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TITLE: Use of Tele-technology for Heart Disease Management: Improving Clinical and Economic Outcomes in a Managed Care Population

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Use of Tele-technology for Heart Disease Management: Improving Clinical and Economic Outcomes in a Managed Care Population

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**Abstract:**
Use novel tele-technology web services incorporated into business process redesign and disease state management to improve the disease management and outcomes of patients with Diabetes, Hypertension, Hyperlipidemia (risk factors for Heart Disease which is the number one cause of death in the United States per World Health Organization, 1998 statistics). Providers (physicians, nurses, pharmacists, educators) and patients will be tied together through improved automation, knowledge management, and disease management processes that link all of the sites of care (inpatient, outpatient, home-based patient monitoring). Our hypothesis is that compared to pre-implementation of tele-technology disease management, there will be a statistically and clinically significant improvement in health care markers of disease treatment, as well as cost, post-implementation of tele-technology disease management.
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INTRODUCTION

Use novel tele-technology web services incorporated into business process redesign and disease state management to improve the disease management and outcomes of patients with Diabetes, Hypertension, Hyperlipidemia (risk factors for Heart Disease which is the number 1 cause of death in the United States per World Health Organization, 1998 statistics). Providers (physicians, nurses, pharmacists, educators) and patients will be tied together through improved automation, knowledge management, and disease management processes that link all of the sites of care (inpatient, outpatient, home-based patient monitoring). Our hypothesis is that compared to pre-implementation of tele-technology disease management, there will be a statistically and clinically significant improvement in health care markers of disease treatment, as well as cost, post-implementation of tele-technology disease management.

Specific Aims

(1) Design and implement a tele-technology disease state management web application (by adding additional functionality to an existing provider/case manager disease state management web application called CEO).

(2) Measure the effect of tele-technology disease management on clinical indicators of diseases and cost of healthcare. These metrics include utilization and cost (number of admissions, length of hospital stay, number of outpatient visits, cost of all services), patient outcomes (blood pressure, cholesterol profile, hemoglobin a1c, microalbuminuria/proteinuria), guideline adherence (patient outcome variables as benchmarked against the threshold values and frequency of testing put forth by national clinical practice guidelines, see Appendix 1).

BODY

A. Statement Of Work
1. Prior to Study
   (a) IRB Protocol/Consent Approval process begins (submit for September 2001 IRB)
   (b) CRDA Approval process begins (submit September 2001)
   (c) Funding received (January 2002)
   (d) Hiring of Programmer, Research Coordinator, Administrative Assistant (January 2002)
   (e) Complete client/server CEO web application (May 2002)
   (f) Order iPQs for Testing. Test web application. (April 2002)
   (g) Hiring of LPN, Clinical Pharmacist Case Manager, Tech Support (April 2002)
2. Study Starts (May 2002)
   (a) Screen patients for inclusion/exclusion criteria using CEO
   (b) Enrollment of patients from Tripler (Adult Medicine and Family Practice Clinics) and Schofield (Family Practice Clinic)
   (c) Gather 1 year baseline data for included patients
(d) Three month data analysis
(e) Six month data analysis
(f) Nine month data analysis
(g) Twelve month data analysis
(h) Complete study (November 2003)
(i) Complete data gathering (November-December 2003)
(j) Complete data analysis and reports (April 2004)
(k) Presentation/Publication (June 2004)

B. Negative as well as positive findings. Include problems in accomplishing any of the tasks.

Currently there has been no enrollment of patients into the study due to:

1. Virtual Health Solutions, Inc. and Computer Training Academy (CTA) are currently in the development of producing and deploying the software to support the solution for the current Handheld Personal Digital Assistant/Pocket PC for the Patients at home monitoring: Blood Pressure, blood glucose, cholesterol, side effects, compliance email, appointment reminders, messages from case managers, and provider alerts.

2. Currently, Tripler Army Medical Center (TAMC) Information Management Department (IMD) will be implementing a transition from ACPG to ICDB. Our current study was budgeted for using the existing technology built on ACPG. With this change in the institution’s platform, our CEO technical lead Dr. Jai, has estimated an increase in the cost to adapt our technology to the new platform ICDB. This has also been confirmed with CTA who is currently working with Dr. Underwood and Joel Tanaka through Tripler’s Information Management Department (IMD) and also Dr. Jai to produce back-end support for the pocket PC. The pocket PC software (created by VHISi) will be responsible for capturing and transmitting patient data through a wireless connection to Internet servers at TAMC. Patients will then be able to enter vital statistics (like blood pressure) from home (or wherever they are), into the PC, which is connected to the internet using wireless technology. The computers at TAMC will receive the values and inform Case Managers and other providers. Further, communications will be possible from the providers to the patient and automated “rules” can generate alerts and perform other functions based upon detection of specific value ranges.

3. The protocol performance site as well as the subaward will be moved from Tripler Army Medical Center to the Portland VA which has a platform which would accommodate our current research study at a minimal cost for completion of our technology and patient enrollment, per The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. through the DoD Congressionally Directed Medical Research and Material Command, which has been approved per Dr. Sherry Ward, Grants Manager, and also Ms. Patricia Evans.
KEY RESEARCH ACCOMPLISHMENTS

Virtual Health Solutions, Inc. and Computer Training Academy (CTA) are currently in the development of producing and deploying the software to support the solution for the current Handheld Personal Digital Assistant/Pocket PC for the patients at home monitoring: blood pressure, blood glucose, cholesterol, side effects, compliance email, appointment reminders, messages from case managers, and provider alerts. Currently, we will be Beta testing in June and July and also there has been a relationship with Microsoft Development in the process of development of PDA capabilities.

REPORTABLE OUTCOMES

Virtual Health Solutions, Inc. and Computer Training Academy (CTA) are currently in the development of producing and deploying the software to support the solution for the current Handheld Personal Digital Assistant/Pocket PC for the patients at home monitoring: blood pressure, blood glucose, cholesterol, side effects, compliance email, appointment reminders, messages from case managers, and provider alerts. Currently, there may be additional support of Microsoft development with the PDA device.

CONCLUSIONS

Evaluation and Analysis of Results

1. Data analysis will be performed on aggregate data with all patient identifiers removed.

2. Health Economics: The institutional perspective will be used and so the pertinent direct costs to the institution will be calculated based upon health system resource utilization of laboratory tests, radiology procedures, prescriptions, appointments, emergency room visits, and hospitalizations.

3. The clinical indicators will be compared using appropriate statistical techniques:

(a) For nominal data (e.g. whether patients meet the ADA hgb1ac goal for good control) we will use a non-parametric method, Chi-square analysis-of-contingency table.

(b) For interval data, we will test the assumption of whether the population values of a specific indicator (e.g. low density lipoprotein cholesterol) are normally distributed. If so, we will use an unpaired t-test. Otherwise, we will assign ranks and use a non-parametric method, Mann-Whitney rank-sum test.

(c) For ordinal data (psychology of compliance assessment tool), Mann-Whitney rank-sum test.
Power Analysis: Enrollment based upon population standard deviation 1.5% HgbA1c, Power 0.80, Alpha 0.05 and ability to detect 0.5% difference between groups and 20% drop out rate. 36% of patients should have hyperlipidemia in order to detect a 20 mg/dl difference between before and after, based upon standard deviation 36 mg/dl LDL, Power 0.80, Alpha 0.05, 20% drop out rate. Preliminary study using CEO determined that 44% of our military beneficiary population in Hawaii of diabetics also have hypertension. Also, 29% have hypercholesterolemia.
REFERENCES

3. Ambulatory Data System data for Army, Navy and Air Force, Region 12, November 1999
4. CEIS, CHCS I or II and the automated clinical practice guideline initiatives. 1998. Ref Type: Personal Communication.


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