Award Number: MIPR 3GD3DP3082

TITLE: Telemedicine Evaluation and Management of Lumbar Disk Herniation

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CONTRACTING ORGANIZATION: Walter Reed Army Medical Center
Washington, DC 20307-5001

REPORT DATE: June 2003

TYPE OF REPORT: Midterm

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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**Title and Subtitle:**
Teledermicine Evaluation and Management of Lumbar Disk Herniation

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**Sponsoring / Monitoring Agency Name(s) and Address(es):**
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**Distribution / Availability Statement:**
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**Subject Terms:**
No subject terms provided.

**Security Classification of Report:** Unclassified

**Security Classification of This Page:** Unclassified

**Security Classification of Abstract:** Unclassified

**Limitation of Abstract:** Unlimited
Mid-Term Report

PROPOSAL NO.: 2002011057

TITLE: Telemedicine Evaluation and Management of Lumbar Disk Herniation

ACCOMPLISHMENTS

1. Office space has been secured. 2. Equipment has been ordered and received to include: camera and accessories, computers, office furniture and laptop. 3. Protocol has been written and submitted. We passed the Clinical Investigation Committee (CIC) and are pending revisions for the Human Use Committee (HUC). 4. Personnel have been hired (WRAMC) and designated at LRMC. 5. We have been testing the system to ensure its feasibility. 6. Originally, COL David Polly was to be the associate investigator here at WRAMC, he has since retired. We are combining the Dept. of Orthopaedics and the Neurosurgery Service on this project. MAJ Michael Rosner, a fellowship trained Spine specialist, will be joining the project.

PI Evaluation: Project Accomplishments Close to Proposal

PROBLEMS/ISSUES

1. The CIC signed off on the protocol with minor revisions and the HUC is asking the entire protocol be re-written. We have enlisted the aid of LTC(P) Martha Lenhart to help expedite this protocol for us. 2. HUC wants a full protocol, not an expedited protocol as was originally planned. 3. Protocol issues have delayed our original start time.

PI's Evaluation: Project Accomplishments Close to Proposal
Project encountered no significant problems/issues
Second Half Project Lifecycle

We are currently working to push the protocol through the HUC with an approximate review date sometime in February. With the assistance of the Telemedicine Department we will begin to test and re-test the system. (January) We currently have a 2-month delay in beginning the enrollment and data transfer. To help us make up the delay we have begun using the referring physician checklist in the Neurosurgery clinic and the Orthopaedic clinic to work out any bugs ahead of time, making any necessary changes to the form. Once approval has been given we will immediately begin to see patients in clinic. We expect to finalize enrollment 2-months later than originally expected. We will then analyze the data on the accuracy and efficacy of the use of telemedicine in treating lumbar disc herniation. Lastly, we will prepare the statistical relevance for the final report.

PI's Evaluation: Project Plan is close to Proposal

Deliverable Update

The benefit of this project is clinical and diagnostic.

How will you quantitatively measure and report the benefit? Based on past experience with the standard of care, between 30 and 50% of subjects sent to WRAMC should have remained at their duty station for treatment. Using the Tele-Spine system this error rate will be reduced by 50%. Controlling the probability of a Type I error at alpha = 0.05, the following sample sizes will have 80% power to detect the differences outlined below: (SOC – standard of care) SOC Incorrect/ Tele-Spine Correct (SOC-I/TS-C); SOC Correct/Tele-Spine Incorrect (SOC-C/TS-I) SOC-I/TS-C SOC-C/TS-I N 25% 5% 50 35% 10% 50 30% 10% 72 To allow for dropouts up to 85 subjects will be recruited for the study.

How will you document efficacy/success? Agreement between evaluators regarding treatment options will be analyzed using the Kappa statistic. The three possible treatment categories will be used: PT with NSAIDS, PT with steroid injection, Surgery. Using the in-person examination (WRAMC) as the gold standard, the proportion of correct responses for the “Standard of Care” recommendation regarding whether a patient is sent to WRAMC will be compared to the correct responses for the Tele-Spine recommendation using McNemar’s test. This will enhance diagnosis and treatment, provide better access to both referring provider and patient and using the SF-36 patient questionnaire improve patient satisfaction.

Is there AMEDD-wide applicability for your project? Yes.
PI's Evaluation: Deliverable has changed from Proposal

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Financial Narrative

The start date for our protocol funds, through the department of telemedicine, was 1 June 2003. We have spent according to plan and remain on budget. Through 30 September we have spent $10,000 on salary for the Program Manager; $1456 on camera and accessories; $2780 on office furniture; $5950 on computers and printers and $2275 on a laptop. We anticipate the purchase of at least one more computer and printer for use at LRMC, and office furniture for that location as well. This is still in keeping with stated budgetary constraints.
The major benefit of this project is to improve patient care. Once this project has been validated, we can eliminate unnecessary travel to WRAMC, sending only those patients with emergent symptoms. Currently, we see all emergent and non-emergent cases and it can take up to 3-months to get an appointment to see a Spine Specialist. Once validated, we can reduce/eliminate the number of non-emergent cases allowing the Spine Specialists to see emergent patients in a more-timely manner. This will also reduce the long profiles and lost duty days associated with the long delay in seeing a specialist.

How can your project reduce the cost of care? By reducing/eliminating the number of patients sent to WRAMC, we can reduce the cost of care. Prolonged profiles, lost duty days, air travel, hotel accommodations and meals would all be eliminated. Of the 1200 referral patients we see per year, about one sixth require surgical intervention. Additionally, development of this method of improving spine care access may also improve our ability to efficiently and effectively manage other spine problems and referrals.

PI's Evaluation: Budget and Resources in line with Proposal

*** END OF REPORT ***