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14. ABSTRACT The Center for Integration of Medicine and Innovative Technology (CIMIT) is a consortium of nonprofit Boston-area institutions based at Massachusetts General Hospital and includes Brigham and Women's Hospital, Massachusetts Institute of Technology, Draper Laboratories, Beth Israel Deaconess Medical Center, Boston Medical Center, Boston University, Children's Hospital Boston, Harvard Medical School, Newton-Wellesley Hospital and VA Boston Healthcare System. The overall goal of CIMIT is to combine clinical and technological excellence and educational components to generate, develop, and reduce-to-practice innovative and high-impact concepts to improve military and civilian healthcare. CIMIT implements research programs in many clinical areas, with an emphasis on military medicine, supported by basic science and engineering development in biomaterials, endoscopic tools, energy delivery, medical imaging, and other novel technologies.					
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Augmented Reality Glasses for the Treatment of Visuospatial Neglect

Chun Lim, Principal Investigator

CIMIT Project # 09-120

Quarter Ending September 30, 2009

Overall Objectives and Approach

Visuospatial neglect is the inability or failure to attend and respond to the left side of space. Patients suffering right cerebral hemispheric damage from stroke or traumatic brain injury frequently suffer neglect and will ignore stimuli located in the left side of space. As a result of their neglect, many of these patients have severe long-term disability. Unfortunately, there is no effective neglect rehabilitation technique. The goal of this project is to create a pair of augmented reality glasses that can display a moving background image onto the lenses. These glasses will create nystagmus in subjects who wear the glasses while the patients wear the glasses and perform their normal activities. Nystagmus has been shown to temporarily improve the symptoms of neglect. The glasses will be used to treat acute and chronic sufferers of neglect.

The objectives for this project will be to create a prototype neglect rehab glasses to determine working parameters, tolerability, and efficacy. Specific aims include:

1. Complete hardware purchase and development of one pair of augmented reality glasses (joint with the Charles Stark Draper Laboratories).
2. Program a variety of moving images onto the augmented reality glasses to identify the optimal operating parameters for the prototype (joint with the Charles Stark Draper Laboratories).
3. Identification and recruitment of chronic neglect patient.
4. Determination of the efficacy of the prototype neglect rehabilitation glasses on patients with neglect.

If our methods succeed, we will have developed an effective and affordable treatment for patients with unilateral visuospatial neglect from right hemispheric brain damage.

Summary of Results

We are in the process of selecting a hardware candidate for our augmented reality glasses.

Progress on Specific Aims

Specific aim I: The development of a prototype neglect rehabilitation glasses.

Several augmented reality hardware companies have been contacted and will be supplying a demonstration pair of glasses for beta-testing. Once a model has been selected and purchased, we will proceed to task II which involves programming the moving images to be displayed on the glasses.

Specific aim II: The identification of optimal operating parameters for the prototype.

Awaiting completion of specific aim I.

Specific aim III: The determination of the efficacy of the prototype in improving neglect symptoms in chronic neglect patients.

Five potential subjects have been identified through medical records review. Once specific aim II has been completed, these patients will be contacted and invited to participate in this study.

Publications and Presentations

None

Proposal Activities

None

Intellectual Property Office

A second technology disclosure form has been submitted to the BIDMC's technology ventures office describing the potential use of the augmented reality glasses as a treatment in patients with homonymous hemianopia and patients with vestibular dysfunction.

Issues and Concerns

No cost extension approved until April 30, 2010.

Handwashing Compliance Reminder and Documentation System

Ronald Newbower, PhD, Principal Investigator

CIMIT Project # 09-221

Quarter Ending June 30, 2009

Overall Objectives and Approach

Five to ten percent of hospitalized patients develop a hospital acquired infection (HAI). These HAI's cause an estimated 90,000 deaths a year in the United States, and cost the system \$4.5B in extra care. From 1975 through 1995 the normalized number of HAI's has increased by 36%. The emergence of particularly virulent strains such as methacyline-resistant Staph Aureus (MRSA), has brought this issue fully to the forefront amongst healthcare safety concerns. The encouraging finding, as we search for solutions, is that proper compliance with clinician hand-hygiene protocols has been shown to be a critical factor in reducing HAI's. The overall goal of this project is to create and test a system which will increase hand-hygiene compliance among clinicians and other caregivers who come in contact with patients, directly or indirectly.

We originally proposed to do this with the development and refinement of a system which can be incorporated into a clinician's or other care-giver's badge to remind them, in real time, if proper hand-cleansing has not occurred. Our proposed design took into account the critical issues of cost and maintenance, and the need to minimize both. Unique features in our proposed system are expected to minimize disruption of clinical efficiency and to facilitate compliance in a non-threatening way – yet still allow complete data-logging to document compliance for quality assurance purposes. The system will be smart enough to “know” when proper washing has or has not occurred in a context-sensitive manner, be flexible enough to conform to different care practices in different units, be fully capable of reminding the clinician in real time of any oversight in compliance and yet be subtle enough to not embarrass the clinician in front of the patient. And, finally, be inexpensive enough to be used by every clinician. It is designed to be installed quickly and easily at the local unit level, without any need for wiring of any kind, yet in a totally scalable manner. Thus it will not require expensive or invasive infrastructure modification, IT system approvals, or highly skilled labor for installation. Ultimately, we believe adoption of this approach will reduce HAI's which will in-turn decrease mortality, morbidity and costs.

The over-arching goal is to reach the point where the system's performance has been demonstrated in a sufficiently compelling manner to win commitment from clinical management for the next step of propagation and to interest a commercial collaborator for manufacturing in pilot quantities for validation studies in a quantitative fashion.

The specific, immediate aims of this project are to:

- o Aim 1: Complete design of a pre-production prototype of this novel hand-hygiene compliance-enhancing system, and build 25 badges, 100 protection zone transmitters and 100 hand-washing station transmitters for proof of concept in functioning military and VA clinical facilities, and for subsequent refinement of the protocol and design and patient-care scenarios.
- o Aim 2: Deploy a system in the Simulation Center and measure hand-hygiene compliance. We will compare this to compliance during similar simulations without the reminder system in place. We will also compare this data to baseline data already collected using the standard MGH practice of human observation of clinician behavior.
- o Aim 3: Survey a wide constituency of clinicians (physicians, nurses, patient-care assistants and ancillary care staff) about their attitudes toward such a system in order to optimize acceptability of the design of the subsystems and the protocols, on a pathway to developing the case for commercial adoption and wider dissemination for maximal impact on patient safety.

Change of Aims

In February 2009 a change-of-scope regarding this grant was presented to Dr. Vosburgh and he accepted the proposed changes to this grant's aims. More specifically, at that time the research team believed it had already won commitment from clinical management at the Veterans Administration (VA) to complete the above referenced "next step of propagation". VA had made written and verbal commitments that they would like to deploy the system in their West Roxbury facility. Given this, new aims were proposed and accepted which now read:

- Aim 1: Complete design of a second-generation prototype of this novel hand-hygiene compliance-enhancing system, and build approximately 200 badges, 200 protection zone transmitters and 200 hand-washing station transmitters. Ensure the system is deployable within the VA physical and IT infrastructure.
- Aim 2: Installation and subsequent on-going support of the system of the system in the VA West Roxbury HCS.
- Aim 3: Support the VA Investigators in their evaluation of the effectiveness of the system. This team has specified the following objectives:
 - Objective 1: Demonstrate that the system is effective at measuring hand-hygiene compliance rates.
 - Objective 2: Demonstrate that the system can increase hand-hygiene compliance.

Summary of Results

Results to date have been excellent and beyond the original scope of the outlined aims. Specifically:

- A “Joint Initiative Fund” proposal was written and submitted to the DOD which would finance the deployment of the system to the VA facility as well as the Institute of Surgical Research (ISR) at Fort Sam Houston. We have been recently informed that this funding will be granted – one of only three funded grants in the entire JIF program in this cycle.
- Visits and demonstrations of the system have been made at Ft. Detrick, ISR, and other DOD facilities.
- In May we visited with three key industrial partners: Steris, EcoLab and GoJo. Follow-up meetings in July, August and September to discuss potential licensing have been had with EcoLab and with Steris and we expect to achieve an agreement with one of them to manufacture then units in production quantities, both to support wider beta-site trials and ultimately to supply broader VA and DoD needs if desired by them.
- A second patent was filed on the technology in June 2009.

Progress on Specific Aims

Due to delays in DOD funding, we were not able to sign the contract with our engineering contractor, Embed Inc. until late June and hence engineering work could not begin. Despite this, Embed has made enormous progress, and in collaboration with them we have solved almost all the technical problems that concerned us at the conceptual level. In order to accomplish Aim 1, there were four sub-aims. Namely:

- 1a) Refining the “badge” receiver portion of the system to reduce its power consumption – progress has been made and continues.
- 1b) Adding functionality to the “badge” receiver to communicate the stored data in it out to a PC via USB – that has been accomplished in the last quarter.
- 1c) Creating a PC application which will receive the stored data from the “badge” receiver and store it as a comma separated file – that has been accomplished.
- 1d) Refining the transmitter or receiver portion of the system as necessary to correct bugs or issues discovered during testing – great progress has been made, particularly in addressing the potential complexities of multi-bedded rooms, and we have demonstrated the ability to distinguish precisely between two protection zones in the same room.

Given this progress, the new “build” of sufficient quantity (approximately 500 total units) can soon begin to support the VA and ISR deployment.

Aims 2 and 3 have not been started yet. They are dependent upon scheduling and logistics work with the VA. It is expected that work on these Aims will begin in earnest in the fall of 2009.

Publications and Presentations

- US Patent Application: Ultrasound Compliance Zone System, filed June 16, 2009
- Massachusetts Technology Transfer Center Life Sciences Innovation Day, June 3, 2009: *Handwashing Compliance Reminder and Documentation System*
- Fort Detrick, OASIS Demo and presentation, *Handwashing Compliance Reminder and Documentation System*; June 17, 2009

Proposal Activities

- Continue work toward refinements under Aim 1.
- Deployment at VA as per Aims 2 and 3.
- Complete licensing negotiations with the two potential industrial collaborators, and select one.

Issues and Concerns

None

Development of safe and effective novel trans tympanic membrane strategy for treatment of acute bacterial otitis media

Stephen I. Pelton, MD, Principal Investigator
CIMIT Project # 09-330
Quarter Ending September 30, 2009

Our initial approach was to bring the Kohane and Pelton labs together to review the data from our preliminary studies and identify what needed to be accomplished to move forward. Our initial studies demonstrated limited success with a ciprofloxacin based approach but also identified several challenges including the relative high concentration of ciprofloxacin needed to inhibit the growth of *Streptococcus pneumoniae* compared to alternative quinolones; second the need for the formulation to remain in contact with the tympanic membrane over a longer time period as the current formulation retracted from the tympanic membrane after 24 hours and limited the transfer of antibiotic into the middle ear; and thirdly we agreed on the need to further develop the animal model for both NTHi and *Streptococcus pneumoniae*. Both are frequent pathogens in AOM in children and our experience in the animal model is such that infection with NTHi directly inoculated into the middle ear space is well tolerated, with significant labyrinthitis or systemic effects but infection with *Streptococcus pneumoniae* when directly inoculated can be associated with both severe labyrinthitis and systemic infection leading to death.

The Pelton lab has focused on further development of the pneumococcal otitis media model to identify strain(s) that do not produce systemic infection. We have identified several strains of pneumococcus with high complement binding that limit their ability to invade beyond the middle ear and are comfortable that the model results in minimal loss of animals which is necessary both for the experimental design and to maintain approval for our protocols with BUSM IACUC.

The plans for the current quarter include further optimization of both ciprofloxacin and levofloxacin based compound using in vitro assessment of flux and preparation of several formulations that will provide longer contact with tympanic membrane and therefore permit diffusion of greater amount of antibiotic across the tympanic membrane and achieve higher concentrations necessary for more complete eradication of both NTHi and *Streptococcus pneumoniae*. We expect to begin evaluation of these in the chin chilla model in the next few weeks and have already requested an official no-cost extension.