TEXAS ACADEMY OF FAMILY PHYSICIANS FOUNDATIONS

Application for Research Project Grant

A. PROJECT TITLE

The Complexity of Family Medicine Visits: An RRNET Study.

B. PRINCIPAL INVESTIGATOR

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C. HUMAN SUBJECTS

If activities involving human subjects are not planned at any time during the proposed study period, check the space marked "NO." If activities involving human subjects, whether or not exempt from regulations, are planned at any time during the proposed study period, check the space marked "YES." If the activities are designated to be exempt from regulation, insert the exemption number(s) corresponding to one or more of the six exemption categories listed on the description of human subjects regulations in PHS document #398.

____NO __X__YES ☐ (if "YES") Exemption #'s ________________________

or

IRB approval date: ____pending____
Assurance of compliance# FWA # 00011753 (JPS IRB)

D. OUTLINE OF SCHEDULE FOR IMPLEMENTATION OF PROJECT

RESEARCH EVENTS	TIMELINE
Apply for IRB Approval	February 15, 2015
Receive IRB Approval	April 1, 2015
Meet with 10 Faculty (Student Supervisors)	May 1, 2015
Student Training	May 23, 2015
Student Data Collection	May 26 – June 19, 2015
Data Analysis	July 1-Sept 15, 2015
Write-Up	July 1, 2015 - March 1, 2016
Dissemination of Results	October 2015 - November 2016

H. APPLICATION ORGANIZATION/AFFILIATION

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J. STUDY DESCRIPTION (Should Not Exceed Ten Total Pages)

J-1. Statement of Purpose

The practice of family medicine is complex. Managing and coordinating care of multiple chronic conditions is routine work in a family physician's workday. Competing demands for the physician's time and attention can threaten adherence to clinical guidelines. (Parchman, Pugh, Romero, & Bowers, 2007) Yet these guidelines, focused on single diseases, do not account for trade-off decisions that physicians must make every day to provide patient-centered care. (Safford, Allison, & Kiefe, 2007) Biomedical complexity is only one part of the picture. Additional variables influence medical decision-making: patients' socioeconomic status; gender; culture/ethnicity; environment/ecology; health behaviors; functional status; cognitive impairment; mental disorders; addiction; social capital; family relationships; personal priorities; health systems barriers; and doctor-patient dissonance. (Grant et al., 2011; Nardi et al., 2007; Peek & Baird, 2009; Safford et al., 2007; Schaink et al., 2012; Shippee, Shah, May, Mair, & Montori, 2012; Smucker, Zink, Susman, & Crabtree, 2001)

Details about outpatient visits have been recorded in large databases organized by the National Ambulatory Medical Care Survey (NAMCS). This was established in 1973 to gather, analyze and disseminate information about health care provided by office-based physicians in the United States. Physicians complete a one-page questionnaire for each patient visit during a limited reporting period. Data include patient demographic characteristics (age, sex, race, ethnicity), and visit characteristics: patients' symptoms, complaints or other reasons for the visit, physicians' diagnoses, diagnostic and therapeutic services ordered or provided at the visit including medications, expected sources of payment, visit disposition, and time spent with physician. (Hsiao, Cherry, Beatty, & Rechtsteiner, 2010)

In 2010, Katerndahl and colleagues developed measures of complexity of outpatient visits using 2000 NAMCS data. (Katerndahl, Wood, & Jaen, 2010) They calculated *quantity* of information and services exchanged between doctor and patient, the *variability* of these exchanges, and overall *diversity* of information and activity across many encounters. Visit "input" included that which the patient brought in the door: reasons for visit, diagnoses, information from exams and testing, and demographic characteristics. Visit "output" included doctors' actions: prescribing medications and therapies, performing procedures, and directing the next step (follow-up, referral, etc.). ***Quantity*** of information included average number of reasons for visit, number of diagnoses, number of medications prescribed, and so forth. But complexity is not limited to counts and averages; Katerndahl and colleagues' measures of complexity also included ***variability*** of information. For example, did patients routinely have one or two reasons for visit, or did that number vary widely from visit to visit? ***Diversity*** of information is a third important measure of complexity. This addresses the wide range of specific reasons for visit, diagnoses made, medicines prescribed, etc. What amount of information makes up 95% of all visits? In a 2011 paper comparing the complexity of family medicine with cardiology and psychiatry, 491 possible diagnoses were identified in the NAMCS database.(Katerndahl, Wood, & Jaen, 2011) Family Medicine practice addressed 47% of the list during 95% of their visits, Cardiology addressed 19% and Psychiatry addressed 6%. Using quantity, variability, and diversity of visit inputs and outputs, a complexity measure is calculated and adjusted for the duration-of-visit, called the "complexity density." Katerndahl et al (2011) found that visit input was similar in Family Medicine and Cardiology until measures of diversity were incorporated. Cardiology output was higher until the duration of visit was included. Looking at complexity density, the complexity of care per hour was 33% higher in family medicine than cardiology, and psychiatry had very low complexity.

While detailed, the NAMCS dataset is limited to the biomedical aspects of patient care, and does not include all of the input and output factors that a family physician incorporates into medical decision making. A variety of other contributing vectors impact patient complexity and consequent medical decision-making, including patient economics, social capital, psychological health, personal priorities, and health systems barriers.

The literature is fairly silent on the "so what" aspect of complexity. Physicians who gather information about the various influences described above should demonstrate improved skills in crafting patient-centered care plans. The complexity of a visit, patient, or practice might influence other concerns in healthcare delivery as well, such as patient safety and quality of care. One might expect that higher complexity would be associated with more imperfections in how care is delivered, as shown in Parchman et al. (2007). The Agency for Health Care Research and Quality (AHRQ) has sponsored a series of research initiatives to better understand the relevant patient safety and quality issues in primary care, and has helped develop an instrument, widely used in the field, to measure the risk for an adverse outcome. (Kaprielian, Ostbye, Warburton, Sangvai, & Michener, 2008)

J-2. Statement of Hypotheses *(one paragraph)*

The purposes of this study are to 1) describe the complexity of outpatient visits in the practices of the Residency Research Network of Texas, and 2) correlate complexity scores to scores of the risk for adverse events. Through careful documentation of 1000 visits across 10 clinical sites, we will be able to describe the characteristics of the RRNeT patient population, their reasons for visits, common diagnoses, care delivered, medicines and other treatments ordered, referral patterns, and nonmedical factors, such as social milieu, economic issues, communication difficulties and health systems barriers. We will also be able to correlate measures of visit complexity (both biomedical complexity and psychosocial complexity) with safety/quality measures in outpatient practice.

We hypothesize that visits of high complexity will be associated with higher probability of medical errors, and increased adverse events.

J-3. Description of Related Work by Others or Yourself

Inefficiencies and Savings in the Health Care System, 2010

In 2010, after reviewing the literature that showed more primary care physicians in an area contribute to better population health at lower cost, RRNET set out to determine why. We conducted a qualitative interview study of 38 family physicians to ask, "What is it that you do that creates quality health care at a lower cost?" (Young et al., 2013) Two major themes emerged: (1) characteristic attitudes and skills that routinely considered cost to the individual and to the system; and (2) the family physician's thorough knowledge of the whole patient. One key skill that physicians reported was the ability to manage complexity.

> *Family physicians managed multiple organ systems and symptoms in the same visit, as well as combinations of acute and chronic conditions. Their ability to triage large amounts of data, enabled by an extensive knowledge of organized medicine, behavioral health, and health care systems was a recurring theme. Subjects commonly believed the best care occurred when family physicians provided as much care as possible as opposed to coordinating a [fragmented] series of specialist visits. (Young et al, 2013, p.314)*

We concluded that family physicians' efficient and effective approach to providing health care was anchored in individualizing the management of multiple new symptoms and chronic conditions. This required comfort with uncertainty, ambiguity and complexity.

Creating a Fairer Physician Payment System, 2011

Are family physicians fairly paid for managing complexity? In 2011, RRNET completed a qualitative study of the payment system for family physicians. (Young, Bayles, Hill, Kumar, & Burge, 2014a) Thirty-two interviews were completed with family physicians in private practices, residency programs and community health centers. Most reported that fees and rules for documentation and coding for procedures and prevention were reasonable. But for all other visit types, physicians felt the existing codes did not describe the actual work for common clinic visits. Physicians reported inadequate payment for complex patients, for multiple patient concerns addressed in a single visit, and work required outside of face-to-face time. One key theme from multiple interviews addressed Care of Complex Patients:

> *Participants believed they were not adequately paid for taking care of patients with complex needs, which could arise from factors including multiple chronic diseases, difficult patients, family/social factors, language/cultural barriers, and financial barriers. (Young et al. 2014a, p.381)*

We concluded that family physicians in Texas felt the system undervalued and under-appreciated them for the complex and comprehensive care they provided. They believed the coding system should take into account the time required to provide care for complex patients. (Young, Bayles, Hill, Kumar, & Burge, 2014b)

The Scope of Outpatient Practice, 2011.

To document what family physicians in RRNET actually *do* during routine office visits, we implemented a NAMCS-like study of 793 outpatient visits in 9 RRNET residency programs. Medical students shadowed randomly selected RRNeT physicians and completed a visit survey for each patient visit over a 4-5 week period. Data included patient demographic characteristics (age, sex, race, ethnicity), and visit characteristics: patients' reasons for the visit, physicians' diagnoses, diagnostic and therapeutic services ordered or provided at the visit including medications, expected sources of payment, visit disposition, and time spent with physician. We carefully documented the demographics of our patient populations and the scope of RRNET outpatient practice.

In the RRNET sample of 793 visits, 66% of patients were female, and 55% were Hispanic. Their median age was 48, ranging from newborn to 97 years old. Thirteen percent were children or teens 20 years old or younger, and 16% were seniors, 65 or older. Obesity was common, 38% in adults, 13% in children. The most frequent reason for an outpatient visit was "follow up for a chronic condition" – 25%. In 42% of visits, physicians managed hypertension; in 27% they treated high lipids; in 26% they addressed diabetes; in 23% of visits, they managed mental health problems, and in 21% of visits, they treated arthritis.

David Katerndahl, family physician faculty at the UT Health Science Center used his measures of complexity of outpatient encounters and applied these calculations to RRNET data for each clinical site.(Katerndahl et al., 2010) The table below shows RRNET measures side-by-side with the 2008 national NAMCS findings. Shown are average visit "inputs" (information received by the physician during the clinical encounter), average "outputs" (physicians' decisions made about therapies and procedures), and complexity measures for Inputs, Outputs, and Total. Visit variability and diversity are not shown here. In the RRNET measures of Outputs, medications vary widely from the NAMCS data because NAMCS limited their list to 7 medications, while RRNET did not. Also, RRNET did not measure procedures, so those outputs were not measurable in this study. Given these limitations, we note that RRNET practices vary widely in complexity measures. Site 4 is an outlier, with the fewest visits recorded, and the longest visit durations.

	2008 NAMCS	n=93	n=98	n=100	n=26	n=92	n=99	n=98	n=97	n=90
		Site 1	**Site 2**	**Site 3**	**Site 4**	**Site 5**	**Site 6**	**Site 7**	**Site 8**	**Site 9**
Input (Means)										
Reasons	1.60	1.63	2.03	1.54	1.69	1.52	1.68	1.64	1.67	1.97
Diagnoses	1.89	1.86	2.03	1.75	1.46	1.73	1.45	1.64	1.76	2.26
Exam/Tests	1.20	1.93	1.67	0.81	2.00	0.47	1.58	1.47	1.25	2.18
New Patients	0.09	0.11	0.07	0.08	0.23	0.10	0.13	0.13	0.06	0.11
Output (Means)										
Medications	2.62	5.27	6.53	4.43	6.31	7.02	3.05	3.57	6.89	7.44
Procedures	0.07	---	---	---	---	---	---	---	---	---
Other Therapy	0.65	0.75	0.96	0.46	0.65	0.47	0.89	0.37	1.68	0.52
Complexity Density										
Visit Duration	19.13	15.14	15.24	12.02	61.02	16.19	19.00	12.17	19.72	20.94
Total Input	13.17	18.29	18.38	19.96	4.46	14.36	13.57	21.69	13.18	14.13
Total Output	8.28	14.74	16.28	15.76	3.67	15.97	8.27	12.87	15.86	12.44
Total Complexity*	152.0	361.2	414.5	251.5	84.8	234.1	162.4	271.8	319.9	379.3

When this study was completed, RRNET felt limited by the 2007 NAMCS format. It allowed only 3 reasons for visit, 3 diagnoses, and 7 medications. Our physicians knew that many patients present with multiple concerns, have long problem lists, and take many medicines. Thus, we suspect that complexity measures that address the 'true numbers' in family medicine will be more accurate.

The 2014 version of the NAMCS survey addresses some of these shortcomings. (http://www.cdc.gov/nchs/ahcd/ahcd_questionnaires.htm)The number of reasons for visit and diagnoses has expanded to five, and the list for medications can accommodate 30 medicines. The lists of exams, lab and imaging tests, procedures and treatments have expanded as well. We will incorporate this version into the current study.

Our previous Scope of Outpatient Practice Study was also limited to measures of biomedical complexity, based on the NAMCS format. In the proposed study, we plan to incorporate additional measures of complexity (including psychological, social, and economic issues, and health systems barriers) to more fully describe the complexity of family medicine visits. Furthermore, we seek to address the impact complexity of care by correlating it an important outcome: quality and safety measures.

J-4. Experimental Design and Methods

Study Population

The Residency Research Network of Texas (RRNeT) is a collaboration of 11 family medicine residency programs located in Austin, Corpus Christi, Dallas, Edinburgh, Fort Worth, Garland, Harlingen, Lubbock, McAllen, and San Antonio (2 programs). About 100 family physician faculty and 300 family medicine residents see more than 300,000 patient visits per year. Nearly 60% of patients are Latino; 25% of them speak Spanish only. About one-third of RRNeT patients have employer-paid health insurance, one-third have government health insurance, such as Medicare or Medicaid, and one-third are uninsured.

This is a study of family medicine *visits* in the outpatient setting. These include visits with any patient who consents to documentation of the visit for research purposes. Study patients may include infants, children, adolescents, adults, and seniors. This year, 10 of the 11 RRNET clinical sites will participate; the Austin program has opted out of this study due to time constraints.

Design and Methods

This is a cross-sectional survey of primary care visits. This study uses a *visit survey* to describe each patient's visit in some detail. NAMCS-derived Information includes the reason for visit; new or continuing patient; diagnoses; screening services; exams; medicines; procedures; nonmedical treatments; and referral patterns. (http://www.cdc.gov/nchs/ahcd/ahcd_questionnaires.htm) We have included additional items derived from Peek and Baird (2009) and Shaink et al. (2012) to address physicians' diagnostic uncertainty; patients' readiness to accept treatment; experiences with family and social networks; health system issues; cultural and socioeconomic issues. The survey will also document safety/quality using medical error items derived from Elder et al. (2004) and Kaprielian et al

(2008). This visit survey is anonymous for patients; no patient identifiers will be included on this form – no birthdates, names, addresses, medical record numbers, or contact information.

This study will randomly select visits *by physician.* During the data collection period (May and June 2015), researchers will identify all physicians (family physician or family medicine residents) working in each half-day clinic session. For each session they will randomly select one physician. Medical student researchers will shadow the selected doctor during that session, observing and documenting every other visit, for a total of 100 visits.

Each student will work in one clinic site, shadowing residents and faculty as they see patients. Students will be responsible for consenting patients, collecting 100 visit surveys (1 per patient) at their respective RRNET clinical site, and entering de-identified data into a secured database. Collection of this number of surveys should take about 4 weeks.

Sample Size

A sample size of 1000 allows us to estimate a 95% confidence interval of approximately .12 of a standard deviation among continuous variables, with alpha = .05 and beta = .80. It also allows for group comparisons (for example, regional differences in diabetes); with 1000 patients we can find 10% differences between group proportions, with alpha < .05 and beta = .80.

Statistical Analysis

NAMCS complexity measures. Because we will gather detailed visit information in a NAMCS format, we will be able to replicate the analyses described by Katerndahl et al (2010). His team calculated measures of complexity of three medical disciplines using *quantity* of information and services exchanged between doctor and patient, *variability* of these exchanges, and overall *diversity* of information and activity. (Katerndahl et al., 2010; Katerndahl et al., 2011) Measures of visit “input” address information coming in to the office: reasons for visit, diagnoses, information from exams and testing, and demographic characteristics. Visit “output” includes doctors’ actions and decisions: prescribing medications and therapies, performing procedures, and directing the next step (follow-up, referral, etc.). The calculations have been described in Katerndahl et al (2010). We will use NAMCS items and apply these measures to evaluate *complexity for each RRNET practice.* This will allow us to describe the complexity of family medicine clinical practice over the entire network and make comparisons between practices.

Visit-level complexity may be estimated with these data as well. While diversity is a practice-level measure, quantity and variability can be assessed per visit, giving us an understanding of the amount of information exchanged during patient visits.

The Minnesota Complexity Assessment Method (MCAM, Peek and Baird, 2009) addresses additional assessments of complexity, such as patients’ readiness to accept treatment, experiences with family and social networks, health system issues, and cultural and socioeconomic issues. This tool has a scoring system for each item, ranking complexity from 0 (very simple) to 3 (very complex). We will create a composite score of the MCAM, and correlate it with the NAMCS-based measures of complexity. Additionally, individual item scores will be correlated with NAMCS-based measures.

Quality/safety can be assessed at the visit-level and the practice-level. At the visit level, we can evaluate quality/safety in three ways. First, we can create a composite score of medical errors, which is a simple count of errors checked per visit. Second, we can consider medical error per visit as present = 1 or absent = 0. Third, we can rate the seriousness of the error by assessing the adverse outcomes for the patient: none, minor, moderate, or serious. At the practice-level, we can record the number of visits with medical errors, or the mean number of errors per visit, or the mean severity of errors across visits. Each of these measures of medical errors will be correlated with the NAMCS- and the MCAM measures of complexity, described above.

Expected Results

We will be able to describe thoroughly the characteristics of the RRNeT patient population and the information exchanged between doctors and patients during outpatient visits: reasons for visits, common diagnoses, medicines prescribed, procedures completed, treatments ordered, and referral patterns. We will calculate measures of complexity and compare our practices side-by-side. We will describe additional issues that add to the complexity of family medicine visits: patients' readiness to accept treatment, experiences with family and social networks, health system issues, and cultural and socioeconomic issues. These measures of complexity will be correlated with measures of medical errors to determine the potential impact of visit complexity on health care quality/safety.

Potential pitfalls

Investigators are doing the following things to avoid pitfalls.

1. Careful training for the faculty mentors in the study procedures.
2. Careful training for the medical student assistants in the study procedures.
3. Early application for IRB in each site, so that it is finalized in all 10 sites.

We anticipate no problems in recruiting the desired number of patients or collecting the data. Previous experience in these settings shows low refusal rates (12% or less).

Estimated number of weeks

We will require 4 weeks for data collection.

Additional time is needed for study preparation, IRB applications, training of medical students and RRNET faculty, database cleanup, data analysis, write-up and dissemination. We anticipate this project will take one year, overall.

J-5. Study Site and Resources

This study will be conducted in the Residency Research Network of Texas (RRNeT), a network of 11 family medicine residency training programs in 10 cities across Texas. These network members have been research collaborators since 1998 and are well-equipped to implement this study successfully. Each residency program has an on-site RRNET investigator who will supervise data collection at his/ her site. Dr. Burge at UTHSCSA will recruit medical students who wish to complete a research elective in family medicine. They will be tasked with collecting data for the study, entering data into a central database, conducting simple analyses, and developing poster presentations for dissemination activities. RRNeT representatives from each program are listed below.

RRNET Representatives		
City	**Hospital**	**Representative**
1. Austin	University Medical Center at Brackenridge	Swati Avashia, MD
2. Corpus Christi	Christus Spohn Hospital Memorial	Jerry Kizerian, PhD
3. Dallas	Charlton Methodist Hospital	Ronya Green, MD
4. Edinburgh	Doctors Hospital at Renaissance	Deepu George, PhD
5. Fort Worth	John Peter Smith Hospital	Richard Young, MD
6. Garland	Baylor Medical Center	Sarah Holder, DO
7. Harlingen	Valley Baptist Hospital	Nina Torkelson, MD
8. Lubbock	Texas Tech University	David Edwards, MD
9. McAllen	McAllen Medical Center	Matiana Gonzalez Wright, PhD
10. San Antonio	Christus Santa Rosa Hospital	Tammy Armstrong, PsyD
11. San Antonio	UTHSCSA – University Health System	Ashok Kumar, MD

J-6. Instruments to be Used

To examine the complexity of visits, the survey borrows items from the *2014 National Ambulatory Medical Care Survey*, the *Minnesota Complexity Assessment Method*, (Peek & Baird, 2009) and ‘elements of complexity’ from Schaink et al. (Schaink et al., 2012) To address quality/safety, the survey merges two medical error documentation systems from Elder et al. and Kaprielian et al. (Elder, Vonder Meulen, & Cassedy, 2004; Kaprielian et al., 2008) The Visit Survey is included in **the Appendix.**

K. PROTECTION OF HUMAN SUBJECTS

Dr. Burge, co-investigator at the University of Texas Health Science Center (UTHSCSA) will first apply for Institutional Review Board (IRB) approval with UTHSCSA. We anticipate an expedited review, because no patient identifiers will be collected and the study has no health risks. An IRB template and model consent form for this study will be distributed among all participating RRNET sites so each can apply for IRB approval locally. Each site will inform us when they receive IRB approval. No data will be collected at a site until that site has IRB approval from their own institution.

This is a simple description of routine primary care visits with no intervention; there are no health risks to patients who choose to participate. Sources of data will include medical students' and physicians' reports of the activities of each patient visit. The only potential risks to participants will be loss of confidentiality of their personal health information. RRNET has 11 hospitals and 12 IRB committees. It is possible that the IRBs will consider both the patient and the physician as subjects in the study, because we will be gathering health information about the patient and information about medical decision-making and healthcare quality/safety from the physicians.

Both patients and physicians will be informed of the aim of the study, the study procedures, and the information that we plan to collect. They will also be informed that their participation is completely voluntary and that they can cease participation at any time. Finally, they will be aware that their participation in this study is anonymous. Patient names and identifying information will not be included on the study instruments.

The proposed Visit Survey describes each patient's visit in some detail. Information includes the reason for visit; new or continuing patient; screening services; diagnoses; medicines; nonmedical treatments; the type of provider; referral patterns; patients' readiness to accept treatment; experiences with family and social networks; health system issues; cultural and socioeconomic issues. The survey will also document medical errors discovered or made during each visit.

Each patient visit will be assigned a subject identification number that will be recorded on each data collection instrument. Subject names will not be recorded on the data collection forms.

All data will be entered in a centralized database with access limited to the research investigators and one statistician. All data will be kept on password protected computers that have the requisite anti-virus software. Data will be kept behind locked doors or on secure investigator laptops.

Before data collection begins, RRNeT representatives in each clinic will identify physicians to participate in the study and elicit their consent for medical students to shadow them and gather data from their visits. Physicians-to-shadow will be selected randomly for each clinic session; those who refuse to participate will not be included in the randomization process.

When potentially eligible patients arrive at the clinic, students or clinic staff will approach them, introduce themselves, and describe the purpose of the study. The student or staff member will give the patient a copy of the information sheet [or consent form], ask the patient's permission to use information about today's visit for the study, and ask their permission for a student to shadow the doctor during this visit.

If the patient is a child aged 17 or younger, or a cognitively disabled adult, the student or clinic staff member will seek permission of their parent or guardian. If the child is 7 years or older, the student/staff will also ask the child's assent (permission) to include their medical information in the study.

If the patients agree to participate in the study, the student/clinic staff member will observe the visit, and complete the *visit survey* based on their observations, post-visit discussion with the physician, and information in the patient's clinical record.

For patients who prefer NOT to participate in the study, students will make a note on a refusal checklist which will include a brief description of the patient (gender, age), and the reason for their refusal provided.

L. BENEFITS OF THE PROJECTS

This project will give us tangible evidence of the complexity of family medicine clinical practice, information that may benefit family medicine policy and practice. Our work reaches beyond the complexities of biomedical care and includes non-disease factors known to interfere with care. Our project also addresses the "so what?" of practice complexity by correlating complexity with safety/ quality measures. Policy makers, including payers, regulators, and quality/safety advocates will have more detailed observations on which to base their decisions. Results of this study could lead to improved quality and safety measures, ambulatory electronic databases, workforce distribution, and primary care payment models. At the practice level, health care providers who have a thorough grasp of patients' challenges can craft plans of action that go beyond the single-disease oriented approach.

M. REFERENCES CITED

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N. APPENDIX

Survey instrument included as a separate document. An information letter will be provided to the observed physician and each patient.