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Award Number: W81XWH-07-2-0064

TITLE: The Economic and Quality of Life Impact of Remote Technologies on High Risk Patients and Their Caregivers

PRINCIPAL INVESTIGATOR: Steven J. Berman, M.D.

CONTRACTING ORGANIZATION: St. Francis Healthcare Foundation
Honolulu, HI 96817-1652

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14. ABSTRACT

This pilot study compares the clinical outcomes, economic impacts, and patient and caregiver ratings of Quality of Life and satisfaction of a Remote Technology (RT) intervention to Home Health Aide (HHA) intervention or Usual Care (UC). 28 high-risk patients with ESRD were randomized into 3 groups for intervention: RT, HHA, or UC. The pre-intervention surveys of Quality of life, satisfaction, and health utilities were conducted. Measurements of healthcare resource utilization including ER visits and hospitalizations have been initiated as well as a mechanism to gather economic evaluations to calculate marginal cost-effective ratios for RT and HHA. Implementation of interventions was delayed for almost 6 months because we underestimated the time required for the IRB review process and our process of randomization to either HHA or RT was flawed. We did not appreciate that chronically ill patients with a high disease burden have developed an unspoken system of support and coping. Home intervention must convince the patient/caregiver of its supplemental value; and, the patient/caregiver must be physically capable of performing the required tasks of the intervention. A sharp interest in the Home Electronic Medical (HEMR) created from the uploaded monitoring data for each patient was expressed by physicians when the monitoring equipment was demonstrated A literature review finds little information of the value of a HEMR in decision-making.

15. SUBJECT TERMS
Remote Technologies; Cost Effectiveness; High-Risk Patients; Caregivers; Dependent Care

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The Economic and Quality of Life Impact of Remote Technologies on High Risk Patients and Their Caregivers

Table of Contents

The Economic and Quality of Life Impact of Remote Technologies on High Risk Patients and Their Caregivers

INTRODUCTION:

The care of patients disabled from chronic disease is costly--not only in terms of increased medical expenditures and loss of productivity, but for caregivers, who are more likely to report increased levels of stress. Improved health outcomes using remote technologies have been demonstrated; however, convincing cost-effective analyses have been lacking, and relief of caregiver burden is uncertain. This is a pilot study testing a patient and caregiver-centered Plan of Care (POC) utilizing remote technologies (RT) or a program of home health assistance by Home Health Aides (HHA) compared to a control group of similar patients receiving Usual Care (UC) or optimal dialysis care. Up to thirty high-risk patients from a population of patients with end stage renal disease will be divided into the 3 groups. The objectives are to determine whether home intervention featuring RT will be more cost effective than HHA or UC, and whether patient Quality of Life and caregiver satisfaction will be higher in the RT group.

BODY:

During the first 12 months of the Pilot Study, the project office was established and personnel were hired. Telehealth equipment was researched, purchased and installed, and staff completed extensive training on its use. Meetings were held with medical personnel, including managers and staff from Liberty Dialysis, Hawaii and affiliated nephrologists to explain the project, garner support, and plan for patient recruitment/enrollment. Local and federal approvals were received, permitting us to proceed with the Pilot Study. Patients were recruited, consented, given baseline surveys, and enrolled in one of the three study limbs. Initiation of interventions was delayed three months: the IRB approval process and initial recruitment and enrollment of patients took longer than planned.

The status of each task in the approved Statement of Work follows.

STATEMENT OF WORK: Initial Period (18 months)

Task 1. Conduct all appropriate procedures with institutional review boards (3 months).

Task 1 is complete. IRB approval was to have been completed by month 3. The process took longer than suggested in the early stages of the project, and the time for completion of this task was 6 months:

- 12 October 2007: The project protocol, consent form and supporting documents were sent to the local Institutional Review Board (IRB), Hawaii Pacific Health (HPH) IRB.
- 13 November 2007: HPH IRB granted initial approval to the study documents pending modifications to the protocol and consent form.
- 18 December 2007: HPH IRB approval received; all documentation was sent to ORP HRPO NGTMR, via TATRC, on 19 December.
- 4 February 2008: ORP requested minor modifications to the protocol, consent form and supporting documents; we submitted revisions on 8 February in response to their Initial Memorandum for Record (MFR).
- 21 February 2008: A follow-up MFR recommended submission of the revised protocol documents, including all ORP recommended revisions, to the HPH IRB; our request was submitted to HPH IRB on 22 February.
- 4 March 2008: Received final HPH IRB approval (Appendix 1); documents were then submitted again to ORP.
- 13 March 2008: Final approval to proceed with the project was received from ORP (Appendix 2).

Reasons for the delays included:

1) The St. Francis Healthcare Foundation did not have a Federal Wide Assurance (FWA) number, a requirement for IRB submission. The Foundation applied for the FWA on 24 September 2007, and the FWA number was received on 26 November.
2) Coordination between a local and federal agency, separately at times, simultaneously at others, to receive necessary approvals for the project and to satisfy both agencies' requirements took longer than expected. We appreciated

USAMRMC ORP HRPO assistance; their feedback was concise and practical in helping us move forward expeditiously with the project.

Task 2. Acquire, install, and test hardware and software for remote monitoring (3 months).

Task 2 is in progress. All equipment has been acquired and tested. We are working with the vendor to reconcile software problems as they arise. Installation is ongoing (please see narrative in Task 4 below.)

Remote technology equipment was selected during the first quarter of the project; quotes were obtained from three vendors. Research staff worked with the selected vendor, VitelNet, to configure the system and to get specifications for IT support in the project office.

Minimal equipment, including the clinical workstation, server, and two remote monitoring units (Turtle 700 units), was initially ordered from VitelNet to enable preliminary training of research personnel and demonstration of capabilities to medical personnel, patients and caregivers. Testing was also done to determine the adequacy of the video-teleconferencing configuration via telephone line vs. internet connection. A VitelNet representative spent one week in the HOPE offices, installing the equipment and training personnel on home installation of the monitoring units and use of equipment, including patient interaction and report acquisition. Key team members trained on use of the system include the Principal Investigator (PI), Associate PI, Remote Care Coordinator/Home Care Coordinator (RCC/HCC), Project Care Manager, IT Specialist and Administrative Assistant. Since receipt of the first installment, research staff training has been ongoing to ensure complete familiarity with the system prior to installation in patients' homes.

The remaining remote monitoring units were received from VitelNet during the third quarter. Additionally, Vitelnet configured a laptop to serve as a "traveling" workstation/server. This allowed the PI to meet with physicians and Liberty Dialysis personnel in their offices to demonstrate the system's capabilities and elicit interest in/support for the pilot project.

The plan was to acquire, test, and install 10 remote units by 1 February 2008. As of 18 July 2008, 4 units have been installed in patients' homes. Reasons for delays included:

1) Final IRB approvals were not received until March 2008, three months later than anticipated. This caused a 3-month delay from the outset for recruitment of subjects, assignment to study limb, and installation of equipment in RT patients' homes.
2) The recruitment, consent and assignment process was lengthier than anticipated (please see narrative in Task 4 below). This delayed the installation of equipment in patients' homes.

Task 3. Train healthcare personnel, patients, and caregivers to competency in use of remote technologies (RT).

and

Train Home Health Aide (HHA) in support assistance tasks and monitoring of patients.

Task 3 is ongoing. A VitelNet representative spent one week in the HOPE offices training personnel on home installation of the monitoring units and use of equipment, including patient interaction and report acquisition. Key team members trained on use of the system include the PI and Associate PI, RCC/HCC and Project Care Manager, IT Specialist and Administrative Assistant. Staff training has continued in the interim, to ensure proficiency with the remote monitoring system prior to installation in patients' homes. Patients and caregivers receive training on use of the remote monitoring equipment upon installation in the home; follow-up training is provided as needed.

One of two home health aides (HHA) was hired and began training during the third quarter. A second HHA was hired a month later. HHA hiring was postponed to conserve funds, since the project had been delayed while awaiting IRB approvals. During the subject recruitment period, the HHAs continued to train for home care responsibilities. One HHA did not pass the probationary period and her employment was terminated.

Task 4. Conduct pilot study of 30 patients (9 months).

- **Develop and test study database.**
- **Gather and enter relevant patient information into database.**
- **Identify potential subjects using Risk Score stratification.**
- **Recruit, consent, and enroll patients and caregivers (30 patients).**
- **Deliver Remote Technology services to study cohort of ten patients using home monitors and video teleconferencing.**
- **Deliver Home Health Assistance services to study cohort of ten patients.**
- **Collect data on hospitalization, emergency room utilization, antibiotic use, and fiscal charges on 30 patients.**

Task 4 is ongoing. Liberty Dialysis, LLC, a for-profit kidney dialysis company permitted research staff to recruit potential subjects from their local patient population. Several informational meetings were held with Liberty Dialysis staff members during the third and fourth quarters to identify and address potential patient questions and concerns about the study; informal sessions were also conducted with affiliated nephrologists to demonstrate the remote monitoring system and solicit support for the pilot project. The physicians and staff were encouraged to talk about the project and to encourage patients to volunteer for the study.

Final IRB approval was obtained in March 2008. Per the IRB, contact with the patients was limited to an informational letter (Appendix 3), which the patients could express interest

through return mail to meet with a research staff member to explain the study and review the consent document.

Letters were given to 450 patients on the campus of Liberty Dialysis' outpatient dialysis units and the St. Francis Foundation's administrative offices. Ninety-six (96) patients responded positively to the letter and the staff met in person with the patient, caregivers, and family. Forty-three (43) patients agreed to participate and signed consent forms; 4 patients later withdrew and 39 patients were in the original cohort.

Medical information on the consented patients was collected from the Liberty Dialysis database, and a Risk Score was calculated for each individual. The Risk Score (Figure 1), a tool to quantify chronic disease burden, was created as part of an earlier study, and has been shown to correlate with risk of future hospitalization (Figure 2).

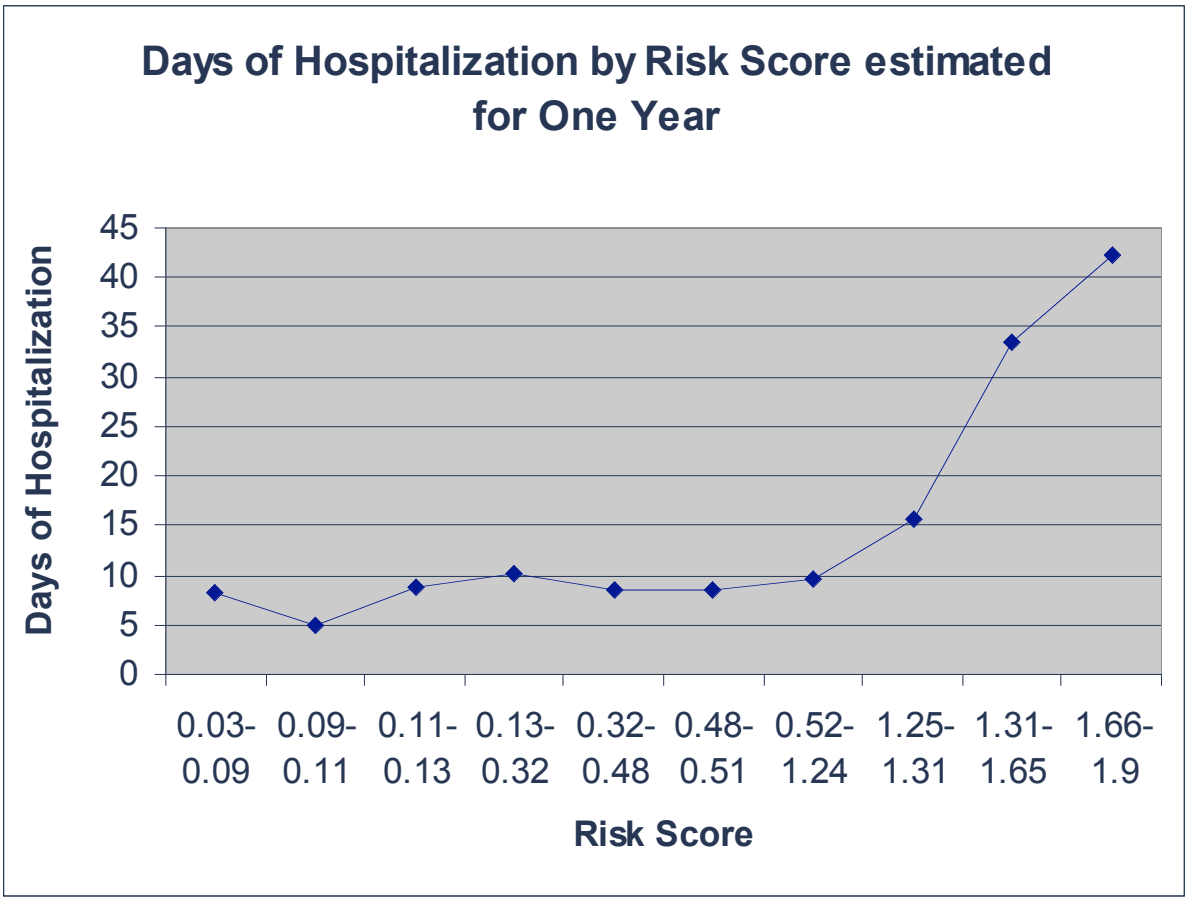
Figure 1: Risk Score Formula

Risk Score =

0.0018 (age) + 0.2181 (if PVD present) + 0.3920 (if Albumin<3 G/dl)

+ 1.1416 (if Karnofsky score <=60)

Figure 2. Days of Hospitalization by Risk Score Estimated for One Year



Twenty-eight of the remaining 39 patients in the subject pool met the high-risk criteria (Risk Score >=1.2) and were randomly assigned to one of the 3 groups.

HHA and RT interventions began in June. Three patients decided not to participate in the RT group.

- One patient withdrew from the study as he felt the equipment was too complex to handle alone.
- A second patient declined to participate as he needed assistance with personal tasks and had expected to be assigned to the HHA limb of the study.
- A third patient was blind.

Eight patients initially assigned to the HHA limb withdrew from the group. Follow up interviews uncovered a variety of reasons.

- Patients /caregivers regarded the HHA as intrusive.
- Caregivers/patients regarded patients as strong; outside assistance leads to dependency.
- Caregivers wanted respite for several hours, not home services.
- Caregivers felt that their care of the patient was complete and outside help was unnecessary.

Individual patient/caregiver reaction to and the acceptance of HHA or telehealth was more complex than the conclusions derived from focus groups conducted during the design phase of the project. Using the Risk Score, we identified a sub-population of frail and disabled patients with a higher risk for hospitalization, who could potentially benefit from the interventions. We did not appreciate that most of these chronically ill patients and their caregivers have developed an unspoken system of support and coping.

For the Pilot Study we have done away with randomization and have allowed those patients who refused HHA to join either the Control limb or the RT limb. Five patients are receiving HHA services and four patients are participating in the RT limb. An additional 3 patients are on schedule to receive HHA services, and 6 patients will have telehealth equipment installed and remote monitoring initiated, by early August. We continue the recruiting effort to fill openings in study groups. To gain a more complete experience with both types of home interventions and to analyze the results of data collection for trends, we plan to request an extension of the Pilot Study.

Task 5. Administer quality of life (SF-36) and satisfaction of service (CSQ-8) surveys (9 months).

Baseline SF-36 and Health Utilities Index (HUI) surveys (Appendices 4 and 5) were completed successfully for all consented patients. CSQ-8 was not administered at the start of the study as the survey measures satisfaction with services. A decision is pending on use of the Labor Supply Survey for the study. The CSQ-8, SF-36, and HUI will be administered to all study participants in September 2008 and in January 2009.

Task 6. Conduct analysis (3 months).

- **Health resource utilization outcomes of HHA and RT compared to UC.**
- **Economic cost effectiveness of HHA and RT compared to UC.**
- **Impact of interventions on quality of life of patient (SF-36).**
- **Impact of interventions on caregiver satisfaction with services (CSQ-8).**

Preliminary data analysis has begun. Baseline SF-36 and HUI surveys were completed, and preliminary analyses are being conducted to determine whether attitudes can be identified which may be better predictors of acceptance of either the HHA or RT limbs (per narrative under Task 4).

The Risk Score tool is being reevaluated as a screening tool. The premise for using the tool was to identify patients at high risk for hospitalizations, who may benefit from home interventions, such as RT or HHA. The Risk Score tool we use to identify our current subjects was developed using data from 1992-2002. We are repeating the analysis using data for a recent 14-month period, January 2007 through February 2008.

Data has been collected on patients for about 4 weeks and has not been analyzed. The initial preliminary analysis will be included in the next Quarterly Report, October 2008.

KEY RESEARCH ACCOMPLISHMENTS:

- established the project office and hired key personnel for the study;
- established communication services;
- selected, purchased and tested the remote technology equipment required for the pilot project;
- created a database and validated the Risk Score tool;
- received local and federal IRB approvals;
- recruited subjects for study: distributed Informational letters to 450 patients, from which 107 “leads” were received;
- conducted individual meetings with 96 patients/caregivers (eleven patients responded that they were not interested in the study);
- obtained signed consents from 43 patients;
- applied Risk Score tool; 28 of the consented patients determined to have high Risk Scores (>=1.2);
- randomly assigned 28 subjects to one of 3 research limbs;
- conducted SF-36 and HUI surveys on consented patients;
- conducted physician interviews to aide in creating Plans of Care (POC) for RT and HHA subjects;
- contacted patients to schedule RT installation and HHA evaluation visits;
- initiated interventions for first increment of RT and HHA subjects.

REPORTABLE OUTCOMES:

Approval of a Continuation Modification request was received 29 May 2008. Funding will be provided for the continuation of research, from 20 December 2008 to 19 January 2010. This study will follow 50 high-risk patients from a population of patients with end stage renal disease, who will be randomized into two groups, RT and UC; the HHA limb will be eliminated during this part of the study. The HHA limb was eliminated because of anticipated budgetary constraints. The priority is to study RT telehomecare in high-risk patients. As there will be only one type of intervention, we do not anticipate the issue of patient/caregiver preference encountered in the Pilot Study.

The intervention will involve remote technology with case management oversight, and the creation of a home electronic medical record (HEMR) from the data generated by the RT intervention, to enable physician access and adjustment of the patient's plan of care. SF-36 and CSQ-8 will measure patients' Quality of Life and satisfaction of the provided services. A Physician Satisfaction Survey will measure physician attitudes toward the HEMR. Measures of healthcare resource utilization will include emergency room visits, hospitalizations, hospital days and mortality. Economic evaluations will calculate marginal cost-effective ratios for RT.

CONCLUSION:

We collected data on consented patients and, using a Risk Tool developed in earlier work, identified high-risk patients for future hospitalization. To date, we have enrolled 5 patients in the HHA limb of the project and 4 patients in the RT limb, with commitments to enroll the full complement as designed in the study. Pre-test surveys were performed and we are collecting clinical data for analysis.

We concluded that we did not appreciate that most of the chronically ill patients with a high disease burden, and their caregivers, have developed an unspoken system of support and coping. For home interventions to be accepted, the patient/caregiver must be convinced of its supplemental value; and, the patient/caregiver must be physically capable of performing the required tasks of the intervention. We will continue the SF-36 and HUI surveys, and track the hospitalizations of patients who have dropped out of the project.

Meetings with attending physicians and demonstration of monitoring equipment indicated sharp interest in the Home Electronic Medical Record (HEMR) created from the uploaded monitoring data for each patient. A review of the literature finds little information of the value of a HEMR in decision-making and the delivery of office care.

To complete the tasks, we will be requesting a 3-month extension of the Pilot Project.

The second phase of the project will include evaluation of a better mechanism to inform patients/ caregivers about the project without violating the intent of the IRB and a survey instrument to measure physician attitude and value of the HEMR.

The issue of the patient choice of intervention will not occur in the second phase of the study as the HHA limb will be eliminated.

REFERENCES:

n/a

APPENDICES:

1. Hawaii Pacific Health Institutional Review Board Approval Letter
2. USAMRMC ORP HRPO Approval Letter
3. Patient Information Letter
4. SF-36 Health Survey
5. Health Utilities Index (HUI)
6. Curriculum Vitae: Steven J. Berman, MD – Principal Investigator

1: Hawaii Pacific Health Institutional Review Board Approval Letter

Hawaii Pacific Health

Institutional Review Board
1100 Ward Avenue, Suite 1045 • Honolulu, Hawaii 96814 • Phone: (808) 522-4583 • Fax: (808) 522-4335

March 4, 2008

Modification Approval

Steven Berman, M.D.
St. Francis Healthcare Foundation
2226 Liliha Street Room B115
Honolulu, HI 96817

RE: **RP #07-118-2-HMC1**
Project Title: The Economic and Quality of Life Impact of Remote Technologies on High Risk Patients and Their Caregivers [version 5 dated 3/4/08].

Dear Dr. Berman:

The Hawaii Pacific Health Institutional Review Board (IRB) is in receipt of your modification request dated February 22, 2008 which included a USAMRMC Memorandum for Record, revised HPH Application Form 1, revised protocol (version 5 dated 3/4/08) – tracked and clean copy, and revised informed consent and authorization form (version dated 5 February 2008) – tracked and clean copy.

The modifications to the protocol (version 5 dated 3/4/08), Informed Consent and Authorization Form, and study personnel have been reviewed and approved by the IRB via expedited review on March 4, 2008. *As the protocol changes include the deletion of patients not capable of providing their own consent, the previously approved waiver of HIPAA authorization is no longer applicable and approval of this waiver (Form 4B) has been withdrawn.* Your approval dates remain unchanged and will expire on November 5, 2008. A Continuing Review Report must be submitted on or about September 1, 2008.

Enclosed is your IRB stamped approved Informed Consent and Authorization Form. Please use this version when enrolling subjects.

If you intend to make changes during the course of your project which will affect the human subjects involved, you must obtain IRB approval prior to implementing these changes.

Any Serious Adverse Event (SAE) or Unanticipated Adverse Event (UAE) must be reported immediately to either the IRB Chairperson or the IRB Administrative Office. A written report of the SAE or UAE must be submitted to the IRB within five calendar days. Any non-serious adverse events that may not be directly related to the study must also be reported within 45 days.

If you have any questions, please contact Nina Miyata at 522-4581.

Sincerely,

David T. Horio, M.D.
David T. Horio, MD
Chair, Institutional Review Board

DH/nm

Enclosures: Informed Consent and Authorization Form (version dated 5 February 2008)

cc: Kathy Wooldridge

KAPI'OLANI MEDICAL CENTER for Women & Children
KAPI'OLANI MEDICAL CENTER at Pali Momi
Straub CLINIC & HOSPITAL
Wilcox Health

2: USAMRMC ORP HRPO Approval Letter

Gmail by Google BETA

Kathy Wooldridge <kathyathope@gmail.com>

A-14200, HRPO Approval Memorandum (Proposal Log Number 06167002, Award Number W81XWH-07-2-0064) (UNCLASSIFIED)

Duchesneau, Caryn L Ms USAMRMC <Caryn.Duchesneau@us.army.mil> **Thu, Mar 13, 2008 at 2:45 PM**
To: sjberman@gmail.com
Cc: Kathy Wooldridge <kathyathope@gmail.com>, "Saiki, Stanley Dr Hui TAMC" <Stanley.Saiki@med.va.gov>, "Bennett, Jodi H Ms USAMRMC" <Jodi.Bennett@us.army.mil>, "Duchesneau, Caryn L Ms USAMRMC" <Caryn.Duchesneau@us.army.mil>, "Brosch, Laura R COL USAMRMC" <Laura.Brosch@us.army.mil>, "Ciccarello, Brigit - Geneva Foundation" <ciccarello@tatrc.org>, sanders@tatrc.org, "Sawyer, Lisa M. Ms. USAMRAA" <lisa.sawyer@det.amedd.army.mil>, "Wilberding, Julie A Dr AMDEX" <Julie.Wilberding@amedd.army.mil>, "Eaton, Karen M Ms AMDEX" <Karen.M.Eaton@us.army.mil>

Classification: UNCLASSIFIED
Caveats: NONE

SUBJECT: Initial Approval for the Protocol, "The Economic and Quality of Life Impact of Remote Technologies on High Risk Patients and Their Caregivers," Submitted by Steven J. Berman, MD, St. Francis Healthcare Foundation, Honolulu, Hawaii, Proposal Log Number 06167002, Award Number W81XWH-07-2-0064, HRPO Log Number A-14200

1. The subject protocol (version 5/ dated 4 March 2008) was approved by the Hawaii Pacific Health Institutional Review Board (HPH IRB) on 4 March 2008. This protocol was reviewed by the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) and found to comply with applicable Federal, DOD, U.S. Army, and USAMRMC human subjects protection requirements.

2. This no greater than minimal risk study is approved for the enrollment of 30 subjects.

3. Please note the following reporting obligations:

a. Major modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the USAMRMC ORP HRPO for approval prior to implementation. All other amendments must be submitted with the continuing review report to the HRPO for acceptance.

b. All unanticipated problems involving risks to subjects or others, serious adverse events related to study participation, and deaths related to study participation must be reported promptly to the HRPO.

c. Any deviation to the subject protocol that affects the safety or rights of the subject and/or integrity of the study data must be

reported promptly to the HRPO.

d. All modifications, deviations, unanticipated problems, adverse events, and deaths must also be reported at the time of continuing review of the protocol.

e. A copy of the continuing review report approved by the HPH IRB must be submitted to the HRPO as soon as possible after receipt of approval. It appears the next continuing review by the HPH IRB is due no later than 1 September 2008.

f. In addition, the current version of the protocol and consent form must be submitted along with the continuing review report and the HPH IRB approval notice for continuation of the protocol.

g. The final study report submitted to the HPH IRB, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the HRPO as soon as all documents become available.

4. Do not construe this correspondence as approval for any contract funding. Only the Contracting Officer or Grants Officer can authorize expenditure of funds. It is recommended that you contact the appropriate contract specialist or contracting officer regarding the expenditure of funds for your project.

5. The HRPO point of contact for this study is Karen M. Eaton, MS, Human Subjects Protection Scientist, at 301-619-9268/karen.m.eaton@us.army.mil.

CARYN L. DUCHESNEAU, CIP
Chief, Human Subjects Protection Review
Human Research Protection Office
Office of Research Protections
U.S. Army Medical Research and Materiel Command

Note: The official copy of this approval memo is housed with the protocol file at the Office of Research Protections, Human Research Protections Office, 504 Scott Street, Fort Detrick, MD 21702. Signed copies will be provided upon request.

Classification: UNCLASSIFIED
Caveats: NONE

3: Patient Information Letter

STEVEN J. BERMAN, MD
H.O.P.E. Project
2226 Liliha Street, Room B115
Honolulu, HI 968178
Telephone: (808) 547-6208

April 2008 - **H.O.P.E Project Information for Liberty Dialysis Patients**

We would like to tell you about a new research project that may be of benefit to you and, if the project is successful, will help dialysis patients in the future. The H.O.P.E. Project's goal is to improve the quality of life for dialysis patients and their caregivers and to reduce the number of times you are admitted to a hospital or go to an emergency room by providing additional health support at home.

This is a voluntary project – no one is required to be part of it. Qualifying individuals will be placed into one of three groups:

- Home Health Aide Group – will have home visits by a Health Aide
- Tele-medicine Group – will be provided a home monitor and will be able to communicate with a research nurse via the monitor connected to your telephone line
- Control Group who will continue to receive best dialysis care

Information meetings will be held to explain the project in detail and we hope it will interest you enough to volunteer. If you, your family, or caregiver would like more information on this research project, please:

1) Contact me by phone at 547-6208 and leave a message

OR

2) Complete the information below and return to the Liberty Dialysis H.O.P.E. Project box

Sincerely,

Steven J. Berman, MD

I would like to learn more about participating in the H.O.P.E. Project:

❑ Yes ❑ No

Patient's Name: _____

Legally Authorized Representative (if applicable): _____

Patient/Legally Authorized Representative Telephone #: _____

SF-36 HEALTH SURVEY

SF-36 Health Survey
(also known as the Medical Outcome Study (MOS) 36-item short from health survey)

AUTHOR: John E. Ware, Jr.

PURPOSE: The SF-36 Health Survey is a generic outcome measure designed to examine a person's perceived health status

DESCRIPTION: The SF-36 is a 36-item, easily scored and administered measure assessing 8 health concepts:

(1) physical functioning (PF);
(2) role limitations because of physical health problems (RP);
(3) bodily pain (BP);
(4) general health (GH);
(5) vitality (VT);
(6) social functioning (SF);
(7) role limitations because of emotional problems (RE); and
(8) mental health (MH).

The SF-36 also includes a single-item measure of health transition or change. The SF-36 can also be divided into two aggregate summary measures the Physical Component Summary (PCS) and the Mental Component Summary (MCS). In the standard version of the SF-36 all scale questions refer to a 4 week time period. Administration time is 5-10 minutes.

NORMS: Based on a national urban sample of adults (N = 2474), the means and standard deviations for the PF, RP, BP, GH, VT, SF, RE, and MH were 84.15 (23.28), 80.96 (34.0), 75.15 (23.69), 71.95 (20.34), 60.86 (20.96), 83.28 (22.69), 81.26 (33.04), and 74.74 (18.05) respectively.

SCORING: The SF-36 Health Survey items and scales were constructed using the Likert method of summated ratings. Answers to each question are scored. These scores are then summed to produce raw scale scores for each health concept which are then transformed to a 0-100 scale. Scoring algorithms can then be applied to produce the PCS and MCS scores. (These two summary scores have the major advantage of being norm based. They also have reduced floor and ceiling effects.)

RELIABILITY: For the multi-item scales the alpha coefficients were PF = .94, RP = .89, BP = .88, GH = .83, VT = .87, SF = .63, RE = .81, and MH = .82 in a random sample of the US Population (N = 1692). In a sample of hemodialysis patients, the alpha coefficients were PF = .90, RP = .76, BP = .79, GH = .82, VT = .62, SF = .76, RE = .90, and MH = .67. Internal consistency was similar for a sample of "normal" persons, persons with depression, and for persons with physical health conditions.

VALIDITY: Concurrent validity was evidenced by the correlation between scale scores. There was also criterion validity as established by correlations between MOS scores and education and age. Known-groups validity is illustrated by different scores on the MOS for different samples in poor health compared to the general population.

PRIMARY REFERENCE: Ware, J.E., Jr., Kosinski, M., Gandek, B. *SF-36 Health Survey: Manual & Interpretation Guide.* Lincoln, RI: QualityMetric Incorporated, 1993, 2000.

AVAILABILITY: Instrument reproduced with permission of Medical Outcomes Trust, Health Assessment Lab, and QualityMetric Incorporated. Permission obtained by completing a License Application Form available at http://www.qualitymetric.com.

Your Health in General

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully, and mark an ☒ in the one box that best describes your answer. ***Thank you for completing this survey!***

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a <u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3
e Climbing <u>one</u> flight of stairs	☐ 1	☐ 2	☐ 3
f Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g Walking <u>more than a mile</u>	☐ 1	☐ 2	☐ 3
h Walking <u>several hundred yards</u>	☐ 1	☐ 2	☐ 3
i Walking <u>one hundred yards</u>	☐ 1	☐ 2	☐ 3
j Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Had difficulty performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?

None	Very mild	Mild	Moderate	Severe	Very Severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. During the past <u>4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Did you feel full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼

☐1 ☐2 ☐3 ☐4 ☐5

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a I seem to get sick a little easier than other people	☐1	☐2	☐3	☐4	☐5
b I am as healthy as anybody I know	☐1	☐2	☐3	☐4	☐5
c I expect my health to get worse	☐1	☐2	☐3	☐4	☐5
d My health is excellent	☐1	☐2	☐3	☐4	☐5

THANK YOU FOR COMPLETING THESE QUESTIONS!

HUI®

HEALTH UTILITIES INDEX®

INTERVIEWER-ADMINISTERED QUESTIONNAIRE

(US English - Self-assess)

Not for quotation or distribution without permission. All copies of this questionnaire should include a cover sheet which clearly acknowledges that it is a Health Utilities Index questionnaire developed by Health Utilities Inc. (see prototype attached).

Do not use this questionnaire without written approval from Health Utilities Inc. This questionnaire is one of many HUI® data collection instruments, and may not be the most appropriate for your study.

HUI23S2US.40Q

HEALTH UTILITIES INDEX MARK 2 AND MARK 3 (HUI2/3) 40-ITEM QUESTIONNAIRE FOR INTERVIEWER-ADMINISTERED, SELF-ASSESSED "TWO WEEK" HEALTH STATUS ASSESSMENT

by
WJ Furlong, DH Feeny and GW Torrance
Health Utilities Inc., Dundas ON Canada

August 2004

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HEALTH UTILITIES INDEX

Notes to researchers regarding the 40-item questionnaire for
interviewer-administered, self-assessed
"two week" health status assessment

The attached 40-item interviewer-administered questionnaire has been designed to ask the minimum number of questions, either in-person or by telephone, required to classify a subject's health status according to the classification systems of both Health Utilities Index Mark 2 and Mark 3 (HUI2 and HUI3). Question 41 is not an HUI® question but is included in this questionnaire because it is often useful to collect this information in health status measurement surveys. **Please note that respondents are to be encouraged to answer all appropriate questions. "Don't know" and "Refused" responses result in missing data and you will not be able to calculate the HUI utility scores for respondents with missing answers**.

This version of the questionnaire is phrased to elicit responses from a wide variety of subjects, aged 8 years and older, about their health status during the past 2 weeks, from their own perspective. Other versions are available to facilitate administration to proxy respondents (eg., family members and health professionals) and to focus questions on other assessment periods. The "current" health focus is often used in clinical studies and economic evaluations of health care programs, in which the concern is to monitor health changes due to treatment. The "usual" health focus has been used in population health surveys, where short-term illnesses like colds are not the major concern. Please contact HUInc to obtain copies of other versions of the questionnaire.

This questionnaire includes a prototype cover sheet of variables that are typically important for identifying each interview (eg., subject ID number and date). All copies of the questionnaire should be clearly marked as a HUInc. questionnaire.

For further information about the HUI® and to obtain a copy of the algorithm[1] for coding responses from the 40-item interviewer-administered questionnaire, please contact the following (and refer to questionnaire HUI23S2US.40Q: 2002-09):

William (Bill) Furlong
Health Utilities Inc. (HUInc)
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1. Furlong WJ, Feeny DH, Torrance GW. Health Utilities Index: Algorithm for determining Mark 2 (HUI2) / Mark 3 (HUI3) health status classification levels, health states, health-related quality of life scores, and single attribute level utility scores for 40-item interviewer-administered health status questionnaires. Health Utilities Inc., unpublished document; February 1, 1999.

HUI23S2US.40Q

HEALTH UTILITIES INDEX MARK 2 AND MARK 3 (HUI2/3)
40-ITEM QUESTIONNAIRE FOR
INTERVIEWER-ADMINISTERED, SELF-ASSESSED
"TWO WEEK" HEALTH STATUS ASSESSMENT

STUDY TITLE:_____

ID NUMBER OF
SUBJECT:_____

NAME OF SUBJECT:_____

NAME OF
INTERVIEWER:_____

DATE OF INTERVIEW: _____

START TIME: _____ a.m./p.m.

END TIME:_____ a.m./p.m.

CONFIDENTIAL (when completed)

For office use only:
Name of person who collected completed questionnaire:_____

Date completed questionnaire received by office:_____

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HUI23S2US.40Q

HEALTH UTILITIES INDEX MARK 2 AND MARK 3 (HUI2/3)
40-ITEM QUESTIONNAIRE FOR
INTERVIEWER-ADMINISTERED, SELF-ASSESSED
"TWO WEEK" HEALTH STATUS ASSESSMENT

The next set of questions ask about various aspects of your health. When answering these questions we would like you to think about your health and your ability to do things on a day-to-day basis, during the past two weeks. To define the 2 week period, please think about what the date was 2 weeks ago and recall the major events that you have experienced during this period. Please focus your answers on your abilities, disabilities and how you have felt during the past 2 weeks.

You may feel that some of these questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar; please excuse the apparent overlap and answer each question independently.

All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities and feelings.

Interviewer:
For each question, read the entire sentence as written on the left-hand side of the page following the question number, emphasizing the underlined words or words in italics, if any. Do not read the response options listed down the right-hand margin of the page except if listed as part of the question (e.g., Q26, Q31, etc.). Do not read the "Don't know" and "Refused" responses. Encourage respondents to answer each question to the best of their recollection. The answer given by the respondent to each question should be clearly marked in the circle/box beside the one appropriate answer listed in the right hand margin of the question page.

VISION

1 **During the past 2 weeks, have you been able to see well enough to read ordinary newsprint *without* glasses or contact lenses?**

- ○ Yes → **Go to 4**
- ○ No
- ○ Don't know
- ○ Refused

2 ***Have you been able to see well enough to read ordinary newsprint* with *glasses or contact lenses?***

- ○ Yes → **Go to 4**
- ○ No
- ○ Don't know / Didn't wear glasses or contact lenses
- ○ Refused

3 **During the past 2 weeks, have you been able to see at all?**

- ○ Yes
- ○ No → **Go to 6**
- ○ Don't know
- ○ **Refused**

4 **During the past 2 weeks, have you been able to see well enough to recognize a friend on the other side of the street *without* glasses or contact lenses?**

- ○ Yes → **Go to 6**
- ○ No
- ○ Don't know
- ○ Refused

5 **Have you been able to see well enough to recognize a friend on the other side of the street *with* glasses or contact lenses?**

- ○ Yes
- ○ No
- ○ Don't know / Didn't wear glasses or contact lenses
- ○ Refused

HEARING

6 **During the past 2 weeks, have you been able to hear what is said in a group conversation with at least three other people *without* a hearing aid?**

- ○ Yes → **Go to 11**
- ○ No
- ○ Don't know
- ○ Refused

7	**Have you been able to hear what is said in a group conversation with at least three other people *with* a hearing aid?**	○ Yes ➞ **Go to 9** ○ No ○ Don't know / Didn't wear a hearing aid ○ Refused
8	**During the past 2 weeks, have you been able to hear at all?**	○ Yes ○ No ➞ **Go to 11** ○ Don't know ○ Refused
9	**During the past 2 weeks, have you been able to hear what is said in a conversation with one other person in a quiet room *without* a hearing aid?**	○ Yes ➞ **Go to 11** ○ No ○ Don't know ○ Refused
10	**Have you been able to hear what is said in a conversation with one other person in a quiet room *with* a hearing aid?**	○ Yes ○ No ○ Don't know / Didn't wear a hearing aid ○ Refused

SPEECH

11	**During the past 2 weeks, have you been able to be understood *completely* when speaking your own language with people who do not know you?**	○ Yes ➞ **Go to 16** ○ No ○ Don't know ○ Refused
12	**Have you been able to be understood *partially* when speaking with people who do not know you?**	○ Yes ○ No ○ Don't know ○ Refused
13	**During the past 2 weeks, have you been able to be understood *completely* when speaking with people who know you well?**	○ Yes ➞ **Go to 16** ○ No ○ Don't know ○ Refused

14 **Have you been able to be understood *partially* when speaking with people who know you well?**

- ○ Yes → **Go to 16**
- ○ No
- ○ Don't know
- ○ Refused

15 **During the past 2 weeks, have you been able to speak at all?**

- ○ Yes
- ○ No
- ○ Don't know
- ○ Refused

GETTING AROUND

16 **During the past 2 weeks, have you been able to bend, lift, jump and run *without difficulty* and *without help or equipment* of any kind?**

- ○ Yes → **Go to 24**
- ○ No
- ○ Don't know
- ○ Refused

17 **Have you been able to walk around the neighborhood *without difficulty* and *without help or equipment* of any kind?**

- ○ Yes → **Go to 24**
- ○ No
- ○ Don't know
- ○ Refused

18 **Have you been able to walk around the neighborhood *with difficulty* but *without help or equipment* of any kind?**

- ○ Yes → **Go to 24**
- ○ No
- ○ Don't know
- ○ Refused

19 **During the past 2 weeks, have you been able to walk at all?**

- ○ Yes
- ○ No → **Go to 22**
- ○ Don't know
- ○ Refused

20 **Have you needed mechanical support, such as braces or a cane or crutches, to be able to walk around the neighborhood?**

- ○ Yes
- ○ No
- ○ Don't know
- ○ Refused

21 **Have you needed the help of another person to walk?**

- ○ Yes
- ○ No
- ○ Don't know
- ○ Refused

22 **Have you needed a wheelchair to get around the neighborhood?**

- ○ Yes
- ○ No
- ○ Don't know
- ○ Refused

23 **Have you needed the help of another person to get around in the wheelchair?**

- ○ Yes
- ○ No
- ○ Don't know
- ○ Refused

HANDS AND FINGERS

24 **During the past 2 weeks, have you had the *full use* of both hands and ten fingers?**

- ○ Yes → **Go to 28**
- ○ No
- ○ Don't know
- ○ Refused

25 **Have you needed the help of another person because of limitations in the use of your hands or fingers?**

- ○ Yes
- ○ No → **Go to 27**
- ○ Don't know
- ○ Refused

26 **Have you needed the help of another person with some tasks, most tasks, or all tasks?**

- ○ Some tasks
- ○ Most tasks
- ○ All tasks
- ○ Don't know
- ○ Refused

27 **Have you needed special equipment, for example special tools to help with dressing or eating, because of limitations in the use of your hands or fingers?**

- ○ Yes
- ○ No
- ○ Don't know
- ○ Refused

SELF-CARE

28 **During the past 2 weeks, have you been able to eat, bathe, dress and use the toilet without difficulty?**

- ○ Yes → **Go to 31**
- ○ No
- ○ Don't know
- ○ Refused

29 **Have you needed the help of another person to eat, bathe, dress or use the toilet?**

- ○ Yes
- ○ No
- ○ Don't know
- ○ Refused

30 **Have you needed special equipment or tools to eat, bathe, dress or use the toilet?**

- ○ Yes
- ○ No
- ○ Don't know
- ○ Refused

FEELINGS

31 **During the past 2 weeks, have you been feeling happy or unhappy?**

- ○ Happy
- ○ Unhappy → **Go to 33**
- ○ Don't know
- ○ Refused

32 **Would you describe yourself as having felt:**
a) happy and interested in life, or
b) somewhat happy?

- ○ a → **Go to 34**
- ○ b → **Go to 34**
- ○ Don't know
- ○ Refused

33 **Would you describe yourself as having felt:**
a) somewhat unhappy
b) very unhappy
c) so unhappy that life is not worthwhile

- ○ a
- ○ b
- ○ c
- ○ Don't know
- ○ Refused

34 **During the past 2 weeks, did you ever feel fretful, angry, irritable, anxious or depressed?**

- ○ Yes
- ○ No → **Go to 37**
- ○ Don't know
- ○ Refused

35 **How often did you feel fretful, angry, irritable, anxious or depressed:**
rarely, occasionally, often, or almost always?

- ○ Rarely
- ○ Occasionally
- ○ Often
- ○ Almost always
- ○ Don't know

○ Refused

36 **During the past 2 weeks did you feel *extremely* fretful, angry, irritable, anxious or depressed; to the point of needing professional help?**

○ Yes
○ No
○ Don't know
○ Refused

MEMORY

37 **How would you describe your ability to remember things, during the past 2 weeks:**
(a) able to remember most things
(b) somewhat forgetful
(c) very forgetful
(d) unable to remember anything at all?

○ a
○ b
○ c
○ d
○ Don't know
○ Refused

THINKING

38 **How would you describe your ability to think and solve day to day problems, during the past 2 weeks:**
(a) able to think clearly and solve problems
(b) had a little difficulty
(c) had some difficulty
(d) had a great deal of difficulty
(e) unable to think or solve problems?

○ a
○ b
○ c
○ d
○ e
○ Don't know
○ Refused

PAIN AND DISCOMFORT

39 **Have you had any trouble with pain or discomfort, during the past 2 weeks?**

○ Yes
○ No ➞ **Go to 41**
○ Don't know
○ Refused

40 **How many of your activities, during the past 2 weeks, were limited by pain or discomfort: none, a few, some, most, all?**

○ None
○ A few
○ Some
○ Most
○ All
○ Don't know

○ Refused

41 **Overall, how would you rate your health during the past 2 weeks?**
(a) excellent
(b) very good
(c) good
(d) fair
(e) poor

○ a
○ b
○ c
○ d
○ e
○ Don't know
○ Refused

Thank you. That ends this set of questions.

TIME FINISHED: _____ a.m. / p.m.

6: Curriculum Vitae – Steven J. Berman, MD – Principal Investigator

Provide the following information for the key personnel listed on the budget page.

NAME	POSITION TITLE
STEVEN JON BERMAN	PRINCIPAL INVESTIGATOR

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include post-doctoral training).

INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR (S)	FIELD OF STUDY
Cornell University, Ithaca, New York	A.B.	1961	Psychology
University of Buffalo, Buffalo, New York	M.D.	1965	Medicine

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order, previous employment, experience and honors. Include present membership on any Federal Government public advisory committee. List in chronological order, the titles, all authors and complete references to all publications during the past 3 years and to representative earlier publication pertinent to this application. If the list of publications in the last 3 years exceeds 2 pages, select the most pertinent publications. PAGE LIMITATIONS APPLY. DO NOT EXCEED 3 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.

Positions

1965 - 1966	Internship, Straight Medicine, Buffalo General Hospital, Buffalo, New York
1966 - 1967	Ward Medical Officer, US Naval Station Hospital, Danang, RVN
1967	Epidemiologist, Preventive Medicine Detachment, III Marine Amphibian Force, Vietnam
1967 - 1969	Project Head, Studies of Acute Infectious Diseases (FUO) in Vietnam, Department of Microbiology, Naval Medical Research Unit-2 (NAMRU-2), Taipei, Taiwan
1969 - 1971	Resident, Internal Medicine, University of Washington, Seattle, Washington
1971	Assistant Professor of Tropical Medicine and Medical Microbiology, University of Hawaii, John A. Burns School of Medicine, Honolulu, Hawaii
1971	Consultant, US Navy Medical Research Unit-2 in acute tropical fevers
1972	Consultant, National Academy of Science, for effects of herbicides on populations in Vietnam
1972	Certified Specialist in Internal Medicine by American Board of Internal Medicine, No. 38155, June 21, 1972
1972	Consultant, World Health Organization, in filariasis
1973	Certified Subspecialist in Infectious Diseases by American Board of Internal Medicine, No. 38155, October 15, 1974
1974	Associate Professor of Medicine, University of Hawaii, John A. Burns School of Medicine, Honolulu, Hawaii
1975	Private Practice, Internal Medicine and Infectious Diseases, Medical Specialty Associates, Inc.
1994	Director of Infection Control and Epidemiology, St. Francis Medical Center, Honolulu, Hawaii
1994	Member of Clinical Affairs Committee, Infectious Disease Society of America
2001 - 2004	Principal Investigator, Renal Database Project, St. Francis Medical Center, Honolulu, Hawaii

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED).

Professional Affiliations and Activities

1972 Member, American Society of Microbiology
1972 Member, Hawaii Medical Association
1972 Member, Honolulu County Medical Society
1972 Member, American Medical Association
1997 Member, Society for Healthcare Epidemiology of America (SHEA)

Honors

1972 Fellow, American College of Physicians
1973 Fellow, Infectious Disease Society of America
1984 Internist of the Year 1984, State of Hawaii
1984 President, Hawaii Chapter, American Society of Internal Medicine
2003 Clinician Award, Infectious Disease Society of America

Selected peer-reviewed publications (in chronological order)

1. Berman SJ. Chloroquine-pyrimethamine-sulfisoxazole therapy in Plasmodium falciparum malaria. An alternative to quinine. JAMA. 1969 Jan 6;207(1):128-30.
2. Berman SJ, Tsai CC, Holmes K, Fresh JW, Watten RH. Sporadic anicteric leptospirosis in South Vietnam. A study in 150 patients. Annals of Internal Medicine. 1973 Aug;79(2):167-73.
3. Berman SJ, Kundin WD. Scrub typhus in South Vietnam. A study of 87 cases. Annals of Internal Medicine. 1973 Jul;79(1):26-30.
4. Berman SJ, Irving GS, Kundin WD, Gunning JJ, Watten RH. Epidemiology of the acute fevers of unknown origin in South Vietnam: effect of laboratory support upon clinical diagnosis. American Journal of Tropical Medicine. 1973 Nov;22(6):796-801.
5. Berman SJ, Boughton WH, Sugihara JG, Wong EG, Siemsen AW. Hemodialysis-associated infections: treatment with cephapirin. Antimicrobial Agents and Chemotherapy. 1978 Jan;13(1):4-6.
6. Berman SJ, Boughton WH, Sugihara JG, Wong EG, Sato MM, Siemsen AW. Pharmacokinetics of cefaclor in patients with end stage renal disease and during hemodialysis. Antimicrobial Agents and Chemotherapy. 1978 Sep;14(3):281-3.
7. Boughton WH, Berman SJ, Boughton MT. Laboratory evaluation of amikacin susceptibility testing by the AutoBac I system. Journal of Clinical Microbiology. 1979 Mar;9(3):397-8.
8. Berman SJ, Hess JR, Sugihara JG. Morbidity of infection in chronic hemodialysis. Dialysis and Transplantation. 1979;8:324-33.
9. Hess JR, Berman SJ, Boughton WH, Sugihara JG, Musgrave JE, Wong EG, Siemsen AM. Pharmacokinetics of ceforanide in patients with end stage renal disease on hemodialysis. Antimicrobial Agents and Chemotherapy. 1980 Feb;17(2):251-3.
10. Patel IH, Sugihara JG, Weinfeld RE, Wong EG, Siemsen AW, Berman SJ. Ceftriaxone pharmacokinetics in patients with various degrees of renal impairment. Antimicrobial Agents and Chemotherapy. 1984 Apr;25(4):438-42.
11. Berman SJ, Sugihara JG, Nakamura JM, Kawahara KK, Wong EG, Musgrave JE, Wong LM, Siemsen AM. Multiple-dose study of imipenem/cilastatin in patients with end-stage renal disease undergoing long-term hemodialysis. The American Journal of Medicine. 1985 Jun 7;78(6A):113-6.
12. Berman SJ. Scrub typhus. In: Hoeprich PD, Jordan MC, Ronald AR, eds. Infectious Diseases 5th ed. Philadelphia: JB Lippincott, 1994. Chapter 113:983-5.

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED).

Selected peer-reviewed publications (in chronological order), continued

13. Tice AD, Slama TG, Berman S, Braun P, Burke JP, Cherney A, Gross PA, Harris P, Reid-Hatton M, Hoffman R, Joseph P, Lawton S, Massanari RM, Miller ZI, Osheroff WJ, Poretz D, Shalowitz M, Simmons B, Turner JP, Wade B, Nolet BR. Managed care and the infectious diseases specialist. Clinical Infectious Diseases. 1996 Aug;23(2):341-68.
14. Sexton DJ, Band J, Berman S, Bradley J, Dalovisio JR, Ingram C, Joseph WP, Petrak RM, Slama TG, Wade BH. Primary care of patients infected with human immunodeficiency virus. Clinical Infectious Diseases. 1998 Feb;26(2):275-6.
15. Berman SJ, Johnson EW. Out-patient parenteral antibiotic therapy (OPAT): clinical outcomes and adverse events. Hawaii Medical Journal. 2001 Feb;60(2):31-3.
16. Berman SJ, Pien F (editors). Infections in end stage renal disease. Infectious Disease Clinics of North America. 2001 Sep;15(3).
17. Berman SJ. Infections in patients with end-stage renal disease: an overview. Infectious Disease Clinics of North America. 2001 Sep;15(3):709-720,vii.
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Change Begins at Home: 2001-2004.

A database of the complete inpatient hospital and outpatient records of 700 patients was created, and from the analysis of these records and focus groups with patients, their families, dialysis staff and physicians, a plan to decrease the burden of infection in these patients and measure the economic impact of the interventions awaits funding. Role: Principal Investigator