to participate, willingness of patients to participate, and completed pastoral visits related to notification by this system.

Please see **Appendix A** for a visual depiction of the study processes.

7. Background Information

➡ ➡

Describe the background information, specific aims, hypothesis or research question, previous experience, and a critical evaluation of existing knowledge (relevant literature) about the research topic. A reference list and copies of pertinent articles can be appended if thought to be of value in the evaluation of the research by the IRB. ***Please contact the IRB if you need assistance in conducting a literature search.*** The IRB needs to understand how this study adds to the knowledge on this topic in order to be able to judge the risks and benefits to the research participants.

Background and Significance:

Hospital care for ill and injured patients should ideally include appropriate patient-specific attention to religion, faith, and spirituality. The Department of Pastoral Care at Vanderbilt University Medical Center (VUMC) includes trained staff representing many different religions and faiths. These individuals provide a number of services, including spiritual guidance, the administration of rites and rituals, and counseling for death or crisis, to help patients and their families/partners during difficult times. Their stated mission is to be "a ministry of compassion dedicated to meeting the spiritual needs of patients and families." Their work serves an important role in VUMC's patient care processes. Nevertheless, Vanderbilt Pastoral Care Staff have confirmed in discussions with proposed project members that many individuals appreciate receiving pastoral visits from their home religious institutions, from clergy members with whom they have an established, trusting relationship.

Pastoral visits from patients' home religious congregations can help inpatients by giving them familiarity, reassurance, and a sense of spiritual control over their otherwise difficult situations. However, patients' home clergy currently have no way of knowing when one of their members has been hospitalized unless they are informed by the patient or someone aware of the patient's situation. The HIPAA law prevents direct hospital disclosure of patient lists to clergy when they visit the hospital. Patients and their families may at times fail to notify home clergy due to the stress and urgency that occur surrounding hospital admissions. When patients have disorders that impair cognition (such as delirium, dementia, or coma), the responsibility to notify home religious institutions regarding their hospitalization typically falls to friends or family members who serve as surrogates. A surrogate may be unaware of the spiritual care preferences of the patient, or may assign a different priority to arranging pastoral visits than would the patient when coherent. As a result of these challenges, religious leaders often have no way of knowing whether members of their congregations are hospitalized and in need of spiritual care.

The proposed project will develop and evaluate an informatics-based model for facilitating pastoral care visits in hospitals. Other potential approaches have drawbacks. For example, the Admissions Office of the hospital might potentially play a role, but there are several reasons why that office cannot solve the entire problem. First, patients admitted via the emergency department and patients "directly admitted" from a physician's office to the hospital ward do not physically pass through the Admissions Office. Second, when patients do enter the hospital through the Admissions Office, the admissions staff will typically ask the patient whether they have a religious affiliation, and, if so, if they would like to request a Vanderbilt Staff clergy member visit. When the patient states a religious preference, the VUH admissions staff must choose one of 22 different religious denominations from a list stored within the computer-based MEDIPAC admissions forms. Even if the admissions staff were empowered to ask if a patient would like for Vanderbilt to arrange a pastoral visit from the patient's home religious institution, the workload in the Admissions Office would preclude staff from obtaining consent for the patient to call such institutions, to determine the exact phone number and name of the institution, and then to notify them of a patient's admission. In addition, for those patients who previously have been hospitalized at Vanderbilt, the computer-based admissions form is automatically populated with the answers that the patient gave on the previous visit. An overwhelmed, rushed, or busy admissions staff member may not remember to ask if there are changes in the patients' responses to questions that look like they have already been answered. Finally, because religious affiliation is for some individuals a sensitive topic, the admissions staff may not feel comfortable asking a patient more open-ended questions about visits from specific clergy members from specific institutions.

The goal of the project is to develop a generic model for supporting inpatient pastoral care visits and supporting algorithms to facilitate home-based pastoral care visits for inpatients, while complying with existing

HIPAA regulations and general ethical principles. The project will evaluate the model's effectiveness in a pilot study. While the goal is general and should apply to any religious institution and any hospital, the current pilot study will use adult patients (age 18 or older) at Vanderbilt University Hospital in Nashville, TN and 8-10 Middle TN agreeable religious institutions as test sites.

Statement of Hypotheses, Specific Aims, and Research Plan:

This study is designed to answer the question of feasibility and acceptability of an informatics-based pastoral visit facilitation tool. We will use qualitative methods to address this question generally as well as quantitative methods to test the following hypothesis. Please see below for more details.

Hypothesis 1: Acceptability. Various groups will rate this project as acceptable for regular use. 1. Before the project is implemented, (a) ≥75% of participating clergy will rate the idea behind the project as something that can improve the existing process at their institution and (b) ≥80% of participating religious institutions' members will participate in the study. During the pilot study, (a) ≥70% of nurses approached will give consent to participate and will carry out with the notification of the patient and (b) patients who match will accept hearing about the project at a rate of ≥75%. Once the project has been implemented and the pilot study has been completed, (a) ≥50% of participating clergy will rate the project as useful enough to warrant continued use, (b) ≥75% of nurses who participated will agree that the project was beneficial to their patients, and (c) ≥60% of these nurses will agree that the tool should be a regular part of nursing practice.

Hypothesis 2: Technical performance. There will be a mechanism to derive unique string extracts that are difficult to identify from the membership information of religious institutions and then encrypt that information for transportation to and storage at Vanderbilt University Medical Center. These strings can then be matched to the hospital patient population list with (a) ≤10% false-positive rate (i.e., ≤10% of matches identified will be incorrect matches of patients to religious institutions to which they do not belong) and (b) ≤20% false-negative rate (i.e., of all participating congregants from participating institutions who are hospitalized during the course of the study, ≤20% of will not be contacted regarding a visit through the use of this tool).

Aim 1: Use surveys and interviews to assess the feasibility of an informatics-based pastoral care facilitation tool.

> **Sub-aim 1:** Identify 8-10 religious institutions willing to participate in this pilot study. Obtain consent from these clergy as well as all contacted clergy who are not interested in participating in the pilot but are willing to participate in surveys and interviews. See Appendix B for this consent form.
>
> **Sub-aim 2:** Send letter (see Appendix C) to one or more clergy at participating institutions explaining the legal and ethical issues involved in the project. Use this letter to ask the clergy to complete a survey, which will assess the perceived need for and utility of the tool at the institutional level. The letter will also provide clergy with key points for verbal and bulletin announcements and a letter for distribution to congregants. This letter will explain the study and allow their members to opt-out if they would not like to be considered for participation in the study Also, send survey from Appendix C (item #4) to clergy who were approached but declined to participate.

Research Plan:

We will identify a sample of religious institutions willing to participate in this study by requesting introductions to clergy from colleagues and friends who have strong ties to particular religious institutions. As we contact these clergy, we will ask for their consent to participate in the study (Appendix B). Once we have identified a sample, we will send a letter (see Appendix C) to the clergy at each participating institution stating that they are agreeing to the use of this tool as a service and that they can withdraw at any time. Should they withdraw, any data that they may have shared with us over the course of the project will be destroyed.

This letter will ask the clergy to complete a single, short, web-based pre-study survey which is designed to determine the need for this project at the religious institution level. This letter will also ask the clergy at each institution to a good faith effort to notify all of their congregants about the project. This notification process will require at least two out of the following three mechanisms: verbal in-service

announcements; a website or blog post announcement; and a letter from the research team to the congregants (Appendix C, item 3) in the form of a newsletter or mailing. The two former methods are expected to reach a smaller number of congregants, and thus we will require that one or both be used in conjunction with the third, a required notification method. This letter to the congregants will explain the study in detail and offer all congregants the opportunity to opt-out of being a potential participant in the study by returning a form in the letter. It will also make it clear to the members that they may withdraw their information from this study at any time and for any reason. Additionally, this letter will ask all participating members to notify their clergy if, at any time during the duration of the study, they are hospitalized at Vanderbilt and not asked if they would like a visit from their clergy. We will ask the clergy to report this information in a post-survey (described below) so that we can determine false-negative rates for matches.

After we have given the letter to clergy, we will send an email with a link to a pre-assessment survey(Appendix C2). This email requesting completion of the survey will be sent to all clergy who have consented to participate in the study, regardless of whether or not they agreed to participate in the part of the study that would require them to use the pastoral visit facilitation tool This survey should take about 5 minutes of their time to complete. The post survey will be discussed in Aim 3.

Aim 2: Develop the informatics-based pastoral care facilitation tool.

Sub-aim 1: Develop a program to extract and encrypt short, partial strings derived from the names, dates of birth, and addresses of religious institution members from the databases from which this membership information is derived.

Sub-aim 2: Install this program on the computers storing membership information at participating religious institutions, and teach the membership administrators how to run it and upload the resulting information to a secure web server on Vanderbilt's secure electronic medical record system. These data will be retained for ≥ 3 months and then destroyed.

Sub-aim 3: Develop an algorithm to match these strings of information to the patient census from Vanderbilt University Hospital.

Research Plan:

We will collect membership information from the religious institutions by installing a small program on the institutional computers that contain their membership database. Sophia Norella and Randolph A Miller, MD, will install this program on the computers and test to ensure it is working properly. This program will take as input a list of members, addresses, zip codes, and dates of birth, and remove parts of that information from each so that what remains will be: the second and fourth characters of the first name, the second, third, and fifth characters of the last name, the decade of birth, the first, third, and fifth characters of the street name, and the last two digits of the zip code. This combination has been chosen for having the highest true positive rate, as calculated using historical census data from StarPanel. That data was analyzed in conjuction with an approval forexempt status as of 08/23/2010 (IRB #100996 "Preliminary Study for Pastoral Visit Facilitation Tool Study").

To collect the membership information, we will set up a secure web service on an existing StarPanel server. Through this web service, institutions can upload the partially de-identified membership data. They will be able to upload this information as often as they think is necessary, based on the rates with which their membership lists change. Once an institution uploads a new/updated membership list, we will remove all information related to the old membership list from our database. We will use the same StarPanel developer box as a secure storage site where we will check for matches between the parts of names, dates-of-birth, addresses, zip codes, and phone numbers found on the membership lists and those of the current patients in the hospital. We will check for matches twice per day, at regular intervals. To limit the number of false positives, we will look for exact matches only. To determine an expected false-positive rate for matches, we will test this matching program on the same identified historical hospital registration data from the past 6-12 months that was used to determine the de-identification scheme.

Aim 3: Determine the attitudes of the nursing staff about the tool and notify patients of matches.

Sub-aim 1: Obtain consent from a potential match's nurse using attached consent form to participate in the study (Appendix D), and interview the nurse (Appendix E) to assess willingness to ask the patient if he or she would like a visit from a specific clergy member. Note: Nurses will be recruited by contacting the

charge nurse on the unit floor of a matching patient and asking for the name of the patient's main nurse (Appendix F).

Sub-aim 2: Ask the nurse to use the script in Appendix G to ask the patient if he or she would like a visit from the clergy at the matching site. Note: patient will have already been informed of the study through the opt-out process. Ask the nurse to record the patient's responses to the questions in the website linked on the form [TBD], asking him or her to sign HIPAA-release form if visit is requested. Use system to send an email (Appendix I) to contact the clergy at that religious institution to ask them to visit the patient.

Research Plan:

The matching algorithm will trigger a notification email to the research team in the event of a match. We will then contact the charge nurse of the unit where the identified patient is located and ask him or her for permission to visit the unit floor and speak with the patient's nurse. The script for this contact is in Appendix F. We will then visit the nurse and obtain his or her consent (using Appendix D) to participate in the study. Once the nurse's consent has been obtained, the research team will use a semi-structured interview to ask the nurse whether or not he or she would be comfortable approaching a patient and asking if he or she would like a visit from a specific clergy member. The general questions for this interview are contained in Appendix E, though they may vary based on the responses given. During this interview, we will also ask the nurse about how he or she would like to be notified of matches in a full version of this tool, whether by the Overview of Patient Care (OPC) section of StarPanel, by email/message, by the Department of Pastoral Care in the hospital, or by the charge nurse on the floor.

If the nurse agrees to ask the patient whether or not he or she would like to participate in the study, we will direct the nurse to a link to a secure website from within StarPanel. This website will contain a script (Appendix G) to aid the nurse in his or her discussion with the patient. In addition, we will give the nurse an envelope containing a piece of paper with the patient's name and the name of the matching religious institution (Appendix H). The nurse will ask the patient if he or she would like to be notified of a potential match. This step assures that all patients, regardless of institution, have the opportunity to make a decision regarding the release of their information at the point of care. If the patient agrees to be notified, the nurse will open the envelope in the presence of the patient, confirm that the information is correct, and ask the patient if he or she would like for the tool to contact a clergy member. If the nurse prefers not to ask the patient whether or not he or she would like to participate in the study, a member of our research team will go through the above process of notifying the patient about the match.

If the patient does not wish to be notified of a potential match, the nurse will destroy the envelope in front of the patient, so that no one sees the information from the paper inside. The nurse will then record the answers on the website that contains the study information [Address TBD]. If all questions are answered affirmatively (i.e., the patient requests a visit), we will notify our contact person (the clergy) at that patient's religious institution in one of the following two ways:

1. Send an encrypted email to our contact person at that religious institution to notify him or her that a patient is at Vanderbilt and requesting a visit (Appendix I). This notification will follow the model of My Health at Vanderbilt, where a message is sent to notify the recipient of important information on a website (the same site where the membership data was uploaded). The clergy will need to log into the website to view the information about which patient is in the hospital and where they can find him or her.
2. Add this person to a list available in StarPanel for Ministers in the Department of Pastoral Care. The Department has decided to assist in the study of this tool as it may potentially add value to their work if the pilot is successful. They will be trained to assist the research team by checking this list and calling appropriate clergy to notify them of patients requesting visits, if necessary.

Aim 4: Evaluate the ability of the tool to identify matches and facilitate pastoral care visits.

Sub-aim 1: Use Survey Instrument 2 (see Appendix L) to survey the clergy at participating religious institutions to determine the value of this tool for them. Use Survey Instrument 3 (see Appendix M) to survey the nurses who participated to determine whether or not they believe the tool was useful.

Sub-aim 2: Use statistical analysis to test the aforementioned hypotheses.

Research Plan:

We will use Likert scales and open-ended questions on Survey Instrument 2 (Appendix L) to survey the clergy who participated in the study. This study will assess whether or not they think that having the tool would improve the existing process at their institution. It will also ask the clergy to comment on what went well and where the tool could have been improved. Likewise, we will use Survey Instrument 3 (Appendix M) to survey the nurses who participated to determine their perception of usefulness for patients and nursing staff members. These surveys will be administered online, through the use of Survey Monkey, and we will send emails to the participants at the appropriate times containing links to the respective surveys and requesting that they be completed within a window of 2 weeks. We will use statistics to calculate the number of matches, the percentage of these that were correct matches, the number of visits resulting from matches, and the number of false negatives.

8. Subject Population(s)

A. Identify all categories or groups, primary or secondary target, age range, total number to be solicited, total number to be consented, and the number expected to complete the study. Primary targets are those who either give consent or those who can only provide assent (e.g., minors). Secondary targets are those who provide data to supplement the primary target data (e.g., parents completing a questionnaire, teachers who supply information and data).

Category/Group (e.g., parents, children, teachers, adults)	**Primary or Secondary Target**	**Age Range** (e.g., 7-12, 13-17, adults)	**Number Directly Solicited** (applies only to mailed survey studies)	**Number to be Consented** (including withdrawals or screen failures)	**Number Expected to Complete the Study**
Adults: nursing staff	☒ Primary ☐ Secondary	adults	☒ N/A	30	15
Adults: clergy	☒ Primary ☐ Secondary	adults	25 ☐ N/A	25	15

Insert additional rows if needed.

TOTALS Enter totals from columns 4, 5, & 6	**25** ☐ **N/A**	**55**	**30**

B.

For multi-center research projects, please provide the total number of participants to be consented at ALL sites, including VU. ***(See item 6.A.)***

☒ **Not Applicable**

C. Check all that are targeted populations for the purpose of the study **(*Complete and attach the appropriate supplemental form(s)):**

☐ Children/minors* (Form #1117)
☐ Cognitively impaired* (Form #1118)
☐ Comatose/Traumatized* (Form #1118)
☐ Elderly/Aged
☐ Females of childbearing potential
☒ Healthy Volunteers
☐ Other, specify:
☐ Pregnant women/fetal tissue/placenta* (Form #1116)
☐ Prisoners* (Form #1115)
☐ Students
☐ Subordinates/Employees (of the VU PI)
☐ Terminally ill participants
☐ VU Students/trainees

D. Describe how the selection of participants is equitable in relation to the research purpose and setting *(e.g., no one ethnic group is targeted or excluded, the same group of participants will benefit from the results of the research*).

Clergy who are willing to participate and located in the Nashville area will be selected. Nursing staff members whose patients have been identified as matches will also be selected. These selections will be regardless of ethnicity, gender, religious affiliation, etc.

9. Does this study target one gender or specific social/ethnic group(s)?

☒ No
☐ Yes *If "Yes," please provide a rationale.*

10. Is the population being enrolled in this study at high risk for incarceration?

☒ No
☐ Yes *If "Yes," will the participants be withdrawn from the study once they are incarcerated?*
☐ No
☐ Yes *If "No," describe how recontacting/reconsenting, treatment, and/or follow-up will occur.*

11. How will non-English speaking participants be consented? ☒
***Not Applicable at this time**

(Federal regulations require the equitable selection of minorities as research subjects to assure that they receive an equal share of the benefits of research and to ensure that they do not bear a disproportionate burden.)

A. Choose one:

☐ A translated written informed consent document in a language understandable to the participant. This should be an accurate translation of the full informed consent document *(consider having a translator present during the consenting process should the participant have any questions).*

☐ Orally, using a qualified translator to translate the English informed consent document to the participant, and a translated short form in a language understandable to the participant (*See* IRB Policy IV.B "Documentation of Informed Consent" for details).

Note: It is acceptable to submit the English informed consent document and the English short form, if there is no current non-English speaking person identified for the study. Once identified, the translated informed consent document or the short form must be submitted to the IRB for expedited review and approval prior to consenting the participant.

B. Identify the name of the individual or translation service that provided the translation.

C. List the qualifications of the individual who provided the translation.

12. Will a waiver or alteration of the consent process or a waiver or alteration of the consent documentation be used?

☒ No
☐ Yes

If "Yes," complete the Request for Waiver of Consent and/or Authorization.

Please refer to IRB Policy IV.C for further guidance. Please be aware, if a protocol is granted a "Waiver of Consent and/or Authorization" by the VU IRB, and the study involves the use of PHI, the PI is responsible for accounting of disclosures. Please contact the Vanderbilt Privacy Office at: http://www.mc.vanderbilt.edu/root/vumc.php?site=HIPAA, or call 936-3594.

13. Participant Identification, Inclusion/Exclusion Criteria, and Recruitment

A. Describe the specific steps to be used to identify and/or contact prospective participants. (If applicable, also describe how you have access to lists of potential participants. Scripts and advertisements should be submitted with this application or examples should be provided for any telephone contacts, advertisements, oral contact, etc.)

We will identify religious institutions that are willing to participate and will conduct qualitative research on the attitudes and processes of the clergy at those institutions. This recruitment will begin through email or phone. This initial contact will request a meeting to describe the study informally, answer any questions about what participation would require, and screen for inclusion criteria. For those who express informal, preliminary interest during this initial contact, we will set up a second meeting to obtain consent. At this time, we will hand the letter (Appendix C) to the clergy. The email is: <<

Hi [name],

I'm a graduate student at Vanderbilt in the Department of Biomedical Informatics. We use information technology tools to improve medical care, and I'm working on a project that will use these tools to facilitate pastoral visits in the hospital. Right now, we're doing a pilot study in which we will develop a tool to use parts of the membership information from several religious institutions to identify when any of that institution's members are in the hospital and to notify the clergy at that church if they are. Our primary concern throughout building this tool will be the protection of the privacy and confidentiality of all participants.

Is there any possibility that you may be interested in participating in this study? If you think it could potentially be useful, I would love to sit down with you to discuss the project further and answer any questions you may have.

Please contact me by email or phone (615-936-1773) to schedule a meeting. I appreciate your consideration.

Thank you!
Sophia Norella

>>

The phone calls follow the same script as this email.

The initial meeting follows mostly the same script as the email, reiterating the very basic project definition and then going into more detail for questions. It also includes: "Do you store your membership data in a database system? If so, what is the name of that system?" to screen for inclusion criteria.

We will also contact the nurses of patients who have been identified as matches and ask them if they are willing to participate in the study. The phone script for recruiting nurses can be found in Appendix F.

B. Describe the specific steps for obtaining informed consent (e.g., by whom, his/her credentials, where, when, etc.).

A member of the research team will use the informed consent document in Appendix B to obtain each clergy's consent in a quiet room in the church. He/she will use the informed consent document in Appendix D to obtain each participating nurse's consent. This consent will preferably be obtained in a quiet room on the unit in the hospital; however, in the case that a quiet room is not available on the unit, it will be obtained in the most quiet area we can find on the unit.

C. Does the person obtaining consent have an existing relationship with the participant?

☐ No
☒ Yes *If "Yes," describe the relationship and how you will protect against undue influence or coercion.*

The answer to this question regarding nursing staff is no. However, in the case of the clergy, the research obtaining consent (Sophia Norella) will have already have met with the clergy once, for less than 30 minutes, to describe the study, answer questions about participating, and screen for inclusion criteria. Sophia will explicitly emphasize o the clergy that they are under absolutely no obligation to participate, regardless of whether or not they have expressed initial interest. We expect that this step will protect against undue influence or coercion.

D. Describe any planned waiting period between informing the potential participants of the research and obtaining consent.

n/a

E. Identify the criteria for inclusion and exclusion and explain the procedures that will be used to determine eligibility. If psychiatric/psychological assessments will be conducted (e.g., depression or suicidal ideation screenings), state who will administer, his/her experience, and how risks will be managed.

To be included, religious institutions must store their membership data in database software on a local computer. They must also have internet access. Only clergy from institutions that meet these qualifications will be considered for this study.

F. Please identify ALL applicable recruitment methods: **NOTE: Please provide a copy of all advertising materials including ads, letters and telephone scripts with this application; must include graphics. In addition, The IRB must review and approve final copies of all audio/videotapes prior to use.**

☒ Not Applicable; or

Choose all recruitment/advertisement methods that apply:

☐ Flyers	☐ Mass E-mail Solicitation	☐ Radio
☐ Internet	☐ Newspaper	☐ Telephone
☐ Letter	☐ Posters	☐ Television
☐ Departmental Research Boards	☐ ResearchMatch (IRB 090207)	☐ Social Media
☐ Other (describe):		

G. Do you agree to release study information to Vanderbilt-approved list services, web sites or publications? (Vanderbilt has a variety of list services and publications, such as the Clinical Trials Website. Posting research protocol information on research-related websites and other listing services, allows potential participants to search and find studies related to their condition or interest**. (*Please be aware that if this research is subject to a contractual agreement, it may be necessary for you to obtain permission from the sponsor prior to authorizing the release of any study information.)***

☒ No, do not release information to research-related web sites and other listing services.
☐ Yes, this information may be released as described in item #1 of the informed consent document (Purpose of the study).

14. Methods and Procedures Applied to Human Participants (Where appropriate, check all that apply)

A. Please provide a chronological narrative of ALL study procedures. ***(For use of multiple assessments, questionnaires, etc., it is suggested that a table is included showing the frequency and duration of each of the study related activities.)***

We will identify a sample of religious institutions willing to participate in this study by requesting introductions to clergy from colleagues and friends who have strong ties to particular religious institutions. As we contact these clergy, we will ask for a meeting to discuss the study with them, screen for inclusion criteria, and answer any questions. If they show initial interest on being contacted further regarding the study during this step, we will request another meeting with them to ask for their consent to participate in the study (Appendix B). We will then send a letter (see Appendix C) to the clergy at each participating institution stating that they are agreeing to the use of this tool as a service and that they can withdraw at any time. Should they withdraw, any data that they may have shared with us over the course of the project will be destroyed. This letter will ask the clergy to complete a single, short, web-based pre-study survey which is designed to determine the need for this project at the religious institution level. This letter will also ask the clergy at each institution to make an in-service announcement to introduce the project to their congregants, using the provided talking points (Appendix C, item 2). Finally, it will include a letter from the research team to the congregants (Appendix C, item 3) that the clergy will need to send out once they have made an announcement to their congregants about the project. Our letter will explain the study in detail and offer all congregants the opportunity to opt-out of being a potential participant in the study by returning a form in the letter. It will also make it clear to the members that they may withdraw their information from this study at any time and for any reason. Additionally, this letter will ask all participating members to notify their clergy if, at any time during the duration of the study, they are hospitalized at Vanderbilt and not asked if they would like a visit from their clergy. We will ask the clergy to report this information in a post-survey (described below) so that we can attempt to determine false-negative rates for matches.

After we have given the letter to clergy, we will send an email with a link to a pre-assessment survey(Appendix C2). This email requesting completion of the survey will be sent to all clergy who have consented to participate in the study, regardless of whether or not they agreed to participate in the part of the study that would require them to use the pastoral visit facilitation tool This survey should take about 5 minutes of their time to complete. The post survey will be discussed in Aim 3.

We will then collect membership information from the participating religious institutions by installing a small program on the institutional computers that contain their membership database. Sophia Norella and Randolph A Miller, MD, will install this program on the computers and test to ensure it is working properly. so that what remains will be: the second and fourth characters of the first name, the second, third, and fifth characters of the last name, the decade of birth, the first, third, and fifth characters of the street name, and the last two digits of the zip code. This combination has been chosen for having the highest true positive rate, as calculated using historical census data from StarPanel. That data was analyzed in conjuction with an approval forexempt status as of 08/23/2010 (IRB #100996 “Preliminary Study for Pastoral Visit Facilitation Tool Study”).

To collect the membership information, we will set up a secure web service on an existing StarPanel server. Through this web service, institutions can upload the partially de-identified membership data. They will be able to upload this information as often as they think is necessary, based on the rates

with which their membership lists change. Once an institution uploads a new/updated membership list, we will remove all information related to the old membership list from our database. We will use the same StarPanel developer box as a secure storage site where we will check for matches between the parts of names, dates-of-birth, addresses, zip codes, and phone numbers found on the membership lists and those of the current patients in the hospital. We will check for matches twice per day, at regular intervals. To limit the number of false positives, we will look for exact matches only. To determine an expected false-positive rate for matches, we will test this matching program on the same identified historical hospital registration data from the past 6-12 months that was used to determine the de-identification scheme.

The matching algorithm will trigger a notification email to the research team in the event of a match. In response, the research team will then contact the charge nurse of the unit where the identified patient is located and ask him or her for permission to visit the unit floor and speak with the patient's nurse. The script for this contact is in Appendix F. We will then visit the nurse and obtain his or her consent (using Appendix D) to participate in the study. Once the nurse's consent has been obtained, the research team will use a semi-structured interview to ask the nurse whether or not he or she would be comfortable approaching a patient and asking if he or she would like a visit from a specific clergy member. The general questions for this interview are contained in Appendix E, though they may vary based on the responses given. During this interview, we will also ask the nurse about how he or she would hypothetically like to be notified of matches in a full version of this tool, whether by the Overview of Patient Care (OPC) section of StarPanel, by email/message, by the Department of Pastoral Care in the hospital, or by the charge nurse on the floor. If the nurse agrees to ask the patient whether or not he or she would like to participate in the study, we will direct the nurse to a link to a secure website from within StarPanel. This website will contain a script (Appendix G) to aid the nurse in his or her discussion with the patient. In addition, we will give the nurse an envelope containing a piece of paper with the patient's name and the name of the matching religious institution (Appendix H). The nurse will ask the patient if he or she would like to be notified of a potential match. This step assures that all patients, regardless of institution, have the opportunity to make a decision regarding the release of their information at the point of care. If the patient agrees to be notified, the nurse will open the envelope in the presence of the patient, confirm that the information is correct, and ask the patient if he or she would like for the tool to contact a clergy member.

If the patient does not wish to be notified of a potential match, the nurse will destroy the envelope in front of the patient, so that no one sees the information from the paper inside. The nurse will then record the answers on the website that contains the study information [Address TBD]. If all questions are answered affirmatively (i.e., the patient requests a visit), we will send an encrypted email to our contact person at that religious institution to notify him or her that a patient is at Vanderbilt and requesting a visit (Appendix I). This notification will follow the model of My Health at Vanderbilt, where a message is sent to notify the recipient of important information on a website (the same site where the membership data was uploaded). The clergy will need to log into the website to view the information about which patient is in the hospital and where they can find him or her. If the nurse prefers not to ask the patient whether or not he or she would like to participate in the study, a member of our research team will go through the above process of notifying the patient about the match.

We will use Likert scales and open-ended questions on Survey Instrument 2 (Appendix L) to conduct a post-survey of the clergy who participated in the study. This study will assess whether or not they think that having the tool would improve the existing process at their institution. It will also ask the clergy to comment on what went well and where the tool could have been improved. Likewise, we will use Survey Instrument 3 (Appendix M) to conduct a post-survey of the nurses who participated to determine their perception of usefulness for patients and nursing staff members. These surveys will be administered online, through the use of Survey Monkey, and we will send emails to the participants at the appropriate times containing links to the respective surveys and requesting that they be completed within a window of 2 weeks. We will use statistics to calculate the number of matches, the percentage of these that were correct matches, the number of visits resulting from matches, and an estimate of false negatives.

B. ☐ **Compensation** ***(Specify the method of compensation (e.g., money, gift certificates, prizes, toys, etc.). If payment schedules are complex, it is suggested that a table is included showing the frequency and amount of compensation.)***

➡ ➡

None.

Are you requesting a waiver for the collection of Social Security numbers? ***(NOTE: Waivers are granted only if the documentation of SS# places participants at risk and the amount is such that it is highly im probable to reach the $600 threshold in a given year)*** ☐No ☐ Yes

If "yes," provide justification:

C. ☐ **Behavioral Observation**

➡ ➡ ➡

Describe the focus, duration, and number of observations and specify how the observations will be recorded. ***NOTE: If this information has been described in detail in item 17.A., it is acceptable to check the box and enter "see 17.A."***

D. ☐ **Randomization**

➡ ➡ ➡ ➡

Describe the randomization process. ***NOTE: If this information has been described in detail in item 17.A., it is acceptable to check the box and enter "see 17.A."***

E. ☐ **Blinding**

➡ ➡ ➡

Describe who will be blinded. Describe if and when research results or previously blinded treatment assignments will be made available to participants. Describe the provisions for breaking the blind (e.g., emergency situations, participant's request, etc.). ***NOTE: If this information has been described in detail in item 17.A., it is acceptable to check the box and enter "see 17.A."***

F. ☒ **Surveys, Interviews, Questionnaires**

➡ ➡ ➡

If surveys, interviews or questionnaires will be conducted with this study, indicate who will conduct the survey, interview or questionnaire and their qualifications. In addition, describe the setting and mode of administering the instrument (e.g., by telephone, one-on-one, group, etc.) and attach a copy of the instrument. ***NOTE: If this information has been described in detail in item 17.A., it is acceptable to check the box and enter "see 17.A."***

The surveys to be used in this study are:
Pre-assessment survey for clergy (Appendix C2)
Post-Assessment of Usefulness of Tool for Clergy (Appendix L)
Post-Assessment of Usefulness of Tool for Nurses (Appendix M)
Each of these three surveys will be administered through the surveymonkey.com website. The research team will send an email to them at the appropriate time to link to the survey and to ask them to complete it by a date (TBD).
The research team will conduct semi-structured interviews with nursing staff members using the list of questions in Appendix E.
Specifically, Sophia Norella, a graduate student in the PhD program in Vanderbilt's Department of Biomedical Informatics, will be administering the surveys and conducting the interviews. She has been trained through a research methods course (BMIF 315: Research Methods in Biomedical Informatics) in both of these areas.

G. ☐ **Document and Artifact Collection**

➡ ➡ ➡

Describe any documents or other artifacts (e.g., student written assignments) that are to be collected.

H. ☐ **Specimen Collection**

i. Blood drawing (indicate total amount drawn for research purposes).
_____ml over _____ period
NOTE: Please include description in informed consent document referencing amount of blood to be drawn in teaspoons, tablespoons, or pints.

ii. Other specimen (describe the type of specimen and frequency of collection).

iii. Will specimens be obtained for genetic testing in association with this study or stored for future use?
☐ No
☐ Yes *If "Yes," include genetic template language in the informed consent document.*

I. ☐ **Deception, Withholding or Postponing Medications/Treatments, or Imposing other Restrictions**

Describe the methods of deception to be used, the medications being withheld or postponed, the length of time medications will be withheld or postponed, any other restrictions to be imposed on participants (e.g., diet, exercise), and the precautions taken to decrease or eliminate risks to participants.

J. ☒ **Data Collection, Storage of Data/Specimens and/or Issues of Confidentiality**
NOTE: Any device (e.g., personal computer, laptop, etc.) used to save or store individually identifiable health information must be either encrypted or saved on a server housed in an approved data center. Vanderbilt Medical Center has agreed to use Check Point. For more information and how to obtain Check Point please visit the website: Information Privacy and Security.

i. Describe the storage of research information including data (hard copies and electronic databases, specimens, audio/videotapes, etc.). Indicate who will have access to the research information, where it will be stored, and how long it will be kept. In addition, describe the final disposition of research information when the study is concluded (e.g., will information be destroyed or will the PI maintain the information). ***NOTE: If this information has been described in detail in item 17.A., it is acceptable to check the box and enter "see 17.A."***

Each participating religious institution will submit a doubly encrypted copy of their membership information via a secure website, where it will be encrypted and transmitted to a password-protected secure StarPanel server in a locked server closet in the basement of the Eskind Biomedical Library, where other protected Vanderbilt Medical Center data (from StarPanel) is stored. This server is protected by firewalls and other security measures consistent with best practices here at Vanderbilt Medical Center. The research team will have access to the data for the duration of the study, and it will be destroyed upon termination of the study. Outcomes measurement will contain no identifying data.

ii. Describe how the confidentiality of participants will be assured. Include a description of any issues specific to the study that might increase the risk of breach of confidentiality. For example, video/audiotapes, discovering information about the participant that could be harmful if released such as mental illness, genetic information, sexual preference, drug abuse, etc. Describe how codes will be generated if codes are used to protect identities, and who will have access to such codes. If a certificate of confidentiality will be provided, include the name of the person holding the certificate. ***NOTE: If this information has been described in detail in item 17.A., it is acceptable to check the box and enter "see 17.A."***

Interv
iews will not be recorded, and all survey data will be stored in an encrypted form on a secure server on Vanderbilt's campus and the data from them will be used only in the aggregate. We will doubly encrypt the membership data from each institution before it is transmitted to Vanderbilt. This data will be used only for matching purposes. That is, it will not be used if there is not a match. In the event of a match, a patient will be asked whether he or she would like to know to which institution he or she has been matched. He or she will receive a note informing them of the match if he or she agrees at that time. Only the research team will have seen the paper with the match, so each patient will be protected from others finding out his or her religious affiliation.

K. ☐ **Audio or Video Taping**

Describe how the audio/videotapes will be stored, how participants' confidentiality will be maintained, and how the tapes will be disposed of when this research is complete.

L. **Use or Disclosure of Protected Health Information**

i. Will Protected Health Information (PHI) be accessed (used) in the course of screening/recruiting for this research?

☒ No
☐ Yes *If "Yes", the following 4 conditions must be met:*

1. The use or disclosure of the PHI is sought solely for the purpose of this research protocol.
2. The PHI will not be removed from the covered entity. *See "The Statement of Hybrid Designation"* for the definition of the Covered Entity.
3. The PHI is necessary for the purpose of this research study.

ii. Does this research use or disclose Protected Health Information (PHI)?
Protected health information (PHI) is individually identifiable health information that is or has been collected or maintained by Vanderbilt's Covered Entity, including information that is collected for research purposes only, and can be linked back to the individual participant.

☐ No
☒ Yes *If "Yes", please indicate below:*

a. indicate the source of the PHI to be collected (e.g., medical records, specimens, data previously collected for research purposes.)
We will access the Hospital Census via StarPanel for the purposes of matching. This data will not be removed from StarPanel at any point.

b. indicate when PHI will no longer be accessed (e.g., closure of study, destruction of database, no expiration).
PHI will no longer be accessed at the closure of the study.

15. Procedures for Study Participants

Complete the table below, indicating who is responsible for payment of research activities and procedures. ***(Limit list to research activities and procedures.)*** Table may be modified as necessary to accommodate more items.

There
will not be payment involved in this study.

16. Minimizing Risks to Participants/Data and Safety Monitoring Plan (DSMP)

NOTE: If VU PI is accepting coordinating center responsibilities, address that specific role in each question below.

A. Is there a data safety monitor or board/committee to review this study for safety and adherence to the study protocol?

☒ No

☐ Yes *If "yes," describe the composition of the committee, their qualifications, and their plans for monitoring the progress of trials and the safety of participants (e.g., timing of DSM reviews and reports, planned interim analysis, etc.).* **Note: DSMB reports are required to be submitted to the IRB at the time of continuing review unless the information affects the risk/ benefit profile of the study.**

NOTE: Regardless of the response to this question, all subsequent questions in this section must be addressed.

No DSMB is planned as there are no physical risks to participants. The identified matches will be reviewed on a bi-weekly basis throughout the study to identify any problems that may arise.

B. Provide a general description of the data and safety monitoring plan and describe plans for assuring data accuracy and protocol compliance.

Membership data will be doubly encrypted before it is sent to Vanderbilt. It will be stored in a secure server (protected by password authentication, physical locks, and a firewall) located within the Department of Biomedical Informatics (StarPanel). Any individual or institutional data will be destroyed at the request of that participating individual or institution, and all membership data will be destroyed when the study is closed. Outcomes measurement will contain no identifying data.

Survey data will be encrypted using a 256-bit encryption, True Crypt, as it is downloaded to a locked computer in the Department of Biomedical Informatics from the survey website. At the time of downloading, names will be removed and replaced with codes. A file containing just the codes and matching names will be encrypted and stored on this machine. The survey data (without names) will be transferred to the same password-protected secure StarPanel server as is used for the rest of the study procedures. The original copy of this data (from the local machine) will be destroyed as soon as this transfer is complete. This way, the key file and the survey data file are stored in two separate places, providing an additional layer of protection. Interview data will be entered directly into this StarPanel server. This server is stored in a locked server closet in the basement of the Eskind Biomedical Library, where other protected Vanderbilt Medical Center data (from StarPanel) is stored. This server is protected by firewalls and other security measures consistent with best practices here at Vanderbilt Medical Center.. Also, we will not share the information regarding a match with anyone except the patient. The nursing staff will have the responsibility to destroy the envelope containing matching information if the patient would not like to receive a visit. Also, the nursing staff will also have the responsibility to retain the HIPAA Information Release-authorization form (Appendix H) until the research team returns to the floor to pick it up. At that point, it will be stored in a locked file cabinet in the Department of Biomedical Informatics on Vanderbilt's campus. The information from matches will be stored only in the aggregate, so that we can have counts of how many correct matches occurred. No names of matched patients will be stored at any time.

Only the research team (Randolph A Miller and Sophia Norella) will have access to the survey, interview, match, and HIPAA-related data. It will all be destroyed at the conclusion of the study.

i. Describe how the risks to participants are minimized (e.g., screening to assure appropriate selection of participants, identify standard of care procedures, sound research design, safety monitoring and reporting).

The participants in this study include the patients who have been identified as matches with the membership of one of the religious institutions in the study. There are no physical risks to participants. The main risk to these patients will be the potential for loss of privacy in the event of accidental disclosure during the collection or storage of membership lists from the participating religious institutions. This risk will be minimized through our process of doubly encrypting the membership data before it is transmitted via a secure website to a password-protected secure server (StarPanel) in a locked room on Vanderbilt's campus. Also, we will not share the information regarding a match with anyone except the patient. The nursing staff will have the responsibility to destroy the envelope containing matching information if the patient would not like to receive a visit. Also, the nursing staff will also have the responsibility to retain the HIPAA-authorization form until the research team returns to the floor to pick it up. At that point, it will be stored in a locked file cabinet in the Department of Biomedical Informatics on Vanderbilt's campus.

iii. Describe how the risks to participants are reasonable in relation to anticipated benefits (e.g., includes benefits to the individual as well as to human kind, indicate how the risks are justified in this population).

The risks to participants include loss of privacy if there is accidental disclosure during the collection or storage of membership lists from the participating religious institutions. This risk is minimal, however, given the security measures that will be in place. There is potential benefit from adding pastoral care visits that would not have otherwise occurred.

C. **Check the appropriate boxes to verify that this information has been read and to certify that you will comply with the necessary requirements for reporting Adverse Events and Suspensions.**

i. ☒ I will comply with requirements regarding the reporting of adverse events (AEs), including plans for reporting of AEs to the IRB and appropriate regulatory agencies. I understand that AEs must be reported to the IRB within 10 working days after learning of the event or problem. ***NOTE: This box must be checked*.**

ii. ***Check one of the following:***

☐ I will report any action resulting in a temporary or permanent suspension of a funded research project to the grant program director responsible for the grant.

☒ This is not a funded research project.

17. Potential Conflict of Interest

A. Is there a potential conflict of interest for the Principal Investigator or key research personnel?

- **The PI is responsible for assuring that no arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research and no arrangement has been entered into where the amount of compensation will be affected by the outcome of the research.**

- **Assessment should include anyone listed as Principal Investigator, or other research personnel on page 1 of this application. Please note that the thresholds of ownership described below apply to the aggregate ownership of an individual investigator, his/her spouse, domestic partner and dependent children (e.g., if an investigator, his/her spouse, domestic partner and dependent children own together $10,000 or 5% worth of equities in the sponsor, it should be reported below). Do not consider the combined ownership of all investigators.**

☒ No
☐ Yes

If "Yes," the protocol must be reviewed by the VU Conflict of Interest Committee.

NOTE: The Investigator may not proceed with the research until a final determination has been rendered by the MCCOIC or the University Conflicts Committee and IRB approval has been granted.

B. *If "Yes," check all that apply*:

☐ Compensation whose value could be affected by the study outcome.

☐ A proprietary interest in the tested product included but not limited to, a patent, trademark, copyright or licensing agreement, or the right to receive royalties from product commercialization.

☐ Any equity interest in the sponsor or product whose value cannot be readily determined through preference to public prices (e.g., ownership interest or stock options).

☐ Any equity interest in the sponsor or product that exceeds $10,000 or 5%.

☐ Significant payments or other sorts with a cumulative value of $10,000 made directly by the sponsor to any of the investigators listed on page 1 of this application as an unrestricted research or educational grant, equipment, consultation or honoraria.

Informed Consent Document Templates

Download from http://www.mc.vanderbilt.edu/irb/forms/ then save and submit as a separate file from the IRB Application.

APPENDIX B

PRE-IMPLEMENTATION SURVEY FOR CLERGY

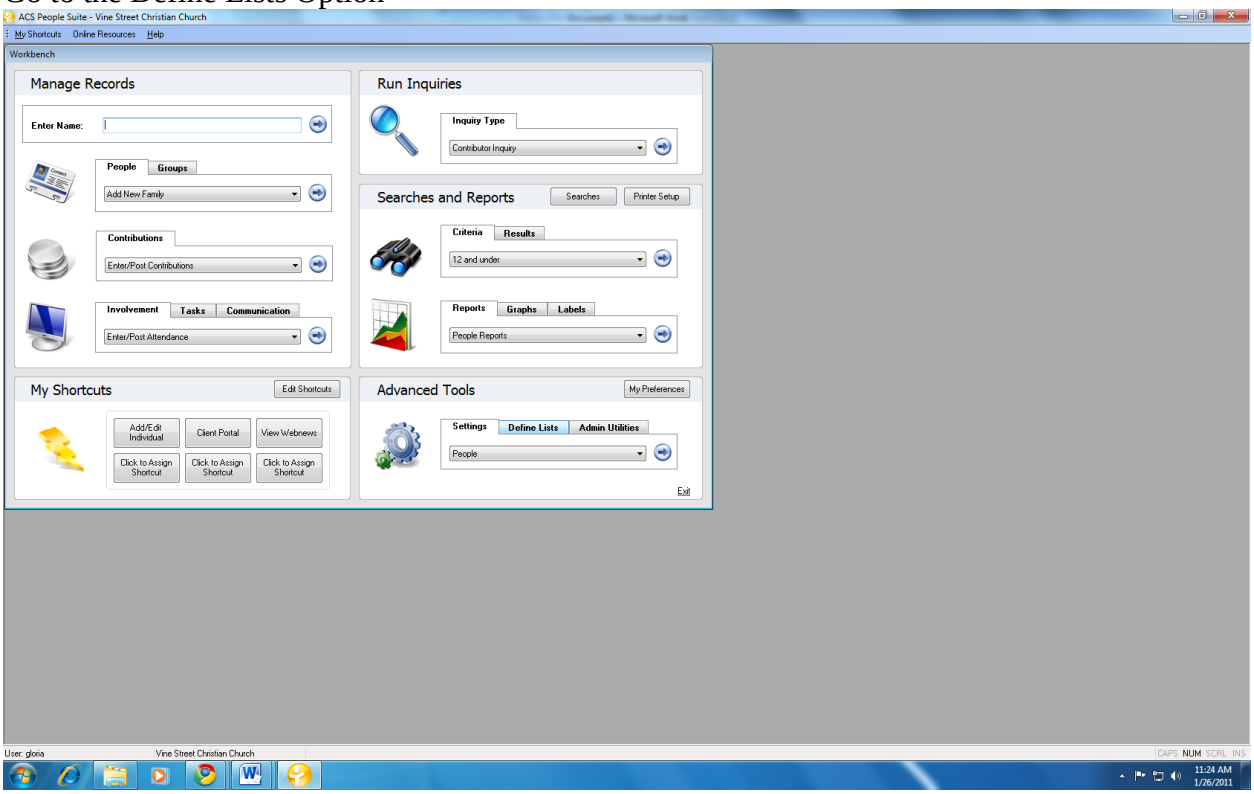
1. What is your role within the ministry of your religious institution (e.g. Head Minister, Director of Pastoral Care, etc.)?
2. How many years have you been a member of the clergy or involved in pastoral care?
3. How long have you been at your current place of worship?
4. Approximately what percentage of your work is spent visiting sick congregants or planning those visits?
5. Have you ever learned about a congregant's hospitalization after the fact, when it was too late to visit him or her?
6. Which of the following best describes your attitude related to the current process of notification for pastoral care visits?
    a. It mostly works well, but we've had a couple incidents where patients did not receive visits as they desired.
    b. It's a struggle to find out when patients are in need of a visit, and we would like a better system.
    c. It's a struggle to find out when patients are in need of a visit, and we would like a better system.
    d. Other (please specify).
7. Do you have any anecdotal stories relating to the process of pastoral care visits that you could share with us? Your responses will be used to help us understand your current workflow and where issues arise.

APPENDIX C

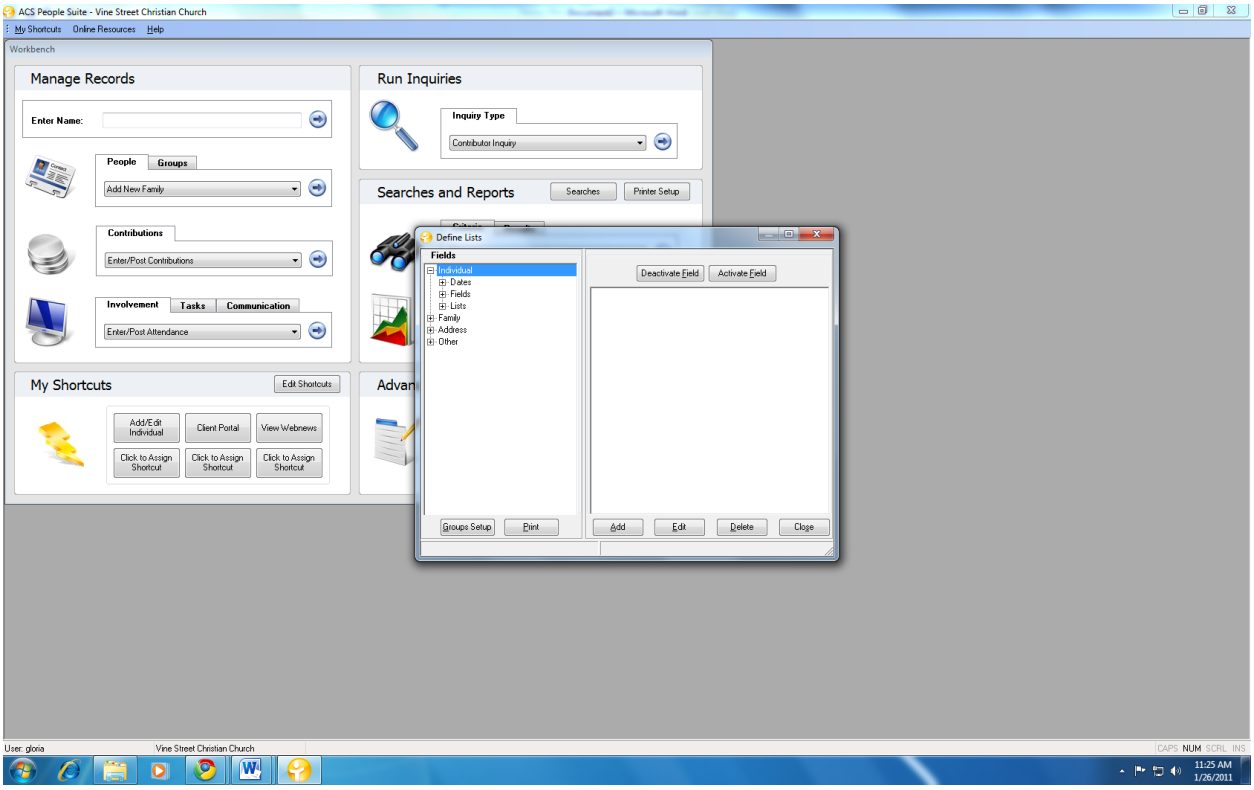
INSTRUCTIONS FOR RELIGIOUS INSTITUTION ADMINSTRATORS IN CHARGE OF MEMBERSHIP DATABASE

1. In ACS, create a list and name it “OptOut.” Put members who have opted out into this list. (Instructions included below.)
2. In ACS, run a search for members, excluding the OptOut list.
3. Choose the Advanced Reports option.
4. Create a new project type, including the fields: “Last Name, First Name,” “Street Address,” “ZIP code,” and “Date of Birth.”
5. In the format tab, choose the icon next to the file location to rename the file. Change the date to match today's date.
6. Run the report, and open the resulting file (an Excel csv file named REPORT_MM_DD_YYYY) in Excel.
7. Save the file as type: Text (tab delimited) with the same file name.
8. In the HOPE folder on your C drive, double click the program that says "CreateSnippets....."
9. Log into the website (https://160.129.203.227/~norellsm/HOPE) and upload the ToUpload file from the HOPE directory.
10. Delete the report export and “ToUpload” files from your HOPE directory.
11. Repeat this process once per month, or as often as you think necessary based on your membership turnover.

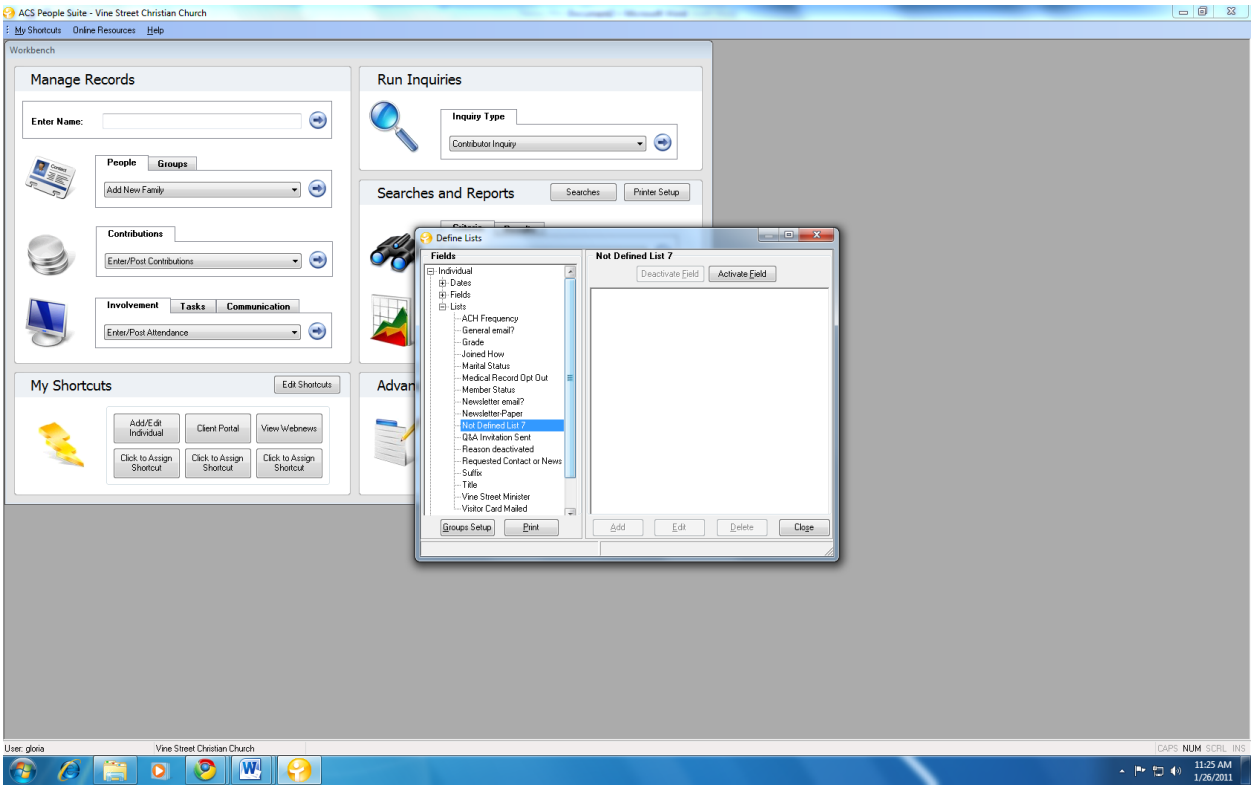
Go to the Define Lists Option



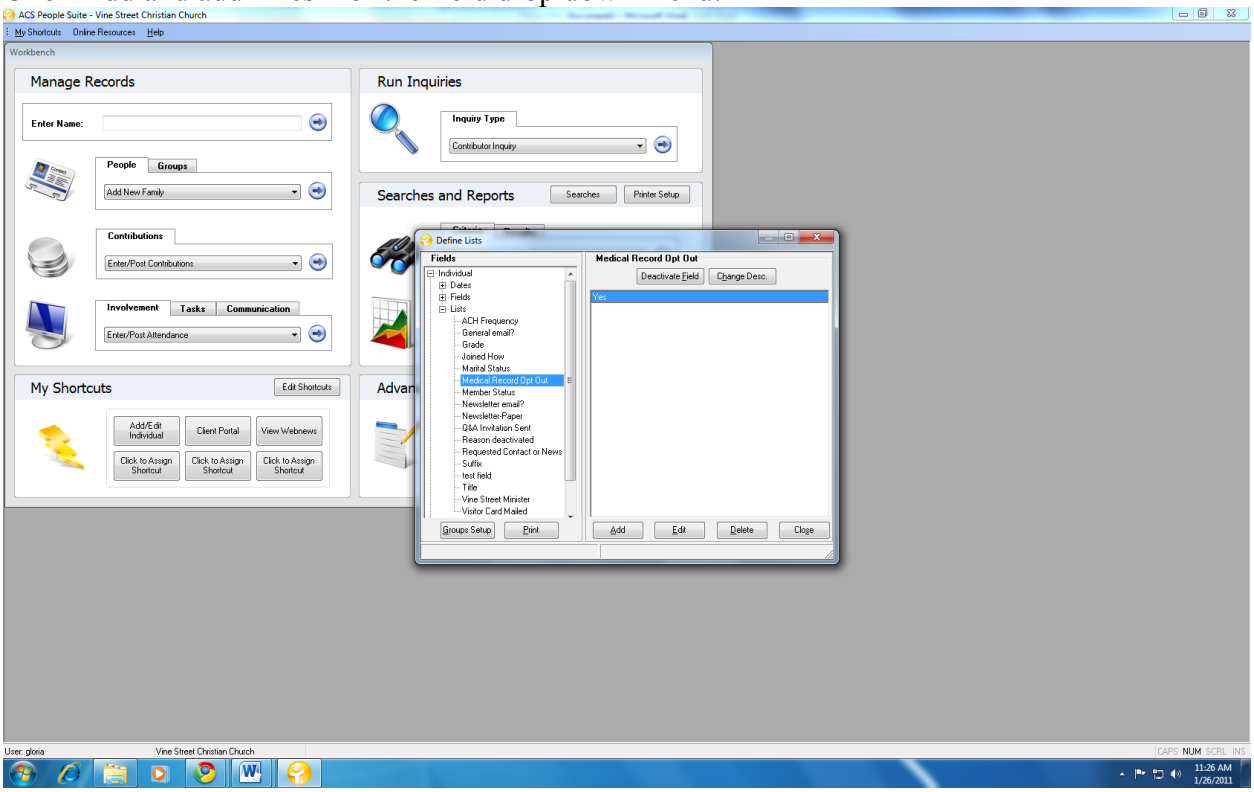
Choose to define a List



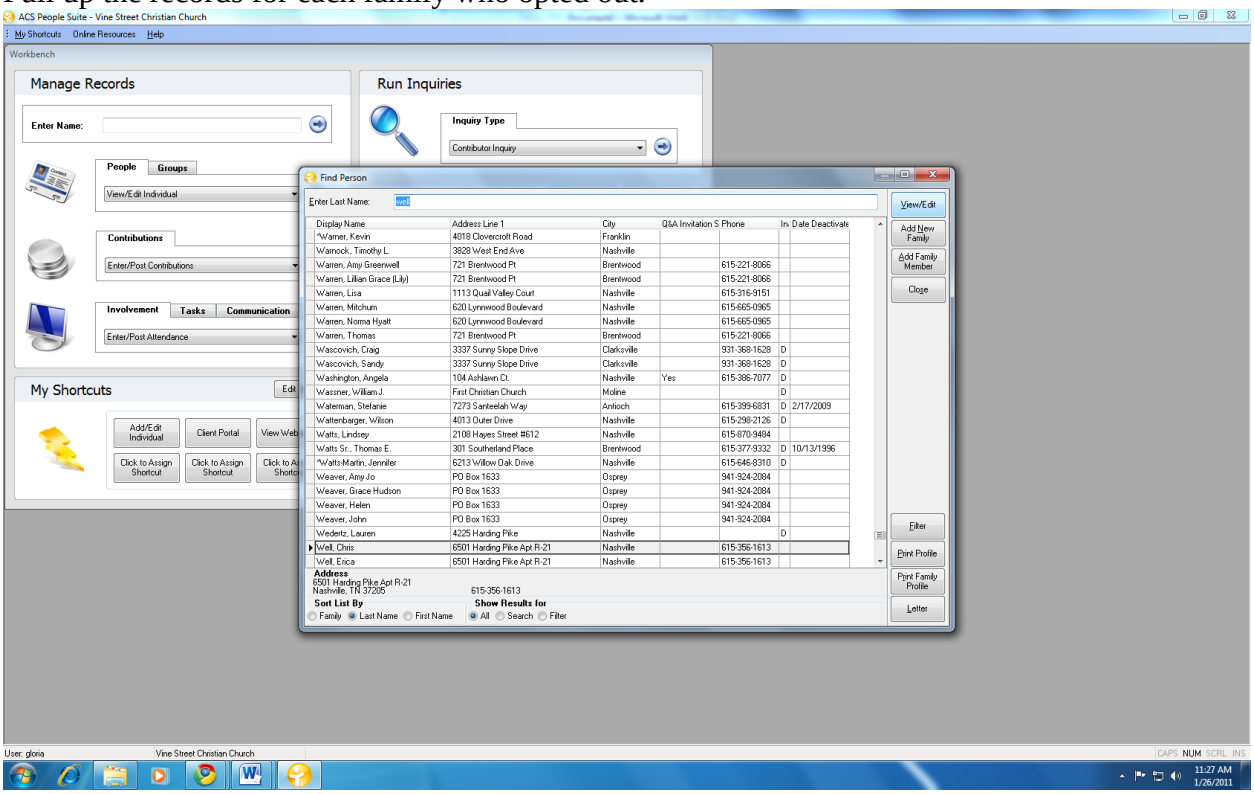
Choose undefined field:



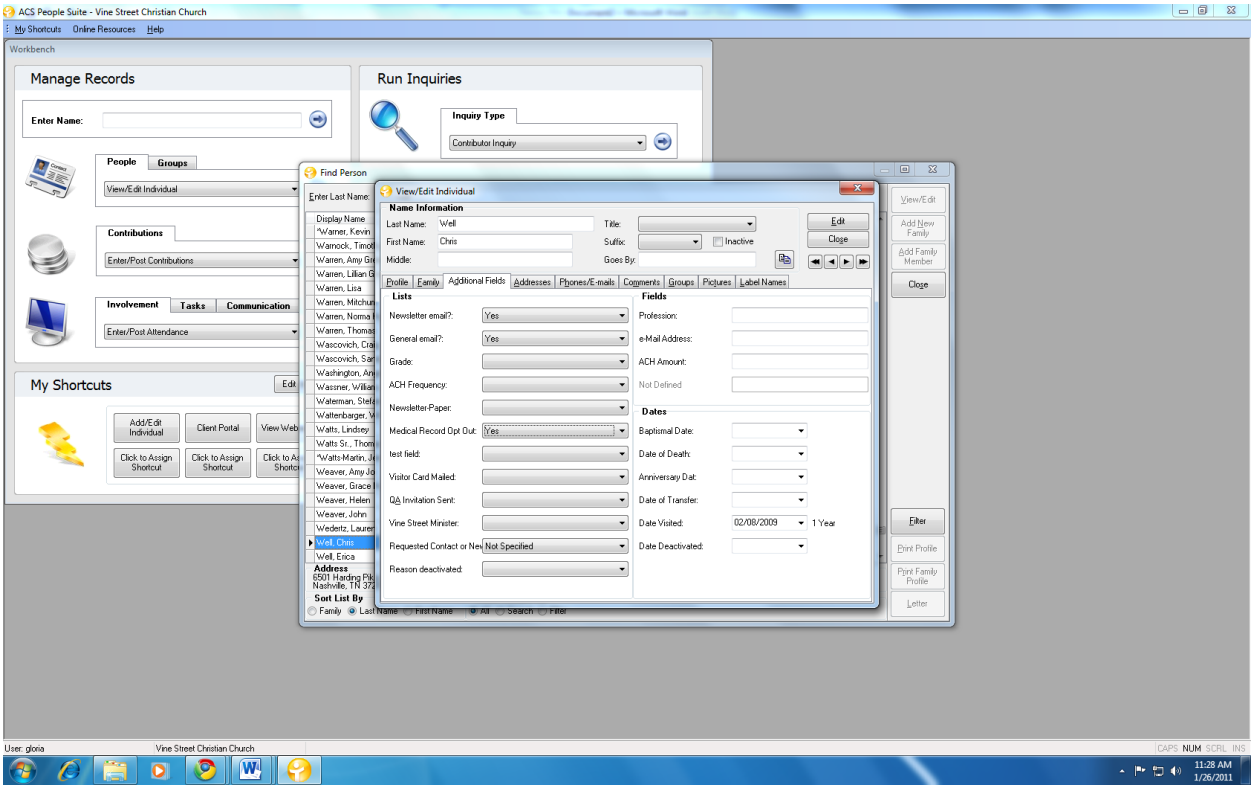
Click Add and add “Yes” for the field drop down menu.



Pull up the records for each family who opted out.



Click the Additional Fields tab. Choose your new Medical Record Opt Out field and select Yes.



Create a new search and use the Medical Record Opt Out field as criteria. You can tell the report to exclude the records that are marked “yes.” Add additional criteria if necessary.

APPENDIX D

HIPAA INFORMATION RELEASE AUTHORIZATION FORM

Vanderbilt University Medical Center

AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION

PATIENT IDENTIFICATION

Name: _____

Date of Birth_____

S.S.#_____

Medical record #_____

(Signed original will be placed in the central medical record and a copy will be provided to the patient)

PLEASE use form# MC3916 when requesting *copies* of records to be sent to other facilities etc.

I authorize the use/disclosure of health information about me as described below.

Description of information that is to be used/disclosed:

We will share your name and room number with the clergy and administrative staff at your religious institution, listed below. This information will be shared so that you can receive a pastoral visit from the clergy at that religious institution.

This information will primarily be shared during business hours for Vanderbilt's Department of Pastoral Care (Monday through Friday between 9am and 4pm), though information may also be released through a member of the study team outside of business hours. Visits may not occur for 1-2 weekdays after the request, and you should contact your clergy directly if you want a more urgent visit.

Who will use/disclose the information:

We wil notify clergy at your home religious institution that they have a congregant requesting a visit. He or she will call Vanderbilt's Department of Pastoral Care, who will disclose your name and room number to your clergy.

In some circumstances, your clergy will not be able to reach someone in the Department of Pastoral Care and will be instructed to call a member of the study team for the release of this information.

Your information will not be used for any other purposes, and we will not save any record of this information following a visit.

If information is to be disclosed outside of VUMC, who will receive it:

Your name and room number will be disclosed to:
Clergy Name(s):
Religious Institution Name:
Contact Phone Number of Religious Institution:

Purpose of the use or disclosure: (not required if the disclosure is requested by the patient)

This information will be disclosed solely for the purposes of attempting to facilitate a pastoral care visit for you. It will not be shared with anyone other than those stated or for any other purposes. There is no guarantee that a pastoral visit will occur; you should call the clergy listed above if no one visits within two weekdays of this notification.

This authorization expires: at the end of this hospital stay. (if blank, then 90 days after date of signature)

I understand that I may refuse to sign this authorization and that my refusal to sign will not affect my ability to obtain treatment. I understand that I may revoke this authorization in writing at any time, except to the extent that action has been taken in reliance on this authorization.

I understand that any information released may be subject to re-disclosure by the recipient and may no longer be protected by federal or state privacy rules related to health information.

Signature of Patient/
Legal Representative: _____ **Date:** _____

Relationship to Patient: _____

To revoke this authorization, please send a written request with a copy of this form to the address below:

Vanderbilt University Medical Center
Medical Information Services – Release of Information
1211 22nd Ave South
Nashville, TN 37232-7350

If you have any questions please call VUMC Medical Information Services at (615) 322-2062.

MC 3173 (7/2003)

BIBLIOGRAPHY

1. VandeCreek L, Grossoehme DH, Ragsdale JR, McHenry CL, Thurston C. Attention to spiritual/religious concerns in pediatric practice: what clinical situations? What educational preparation? *Chaplaincy Today*. 2007;23(2):3-9.

2. Feudtner C, Haney J, Dimmers MA. Spiritual care needs of hospitalized children and their families: a national survey of pastoral care providers' perceptions. *Pediatrics*. 2003;111(1):e67-72.

3. Galek K. Referrals to chaplains: The role of religion and spirituality in healthcare settings. *Mental Health, Religion, and Culture*. 2007;10(4):363.

4. Winter Pfändler U, Winter-Pfändler. Referrals to Health Care Chaplaincy by Head Nurses: Situations and Influencing Factors. *Holist Nurs Pract*. 2011;25(1):26.

5. Clark PA, Drain M, Malone MP. Addressing Patients' Emotional and Spiritual Needs. *Joint Commission Journal on Quality and Patient Safety*. 2003;29:659-670.

6. Maureen R. Benjamins. Does Religion Influence Patient Satisfaction? 2006. Available at: http://www.atypon-link.com/doi/abs/10.5555/ajhb.2006.30.1.85. Accessed June 28, 2011.

7. McClain CS, Rosenfeld B, Breitbart W. Effect of spiritual well-being on end-of-life despair in terminally-ill cancer patients. *The Lancet*. 2003;361(9369):1603-1607.

8. Meraviglia M. Effects of Spirituality in Breast Cancer Survivors. *Oncology Nursing Forum*. 2006;33(1):E1-E7.

9. Mueller PS, Plevak DJ, Rummans TA. Religious involvement, spirituality, and medicine: implications for clinical practice. *Mayo Clin. Proc*. 2001;76(12):1225-1235.

10. Curlin FA, Roach CJ, Gorawara-Bhat R, Lantos JD, Chin MH. How Are Religion and Spirituality Related to Health? A Study of Physicians' Perspectives. *Southern Medical Journal*. 2005;98(8). Available at: http://journals.lww.com/smajournalonline/Fulltext/2005/08000/How_Are_Religion_and_Spirituality_Related_to.4.aspx.

11. Yates JW, Chalmer BJ, St James P, Follansbee M, McKegney FP. Religion in patients with advanced cancer. *Med. Pediatr. Oncol*. 1981;9(2):121-128.

12. Ai AL, Ladd KL, Peterson C, et al. Long-term Adjustment After Surviving Open Heart Surgery: The Effect of Using Prayer for Coping Replicated in a Prospective Design. *The Gerontologist*. 2010. Available at: http://gerontologist.oxfordjournals.org/content/early/2010/07/15/geront.gnq046.abstract. Accessed July 4, 2011.

13. VandeCreek L. Defining and advocating for spiritual care in the hospital. *J Pastoral Care Counsel*. 2010;64(2):5.1-10.

14. Baldacchino DR. Nursing competencies for spiritual care. *J Clin Nurs*. 2006;15(7):885-896.

15. McSherry W, Draper P. The debates emerging from the literature surrounding the concept of spirituality as applied to nursing. *J Adv Nurs*. 1998;27(4):683-691.

16. Clarke J. A critical view of how nursing has defined spirituality. *J Clin Nurs*. 2009;18(12):1666-1673.

17. Swinton J, Pattison S. Moving beyond clarity: towards a thin, vague, and useful understanding of spirituality in nursing care. *Nurs Philos*. 2010;11(4):226-237.

18. Narayanasamy A. The impact of empirical studies of spirituality and culture on nurse education. *J Clin Nurs*. 2006;15(7):840-851.

19. van Leeuwen R, Tiesinga LJ, Post D, Jochemsen H. Spiritual care: implications for nurses' professional responsibility. *J Clin Nurs*. 2006;15(7):875-884.

20. Flannelly KJ, Weaver AJ, Handzo GF. A three-year study of chaplains' professional activities at Memorial Sloan-Kettering Cancer Center in New York city. *Psychooncology*. 2003;12(8):760-768.

21. Vanderwerker LC, Flannelly KJ, Galek K, et al. What do chaplains really do? III. Referrals in the New York Chaplaincy Study. *J Health Care Chaplain*. 2008;14(1):57-73.

22. Vlasblom JP, van der Steen JT, Knol DL, Jochemsen H. Effects of a spiritual care training for nurses. *Nurse Educ Today*. 2010. Available at: http://www.ncbi.nlm.nih.gov/pubmed/21146259. Accessed June 28, 2011.

23. Swinton J. Identity and resistance: why spiritual care needs "enemies." *J Clin Nurs*. 2006;15(7):918-928.

24. Herdman T, North American Nursing Diagnosis Association. *NANDA-I nursing diagnoses : definitions & classification, 2009-2011*. New ed. Oxford: Wiley-Blackwell; 2008.

25. McClung E, Grossoehme DH, Jacobson AF. Collaborating with chaplains to meet spiritual needs. *Medsurg Nurs*. 2006;15(3):147-156.

26. Fleming DA. Making difficult choices at the end of life: a personal challenge for all participants. *Mo Med*. 2005;102(2):147-152.

27. Anandarajah G, Craigie F, Hatch R, et al. Toward Competency-Based Curricula in Patient-Centered Spiritual Care: Recommended Competencies for Family Medicine Resident Education. *Academic Medicine*. 2010;85(12):1897-1904.

28. King DE, Bushwick B. Beliefs and attitudes of hospital inpatients about faith healing and prayer. *J Fam Pract*. 1994;39(4):349-352.

29. Luckhaupt SE, Yi MS, Mueller CV, et al. Beliefs of primary care residents regarding spirituality and religion in clinical encounters with patients: a study at a midwestern U.S. teaching institution. *Acad Med*. 2005;80(6):560-570.

30. Curlin FA, Chin MH, Sellergren SA, Roach CJ, Lantos JD. The Association of Physicians??? Religious Characteristics With Their Attitudes and Self-Reported Behaviors Regarding Religion and Spirituality in the Clinical Encounter. *Medical Care*. 2006;44(5):446-453.

31. Ehman JW, Ott BB, Short TH, Ciampa RC, Hansen-Flaschen J. Do patients want physicians to inquire about their spiritual or religious beliefs if they become gravely ill? *Arch. Intern. Med*. 1999;159(15):1803-1806.

32. Koenig HG. Religion, Spirituality, and Medicine: Research Findings and Implications for Clinical Practice. *Southern Medical Journal*. 2004;97(12). Available at: http://journals.lww.com/smajournalonline/Fulltext/2004/12000/Religion,_Spirituality,_and_Medicine__Research.16.aspx.

33. Fawcett TN, Noble A. The challenge of spiritual care in a multi-faith society experienced as a Christian nurse. *J Clin Nurs*. 2004;13(2):136-142.

34. Rodríguez Del Pozo P, Fins JJ. Death, dying and informatics: misrepresenting religion on MedLine. *BMC Med Ethics*. 2005;6:E6.

35. Anon. ACPE. Available at: http://www.acpe.edu/. Accessed July 5, 2011.

36. VandeCreek L, Burton L. Professional chaplaincy: its role and importance in healthcare. *Journal of Pastoral Care*. 2001;55(1):81-97.

37. VandeCreek L, Gorey E, Siegel K, Brown S, Toperzer R. How many chaplains per 100 patients?: Benchmarks of health care chaplaincy departments. *Journal of Pastoral Care*. 2001;55(3):289-301.

38. Bookbinder M, Blank AE, Arney E, et al. Improving End-of-Life Care: Development and Pilot-Test of a Clinical Pathway. *Journal of Pain and Symptom Management*. 2005;29(6):529-543.

39. Broccolo GT, VandeCreek L. How are health care chaplains helpful to bereaved family members? telephone survey results. *Journal of Pastoral Care & Counseling*. 2004;58(1-2):31-39.

40. VandeCreek L, Smith D. Measuring the spiritual needs of hospital patients and their families. *Journal of Pastoral Care*. 1992;46(1):46-52.

41. Piderman KM, Marek DV, Jenkins SM, et al. Patients' expectations of hospital chaplains. *Mayo Clin. Proc*. 2008;83(1):58-65.

42. Piderman KM, Marek DV, Jenkins SM, et al. Predicting patients' expectations of hospital chaplains: a multisite survey. *Mayo Clin. Proc*. 2010;85(11):1002-1010.

43. Fitchett G, Meyer PM, Burton LA. Spiritual care in the hospital: who requests it? Who needs it? *J Pastoral Care*. 2000;54(2):173-186.

44. Bush JF Jr. Informed consent and parish clergy. *J Pastoral Care Counsel*. 2003;57(4):427-436.

45. Clancy CM. Patient Engagement in Health Care. *Health Services Research*. 2011;46(2):389-393.

46. Berry LL, Seiders K, Wilder SS. Innovations in Access to Care: A Patient-Centered Approach. *Annals of Internal Medicine*. 2003;139(7):568 -574.

47. VandeCreek L. How satisfied are patients with the ministry of chaplains? *Journal of Pastoral Care & Counseling*. 2004;58(4):335-342.

48. OCR. Summary of the HIPAA Privacy Rule. Available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html. Accessed June 28, 2011.

49. Hofmann PB. Data release procedures ensure clergy's access, patients' privacy. *Hospitals*. 1977;51(8):71-73.

50. Tovino SA. Hospital Chaplaincy under the HIPAA Privacy Rule: Health Care or Just Visiting the Sick. *Ind. Health L. Rev.* 2005;2:51.

51. Loewy RS, Loewy EH. Healthcare and the hospital chaplain. *MedGenMed*. 2007;9(1):53.

52. Johnson SC. Coping with breast cancer: the roles of clergy and faith. *JOURNAL OF RELIGION HEALTH*. 1991;30(1):21.

53. VandeCreek L, Gibson S. Religious Support from Parish Clergy for Hospitalized Parishioners : Availability, Evaluation, Implications. *Journal of Pastoral Care*. 1997;51(4):403-414.

54. OCR. Are hospitals able to inform the clergy about parishioners in the hospital? Available at: http://www.hhs.gov/ocr/privacy/hipaa/faq/facility_directories/357.html. Accessed June 28, 2011.

55. Erde E, Pomerantz SC, Saccocci M, Kramer-Feeley V, Cavalieri TA. Privacy and patient–clergy access: perspectives of patients admitted to hospital. *Journal of Medical Ethics*. 2006;32(7):398 -402.

56. Cashen MS, Sklar BM, Nguyen HHT, et al. Implementing a Web-based information resource at an inner-city community church: lessons learned. *Comput Inform Nurs*. 2002;20(6):244-250.

57. Burkhart L, Androwich I. Measuring spiritual care with informatics. *ANS Adv Nurs Sci*. 2009;32(3):200-210.

58. Ledbetter TJ. Screening for pastoral visitations using the Clinical+Coping Score. *J Pastoral Care Counsel*. 2008;62(4):367-374.

59. Madhavan S, Sanders AE, Chou W-YS, et al. Pediatric palliative care and eHealth opportunities for patient-centered care. *Am J Prev Med*. 2011;40(5 Suppl 2):S208-216.

60. Verykios VS, Karakasidis A, Mitrogiannis VK. Privacy preserving record linkage approaches. *International Journal of Data Mining, Modelling and Management*. 2009;1(2):206 - 221.

61. Hall R, Fienberg SE. Privacy-Preserving Record Linkage. In: Domingo-Ferrer J, Magkos E, eds. *Privacy in Statistical Databases*.Vol 6344. Berlin, Heidelberg: Springer Berlin Heidelberg; 2010:269-283. Available at: http://www.springerlink.com/content/m32xq75577623387/. Accessed June 28, 2011.

62. Schnell R, Bachteler T, Reiher J. Privacy-preserving record linkage using Bloom filters. *BMC Medical Informatics and Decision Making*. 2009;9(1):41.

63. Durham E, Xue Y, Kantarcioglu M, Malin B. Quantifying the correctness, computational complexity, and security of privacy-preserving string comparators for record linkage. *Information Fusion*. In Press, Corrected Proof. Available at: http://you.myipcn.org/science/article/pii/S1566253511000340.

64. Grannis SJ, Overhage JM, Hui S, McDonald CJ. Analysis of a Probabilistic Record Linkage Technique without Human Review. *AMIA Annu Symp Proc*. 2003;2003:259-263.

65. Navarro G. A Guided Tour to Approximate String Matching. *ACM COMPUTING SURVEYS*. 1999;33:2001.

66. Anon. Drupal Security White Paper | drupalsecurityreport.org. Available at: http://drupalsecurityreport.org/. Accessed July 13, 2011.

67. Anon. TCP/IP Protocols. Available at: http://www.w3schools.com/tcpip/tcpip_protocols.asp. Accessed July 14, 2011.

68. Anon. Johnson, P. Authentication and session management on the web. Written for GIAC S.

69. Sandhu R, Coyne E, Feinstein H, Youman C. Role-Based Access Control Models. 1996. Available at: http://citeseerx.ist.psu.edu/viewdoc/summary?doi=10.1.1.50.7649.

70. United States. *The Belmont report : ethical principles and guidelines for the protection of human subjects of research*. [Bethesda]: The Commission ; Washington for sale by the Supt. of Docs. U. S. Govt. Print. Off. [1978]; 1978.

71. Roden DM, Pulley JM, Basford MA, et al. Development of a large-scale de-identified DNA biobank to enable personalized medicine. *Clin. Pharmacol. Ther*. 2008;84(3):362-369.

72. Brennan PF, Strombom I. Improving Health Care by Understanding Patient Preferences. *J Am Med Inform Assoc*. 1998;5(3):257-262.

73. Aboul-Enein B, Aboul-Enein F. THE CULTURAL GAP DELIVERING HEALTH CARE SERVICES TO ARAB AMERICAN POPULATIONS IN THE UNITED STATES. *Journal of Cultural Diversity*. 2010;17(1):20.

74. Laird LD, Amer MM, Barnett ED, Barnes LL. Muslim patients and health disparities in the UK and the US. *Archives of Disease in Childhood*. 2007;92(10):922 -926.

75. Christen P, Zhu J, Hegland M, et al. High-Performance Computing Techniques for Record Linkage. 2002. Available at: http://citeseerx.ist.psu.edu/viewdoc/summary?doi=10.1.1.19.8760.

76. Christen P, Hegland M, Roberts S, et al. Parallel Computing Techniques for High-Performance Probabilistic Record Linkage. 2002. Available at: http://citeseerx.ist.psu.edu/viewdoc/summary?doi=10.1.1.19.9857.