TECHNOLOGY TO ASSIST SUDDENLY SPEECHLESS PATIENTS’ COMMUNICATION WITH HOSPITAL STAFF

By

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To my family
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Hospitalized patients can develop sudden inability to speak as a result of head and neck surgery or trauma, endotracheal intubation, or brain damage. Familiar methods for communicating are ineffective to convey needs during a sudden speechlessness event, especially when urgent needs must be communicated. Moreover, there are no reliable strategies to adequately address this population’s need for communication with healthcare staff, resulting in frustration, anxiety, fatigue, and dissatisfaction with provided care. A research project was proposed focusing on the following aims: 1) to construct a template of illustrations associated with messages representative of the unique needs of the hospitalized suddenly speechless population for a prototype communication system; 2) to test the feasibility and usability of a multi-functional prototype communication system tailored to the needs of hospitalized suddenly speechless patients. Eleven participants from a tertiary care institution in the southeast region of the United States completed each pilot study. Messages and illustrations incorporated in the proof-of-concept prototype communication device were representative of the needs of study participants. Five new messages were
recommended by participants to enhance the prototype template. Suddenly speechless patients admitted to the critical care setting demonstrated ability to independently activate functions integrated in the prototype communication system on command to communicate safety, care and comfort needs. Participants considered the communication system important during a speechlessness event, and reported a high level of satisfaction with use of the communication system.
Hospitalized patients can become suddenly speechless (SS; suddenly unable to speak) as a result of multiple conditions including head and neck (H & N) surgery or trauma, endotracheal intubation, or brain damage. In these situations, familiar methods for communicating safety, comfort and care needs that emerge as a result of an SS event are limited.1-5 The state of current practice does not adequately address this population’s need for communication with healthcare staff to prevent and rapidly treat dangerous situations and lessen frustration, anxiety, fatigue, and dissatisfaction with provided care.6-10

Sudden Speechlessness and the Acute Care Setting

Sudden speechlessness is the sudden inability to communicate by using spoken words. SS is often experienced by patients admitted to the critical care setting; however, patients experiencing SS may be admitted to other acute care units while recovering from surgery or trauma to the H & N area, when prolonged respiratory support is required, or as a result of neurological conditions that impair the ability to speak. The most common conditions leading to SS are surgery of the head and neck area and the need for respiratory support via artificial airways such as endotracheal intubation or placement of a tracheotomy.

SS as a Result of Artificial Airways

Endotracheal intubation and/or the placement of a tracheotomy tube, common airway management techniques to assist individuals who are having difficulty breathing or are unable to breathe on their own, results in SS.11-14 Patients with artificial airways
breathe through an airway tube, and consequently, air cannot pass directly through the vocal cords, causing speechlessness. The use of airway management techniques is associated with multiple medical conditions, particularly those associated with acute respiratory failure.

Acute respiratory failure (ARF) is commonly associated with congestive heart failure, neuromuscular or respiratory disease, postoperative complications, sepsis, and trauma. Patients experiencing ARF frequently require clinical management that leads to an SS event, including mechanical ventilation or respiratory intubation. The incidence rate for ARF is 137.1 hospitalizations per 100,000 US residents, with increased incidence among persons 65 years of age or greater. The Nationwide Inpatient Sample (NIS) database is representative of 37 states and more than 115 million hospital discharges in this country. Recent studies reveal a trend for a dramatic 9 to 11% increase in this population and projections of a 31% increase by the year 2026.

**SS as a Result of Head and Neck Cancer**

The American Cancer Society predicted that as many as 52,140 cases of H & N cancer will be diagnosed by the end of 2012 with 76% associated with the oral cavity and pharynx and 24% percent with the larynx. These types of cancers, often diagnosed at an advanced stage, require extensive surgical treatment that may result in damage to the organs critical for speech. For instance, surgical interventions such as a glossectomy or laryngectomy may result in permanent speech impairment as damage or removal of structures critical to speech interferes with the ability to verbalize needs. Additionally, patients recovering from H & N cancer often require respiratory support (e.g., artificial airway management) to facilitate breathing while recovering from surgery of the H & N region.
SS as a Result of Primary Medical Conditions

The 2010 American Heart Association report on heart disease and stroke indicated that approximately 795,000 individuals suffer a new or recurrent stroke every year. A number of these patients have the potential to develop aphasia, a disorder that results from damage to sections of the brain that contain language and may result in impairment of some or all of the following: speaking, listening, reading, and writing (American Speech-Language-Hearing Association, n.d.). Reports from the National Institute on Deafness and Communication Disorders (2008) indicated that approximately 80,000 patients acquire aphasia each year, often requiring hospitalization while recovering from the effects of a stroke. According to Lasker, although patients recovering from a sudden cardiovascular event, such as a stroke, differ in the level of complexity associated with linguistic and cognitive challenges, some patients experience unexpected cardiovascular events that result in sudden speechlessness.

Conditions associated with neurodegenerative progressive disorders such as amyotrophic lateral sclerosis, Parkinson’s disease or traumatic brain injury may also result in communication impairments. Patients with amyotrophic lateral sclerosis may experience inability to communicate as a result of progressive brain disease that has an effect on neurons and consequently, voluntary muscle control limiting ability to speak. Parkinson’s disease is also associated with progressive involvement of the central nervous system resulting in disturbances of speech and voice.

Outcomes Related to Communication Loss

Communication between the patient and healthcare provider facilitates the development of a relationship and fosters accurate interpretation of health related issues. Effective communication is associated with positive patient outcomes such as
decreased anxiety and enhancement of the recovery process.\textsuperscript{28} Research exploring emotional responses of individuals unable to speak during mechanical ventilation indicate that poor communication is associated with negative outcomes such as discomfort,\textsuperscript{29} anger,\textsuperscript{30} worry,\textsuperscript{31} fear,\textsuperscript{30} frustration,\textsuperscript{9, 10, 31} stress,\textsuperscript{13, 14, 31, 32} and/or spells of terror.\textsuperscript{33} Studies associated with postoperative H & N patients experiencing SS also document difficulties that patients experience when trying to communicate symptom management needs that emerge during the post-surgery recovery period, and the significant frustration resulting from ineffective communication.\textsuperscript{6, 7, 31} Moreover, healthcare providers and family caregivers also experience frustration as they attempt to adjust to the patient’s condition.\textsuperscript{7, 8, 34-37}

**Nature of SS Communication Impairments and Standard of Care**

Factors such as diagnosis, severity of illness, and co-morbidities may impact the duration of speechlessness. The average stay for postoperative H & N cancer patients with SS is approximately 7 days, with a range of 3-14 days.\textsuperscript{38} Patients in need of mechanical ventilation assistance may experience SS for similar periods of time or even longer, depending on pre-existing medical conditions and the current state of illness.\textsuperscript{9, 27, 39} Regardless of the cause of SS, communication difficulties exist because there is no consistent method to communicate with hospitalized SS patients or to ensure that their needs are understood by healthcare staff.\textsuperscript{6, 28, 37}

Non-verbal communication strategies such as gestures, mouthing words, or the use of alphabet boards have limited use for the SS population because they are time consuming, energy draining, and often require the use of body parts such as the head, face, hands and arms. For instance, postoperative H & N cancer patients with SS, experience inability to turn the head and facial swelling that restricts mouthing words or
making gestures, limiting the ability to use non-verbal strategies effectively. Patients with endotracheal intubation fatigue very easily, have limited arm movement due to medical devices, and often have their mouth obscured by a tube or tape, limiting ability to use non-verbal communication strategies effectively. As a result, using gestures, mouthing words, and/or attempting to communicate a message one letter at a time on an alphabet board is ineffective, especially when in need of expressing emergent, life-threatening needs such as difficulty breathing, and inadvertent disconnection of ventilators/oxygen.

Another conventional strategy is the use of the nurse call button. This is an approach of high functionality for hospitalized patients, but ineffective for individuals that are unable to verbalize their needs. The nurse call button system requires a verbal response from the caller, and consequently, is most appropriate for individuals who can verbalize their needs upon request from an operator or clerk. SS patients are particularly vulnerable since they cannot speak into intercom systems or call out to get staff attention.6, 40, 41

The state of current practice does not adequately address SS patients' need for communication with healthcare staff. Familiar methods of communication such as non-verbal strategies are ineffective to assist hospitalized SS patients, especially when in need of expressing emergent and urgent needs during the acute phase of their rehabilitation process. The development of communication strategies adaptable to the hospital setting is essential to enhance the communication process between SS patients and healthcare staff.

Limited research has been conducted to explore effective strategies to enhance
the communication process between SS patients and healthcare staff in acute care settings. The development of reliable approaches is an essential step to facilitate SS patients’ self-expression and to lessen frustration and dissatisfaction with provided care.\textsuperscript{14, 42-43} Speech generating devices (SGDs), a technological approach consistently used as a single user communication strategy for individuals with permanent speech impairments (e.g., neuromuscular diseases, brain injuries) in the home or school setting, has the potential to benefit individuals experiencing SS in acute care.\textsuperscript{14, 34, 44-49} However, tailoring of technology to incorporate a systematic approach where patients with a history of SS directly provide input about the development of the device and how to best adapt to their communication needs has not been explored. The most appropriate critical next step is to develop and test technologies tailored to the communication needs of SS patients and determine feasibility and usability in the clinical setting. Considering requirements intrinsic to the SS population is of essence to develop interventions with the potential to enhance the communication process between SS patients and healthcare staff.

**Conceptual Framework**

The conceptual framework for the proposed project is based on Happ’s Process of Interpretation in Response to Voicelessness Framework\textsuperscript{8} from a participant observation study associated with older adults in the critical care setting.\textsuperscript{8} According to Happ, voicelessness, or SS, is a construct that represents communication barriers that limit the abilities of patients to convey their thoughts, feelings, desires and needs to others. Voicelessness is associated with detrimental effects such as delays in being able to communicate symptoms or problems, misinterpretation of non-verbal communication, and feelings of fear and anxiety in this uncertain situation.
In her original model, Happ described the individual experiencing communication barriers as a voiceless patient. She identified four distinct communication outcomes that could be improved as a result of interventions to enhance voiceless patients’ ability to interact with others: ease, quality, frequency, and success of the communication process. According to Happ, the integration of communication interventions at a time when critical information must be shared between clinicians and patients may result in a more effective communication process (quality/success), a decrease in the difficulty level associated with the inability to verbalize needs to others (ease), and an overall increase in satisfaction levels for the voiceless individual, the family member and the clinicians. Happ’s model was adapted in the proposed pilot studies. In this model, the communication system (GatorVoice) is hypothesized to facilitate the communication process and potentially improve the success, ease and frequency of communication for SS patients (Figure 1-1).

**Purpose Statement**

The overall purpose of this research was to refine proof-of-concept communication intervention prototype software (GatorVoice) and test its feasibility and usability in the clinical setting. Two observational descriptive pilot studies were proposed. Pilot study 1 focused on refining and confirming the completeness of direct selection of pre-recorded messages (pictorial hot-buttons) to communicate safety, care and comfort needs of hospitalized SS patients. Pilot study 2 focused on conducting the initial test of the communication intervention in the acute care setting to determine the feasibility and usability of the communication intervention in the clinical setting.

The following aims were proposed:
1. To construct a template of illustrations associated with messages representative of the unique needs of the hospitalized SS population for a prototype communication system.

2. To test the feasibility and usability of a multi-functional prototype communication system tailored to the needs of hospitalized SS patients.

The following research questions were the focus of the pilot studies:

1. Pilot 1: Are messages and illustrations incorporated in the proof-of-concept prototype communication device representative of the needs of hospitalized SS patients?

2. Pilot 2:
   
   A. Can suddenly speechless patients admitted to the critical care setting independently activate strategies integrated in the communication system on command to communicate safety, care and comfort needs?
   
   B. What are the difficulties encountered by hospitalized SS patients using the communication system?
   
   C. How do study participants rate the level of importance and satisfaction with the use of the communication system?

**Summary of Chapter**

Currently, hospitals do not have reliable strategies to consistently facilitate communication with patients experiencing sudden speechlessness. The absence of reliable communication methods results in significant communication challenges for this vulnerable population. Because SS patients do not have adequate methods to communicate while in the hospital setting, research efforts should be directed toward addressing the communication needs of this vulnerable population.
Figure 1-1. Adaptation of GatorVoice communication intervention to Happ’s model. Concepts developed for this study are in italics. Concepts from Happ’s original model are in bold.
Chapter 2 includes a literature review for this research. This review incorporates the analysis and synthesis of research findings related to the use of technological interventions to facilitate the communication process of SS patients. Research studies were obtained through a computerized search of the Cumulative Index of Nursing and Allied health Literature (CINAHL) and Medline databases, and index review. Six pilot studies and two case studies related to sudden speechlessness and communication interventions involving technology in hospitalized patients were obtained. Search terms included speechlessness, communication interventions, and hospitalized patients.

**Use of Technology to Improve Communication of SS Patients**

There is a paucity of literature examining how to improve the communication process of SS patients. Six pilot studies\(^42, 44-45,47-49\) with small sample sizes and two case studies\(^34,46\) explored the use of technology as a communication intervention.

Costello (2000) reported case studies of post-operative SS patients that were able to successfully use SGD while hospitalized.\(^34\) Preoperatively, speech-language pathologists, in conjunction with each patient, individualized a commercial SGD to facilitate the communication process for patients during the postoperative period. A pre-programmed SGD (The MessageMate\(^\text{TM}\)) integrating preprogrammed messages with their respective symbols was used by 43 patients (age range, 2.8-44 years) who developed SS after surgery for craniofacial anomalies, tumors of the face, and/or placement of an airway tube or a tracheostomy. Discharge interview findings reported by Costello indicated that participants were satisfied with the ability to use technology to communicate, however, device improvements were recommended. For instance,
participants recommended additional communication strategies beyond pre-recorded topics/messages to meet their communication needs and solutions to ensure that the device was easily accessible during the hospital stay. While reports of study findings are supportive of the use of SGDs for hospitalized SS patients, the use of a case study format limited ability to generalize findings.

Happ et al. conducted two pilot studies\textsuperscript{44,47} to explore the use of technology as a communication intervention for H & N cancer patients with SS (n=10), and patients undergoing mechanical ventilation (n=11). Patients received minimal training related to the use of commercially available electronic communication devices (DynaMyte\textsuperscript{TM} and MessageMate\textsuperscript{TM}, DynaVox Technologies, Pittsburgh, PA\textsuperscript{50}), featuring direct selection of pre-stored messages associated with graphic illustrations (pictorial hot-buttons). In both studies, most participants used the devices, and although positive feedback about the devices was provided participants did not use the devices for the majority of their communication needs. Other communication strategies included handwriting (cancer patients= 20\%, intubated= 31\%) and non-verbal methods (e.g., gestures, facial expressions) (cancer patients=40\%, intubated= 46\%). Issues which limited use of the device included complexity in activating messages on the device, lack of nursing staff familiarity with the device, and problems attaching the device in a manner that could be easily used by patients. The concept of using technology to communicate needs was well-accepted; however, problems with device complexity, staff familiarity and access limited its use.

Etchels et al.\textsuperscript{45} explored the use of a computer based communication device (ICU-Talk), with intubated patients in an intensive care unit (ICU). A multidisciplinary team
participated in the development of the device. The device featured recording capability of all selections made by study participants, and the options to interact via touch screen, mouse emulation or a single switch to retrieve a list of messages. Study participants (n=6) were able to use the device to communicate with nursing staff, family, and friends during the period of speechlessness. Although the device was considered to provide assistance, 71% of the nursing staff felt that it obstructed their ability to view the patient, and 55% reported difficulties maneuvering the device. The availability of approximately 250 pre-stored messages was associated with patients' limitations in identifying which phrases were available or where they were stored upon initial use of the device. Consequently, while the use of a computer-based communication device was of assistance to SS patients, software issues, the organization of data for easy retrieval by patients, and adaptability of the technology to the ICU environment limited its effectiveness.

In a pilot study with trauma patients in a critical setting, Miglietta, Bochicchio, and Scalea (2004) also explored the feasibility of using computer-assisted communication (LifeVoice™). Patients (n=35) unable to use upper extremities (fractures or external fixation devices) and those with cervical cord injuries used a preprogrammed portable computer that played synthesized messages related to common complaints and phrases upon activation of a hot-button. LifeVoice™ was developed specifically for patients with intact auditory and visual acuity (able to read at a distance of 24 inches); required patients to use eye blinking, touch functions and controls; and to use an alphabet system (screen keyboard). SS patients who experienced limited or no ability to
blink appropriately (e.g., postsurgical patients with facial swelling) and those with literacy issues were excluded. A number of patients were able to use the device’s features, including eye-blink mode (n=8, 22%), touch-screen mode (n=22, 63%) and touch-button control (n=5, 14%). The multifunctionality approach of this device was useful in meeting the range of needs experienced by recovering trauma SS patients over their hospital stay. However, the device required individualized programming for each subject enrolled in the study.

In a pilot study, Rodriguez and Blischak (2010) investigated communication needs commonly experienced by postoperative H & N cancer patients (n=11). SS patients identified communication priorities related to urgent needs (pain, breathing, suctioning and need for a nurse), basic care (use of urinal/bedpan, sleep/rest), and psychosocial issues (calling their relatives, feelings). These communication priorities were integrated in a single-function mode (hot buttons) programmable speech-generating device called the SpringBoard™. Hospitalized post-operative patients experiencing SS demonstrated independent use of the SpringBoard™ to communicate messages programmed in the device after receiving a brief introduction to device use. However, other strategies (e.g., paper and pencil, gestures/signs) were necessary to meet SS patients’ communication needs as the postoperative period progressed. Difficulties with use of the device were reported including: inability to lift the device due to mobility restrictions, accessibility issues (frequent removal after daily care or placement at a difficult to reach location), and not keeping the device battery charged. Participants gave recommendations to tailor the device to needs that emerged during their recovery period including: having the option to use other communication strategies such as
writing and/or typing with the device, using a lighter device, and facilitating consistent access and/or positioning of the device.

**Summary of Chapter**

Research findings associated with communication interventions for SS patients are supportive of the use of technological interventions to enhance the communication process between SS patients and healthcare staff. However, limitations associated with technological interventions evaluated in available studies suggest that current electronic communication devices are not adequate to meet the unique needs of patients who are SS.
CHAPTER 3
METHODS

Chapter 3 describes the methodology of this project. The chapter is organized in sections addressing the methods for two pilot studies. The pilot studies were constructed to meet proofs of feasibility that were consistent with the aims established for an SBIR-Phase 1 grant.

Pilot Study 1

An observational descriptive study design was selected. The aim of the study was to evaluate if messages and illustrations incorporated in a proof-of-concept prototype speech-generating device (GatorVoice) were representative of the needs of hospitalized suddenly speechless (SS) patients. The proof of feasibility/usability associated with the study was: GatorVoice will have pictorial hot-buttons that communicate the safety, care and comfort needs of SS patients. Individual interviews were used to collect data about communication needs experienced by participants during an SS event associated with a current or recent hospitalization (1-6 weeks after hospital discharge), and to identify appropriate graphical representation for each message by choosing from a template of pictures available for review.

Sample

Potential participants included postoperative H & N surgery patients, and/or patients with endotracheal intubation. Inclusion criteria were as follows: (1) ≥ 21 years of age, (2) ability to read and write English, (3) recent SS event with ability to communicate at data collection point, and (4) H & N surgical patients (1-6 weeks after hospital discharge during a follow-up clinic visit) or hospitalized patients who have been extubated for at least 24 hours.
Study Measures

After consent was obtained, individualized interviews were coordinated to facilitate data collection. Data collection occurred at participants’ hospital bedside or at the outpatient clinic during a follow-up appointment. Demographic data were obtained from participants or from their medical records. Four instruments (Table 3-1) were used to obtain the following: demographic data, confusion, sedation and agitation levels, communication needs during the hospital stay.

Protection of Human Subjects and Recruitment and Consent

Approval from the Institutional Review Board at the University of Florida was obtained. All participants were voluntary, and each signed a consent form. Investigators identified as inventors of the communication system did not obtain informed consent during this study. The responsibility of obtaining informed consent was assigned to a co-investigator not associated with development of the invention. Investigators in the study were not blinded to the data collection process.

Participants were recruited from two specific patient populations. The first group consisting of H & N surgery patients that was recruited approximately 6-10 weeks prior to a planned surgical intervention during their preoperative visit. Ear, nose, and throat (ENT)/H & N service staff from the study site informed potential subjects about the study. Those interested in participating received a copy of the informed consent at the preoperative visit for review, and were formally consented at their two-week postoperative visit by a co-investigator not associated with the development of the invention. The second group consisted of patients in the process of respiratory extubation who met study criteria, and were identified by the charge nurse. Individuals interested in participating were informed about the study and consented by a co-
investigator not associated with the development of the invention. A total of 21 potential participants were recruited of which 11 (52%) completed the study. Reasons for not completing the study included health status changes limiting participation (n=5; 50%), decision change from interest in participating to no interest in participating (n=2; 20%), initiation of training with Passy-Moir valve (n=1; 10%), discharge to a rehabilitation unit (n=1; 10%), and surgical cancellation (n=1; 10%).

Data Collection

Each participant was asked to list in writing or orally, all needs he/she wanted to communicate during their hospital stay. Participants were then shown a prototype paper template of illustrations with messages previously identified as useful by SS patients in other pilot studies \(^{44,45}\) to determine if each of the needs identified on the list had a corresponding picture from the template. If no corresponding illustration was selected from the template, participants were asked to describe/draw a symbol/pictorial representation appropriate for the need. When participants recommended revisions, the research team met to determine how to revise illustrations on the template to reflect unrepresented needs. The paper template was revised based on participants’ feedback and the team’s consensus (Figure 1-1). The revised template was used for subsequent participants until five consecutive participants (with both participant populations represented) were able to identify a pictorial representation for every need on the list he/she created.

Data Analysis

Descriptive statistics were used to synthesize data regarding communication needs and pictorial representation identified by participants. Commonalities associated with descriptions or drawings recommended by participants were identified to select
illustrations and revise the template of pictures used during the study. Data were analyzed with IBM® SPSS® Statistics (Version 19, 2010).

Pilot Study 2

The purpose of this study was to continue the development of a prototype GatorVoice software program and make a working GatorVoice system using a tablet computer. The final version of a picture template (validated during pilot study 1) was integrated into an IBM® Thinkpad® (Version X41, 2007) tablet computer providing multifunctional communication capability including: direct selection of hot buttons that if selected with a stylus, activated the audio recording of that symbol; handwriting with a stylus; and typing with an external keyboard. The communication system was assigned to hospitalized SS patients, and data related to usability of the communication system and degree of satisfaction with the system was collected. The proofs of feasibility/usability associated with the study were: Correct use of GatorVoice to communicate safety, care and comfort needs; activation of an urgent button within 10 seconds; confirmation of the completeness of pictorial hot-buttons to communicate safety, care and comfort needs; report of a degree of satisfaction <3 on the Satisfaction with Communication Method Scale (1=strongly agree-5=strongly disagree; 1-5 range).

Sample

Potential participants included patients who were currently experiencing SS including postoperative H & N surgery patients and/or hospitalized patients with endotracheal intubation. Inclusion criteria were as follows: (1) ≥ 21 years of age, (2) ability to read and write English, (3) H & N surgical patients (2-10 days post-surgery), or hospitalized intubated patients (being weaned from the ventilator), (4) absence of delirium as measured by the Confusion Assessment Method Form (CAM), and (5) a
score between ±1 to ± -1 on the Richmond Agitation-Sedation Scale (RAS). Patients with an inability to use at least one arm or with long term speechlessness resulting in the use of an adaptive SGD were excluded.

After consent was obtained, daily visits and individualized interviews were coordinated with participants of the study to facilitate data collection by research staff (research assistants, co-investigator and/or principal investigator). Data collection occurred at participants’ hospital bedside over participant’s hospital stay (maximum of 10 days). Demographic data were obtained from participants or their medical records. Five instruments (Table 3-2) were used to obtain the following data: demographics; presence of delirium, agitation or sedation; participants’ ability to use different communication strategies (included in GatorVoice and urgent button devices); difficulties encountered by participants while using the devices; information about level of importance and satisfaction in association with the use of GatorVoice and the urgent button. Patients were reassessed daily with the CAM and RAS during their hospital stay to determine their ability to participate in the study.

**Clinical Setting**

Approval from the hospital’s departments of engineering, infection control, and safety was obtained prior to use of the communication system in the acute care setting. In-services were provided to staff involved in the management of study participants, individually and/or as a group during regular unit meetings.

**Protection of Human Subjects**

Approval from the Institutional Review Board at the University of Florida was obtained before study implementation in three adult critical care units (surgical, medical, cardiac) and a medical surgical unit where study participants were transferred at a
tertiary care institution in the southeast region of the United States. Prior to initiation of the study, information related to the study was provided to nursing staff on participating units using in-services during scheduled unit staff meetings and/or one-to-one in-services.

**Recruitment and Consent**

Participants were recruited from two specific patient populations. All participants were voluntary, and each signed a consent form. The first group, H & N surgery patients, was recruited approximately 6-10 weeks prior to a planned surgical intervention during their preoperative visit. Ear, nose, and throat (ENT)/H & N service staff from the study site informed potential subjects about the study. Those interested in participating received a copy of the informed consent at the preoperative visit for review, and were formally consented at their pre-operative visit. The second group, patients in the process of respiratory extubation who met study criteria, was identified by the charge nurse of the critical care unit where patients were admitted. Consent from a family member proxy/surrogate was obtained for patients being weaned from the ventilator who assented to participate but were unable to fully participate and complete the consent process. Research staff obtained consent from patients at a later time after extubation and/or when the participant had regained a competency that allowed for full participation in the consent process. A total of 21 potential participants were recruited of which 11 (52%) completed the study. Reasons for not completing the study included health status changes limiting participation (n=5; 50%), decision change from interest in participating to no interest in participating (n=2; 20%), initiation of training with Passy-Moir valve (n=1; 10%), discharge to rehabilitation unit (n=1; 10%), and surgery cancellation (n=1; 10%).
Data Collection

Data collection was conducted on the admitting units including: cardiac intensive care unit, medical intensive care unit, and surgical intensive care unit. Additionally, the data collection was not interrupted for study participants who were transferred to medical-surgical units, after critical care management was no longer needed.

Study day 1: After verification that consent had been obtained and/or that the subjects continued with their desire to participate in the study (patients that signed consent during their pre-operative visit), the CAM and the RAS were administered. Patients with no delirium and a RAS score of <±2 were provided with GatorVoice/Urgent Button combination and an orientation on how to use the device. Demographic data related to each participant was obtained on study day 1 and completed any other day when the subject was able to provide the information. Patients were reassessed daily with the CAM and RAS during their hospital stay to determine their ability to participate in the study.

Study days 2-10: Each successive day for up to 10 days, the Usability of GatorVoice form was completed by research staff to collect data related to the participants’ ability to use different communication strategies included in GatorVoice and the Urgent Button, and difficulties encountered by participants while using the devices. Participants were given refresher information on use of GatorVoice/Urgent Button as needed during the study.

Final study day: Twice before discharge or on day 10, patients completed the Patient Satisfaction and Usability Instrument to provide information about their level of importance and satisfaction in association with the use of GatorVoice and the Urgent Button. This instrument was administered twice to collect reliability data.
Data Analysis

Descriptive statistics were used to summarize the sample demographics, clinical variables, and scores for all satisfaction and importance items. Data were analyzed with IBM® SPSS® Statistics (Version 19, 2010).

Table 3-1. Study instruments – pilot study 1

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Variables</th>
<th>Reliability/Validity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic data form</td>
<td>Age, gender, education, diagnosis, ethnicity, speech impairment, use of adaptive speech devices</td>
<td>Developed by investigator for study</td>
</tr>
</tbody>
</table>
| Confusion assessment method       | Presence of delirium                                                      | Compared with Diagnostic and Statistical Manual of Mental Disorders-IV criteria for delirium: interrater reliability k=0.79-0.96; sensitivity 93%-100%; specificity 89%-100%  
<p>| Richmond Agitation-Sedation Scale | Agitation and sedation levels                                             | Interrater reliability (r=0.964l lower 90% CI limit=0.951; k=0.80, 95% CI=0.69, 0.90), validation against Ramsay Sedation Scale (r=-0.78) and Sedation Agitation Scale (r=0.78), and construct validity for correlation with attention screening examination (r= 0.78, P&lt;.001), Glasgow Coma Scale scores (r= 0.91, P&lt;.001)  |
| Communication needs during hospital stay | communication needs as a result of SS event; template images &amp; symbols' selection | Investigator-developed tool; Interrater reliability established with research staff prior to initiating data collection to determine consistency among raters |</p>
<table>
<thead>
<tr>
<th>Variables</th>
<th>Instrument</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic data</td>
<td>The Demographic &amp; Clinical Survey: Used to collect data about age, gender, reason for SS, ethnicity, years of education, previous experience with SS, and support obtained while experiencing SS and hospitalized.</td>
<td>Upon initiation of study.</td>
</tr>
<tr>
<td>Presence of delirium, agitation/sedation</td>
<td>The Confusion Assessment Method (CAM) and the Richmond Assessment Scale (RAS) have established reliability to assess for the presence of delirium and/or agitation/sedation.</td>
<td>Pre-screening prior to consent process and daily completion of measures.</td>
</tr>
<tr>
<td>Ability to use SGD on command, difficulties encountered</td>
<td>The Usability of Communication Intervention Form: used to evaluate participants’ ability to use the SGD system, difficulties encountered, technology functionality, and clerk’s understanding of message via nurse call button. Participants’ ability to use device on command is evaluated with the following coding: 1= independent; 2=minimal assistance (2 prompts or less); 3=needs considerable assistance (&gt; 2 prompts); 4=unable to perform). Successfully used by SS patients on previous pilot study.</td>
<td>Daily for 10 days or less based on participants’ discharge.</td>
</tr>
<tr>
<td>Level of importance and satisfaction with the use of the SGD</td>
<td>The Patient Satisfaction and Usability Instrument measured the satisfaction (7 items) and importance level (5 items) associated with the use of the SGD. Item scores range from 1 to 5 with 1 indicating greater satisfaction with the item. Successfully used by SS patients on previous pilot studies.</td>
<td>Twice before discharge or day 10.</td>
</tr>
</tbody>
</table>
CHAPTER 4
RESULTS

Pilot Study 1

The research question associated with this pilot study was: Are messages and
illustrations incorporated in the proof-of-concept prototype communication device
representative of the needs of hospitalized SS patients?

Sample Characteristics

The sample consisted of 11 participants. Demographic and clinical characteristics
are included in Table 4-1. Participants were mostly male (72.7%), with a mean age of
60 years (range=46-82), and mean years of education equivalent to 14 years
(range=10-28). Most participants were White (n=7; 73%), and developed SS as a result
of respiratory intubation to manage chronic obstructive pulmonary disease (COPD).
One of the participants experienced SS resulting from H & N surgery as well as
complications resulting in respiratory failure.

Communication Needs During the Hospital Stay

Study participants generated between one to nine messages when asked by the
research staff to list all the needs they wanted to communicate while hospitalized and
speechless. Messages were classified in six categories as follows: basic care needs,
clarifying/informational needs, general responses, immediate needs, and psychosocial
needs (Table 4-2).

Template Illustrations and Messages

Study participants identified messages and illustrations incorporated in the
prototype communication device template after messages were read aloud by research
staff. Participants identified messages on the template representative of their
communication needs (in addition to messages identified on original list), and messages not considered appropriate for use while hospitalized and experiencing SS (Table 4-3).

**Messages and Illustrations Representative of SS Patients’ Communication Needs**

A range of 73%-100% of participants considered messages read by the research staff as “not on original list prepared, but wanted” to represent their needs (Table 4-3). Messages matching with template illustrations that were identified by 100 % of participants were associated with basic needs (elimination), urgent needs (immediate need for a nurse), and informational needs (what is taking place).

**Messages and Illustrations with Limitations to Represent SS Patients’ Communication Needs**

Three study participants (27%) provided feedback about messages included on the template that were identified as inadequate to represent SS patients’ communication needs. Participants considered that an illustration of a urinal would only be appropriate based on gender specific needs (n=2; 18%), and that a bathroom illustration was not appropriate for a critical care setting (n=1; 9%).

**New Messages or Illustrations Recommended by Study Participants**

The first group of participants in the study (n=4) identified messages that were not included on the template but considered of importance during SS periods including: dry mouth, drink, I want water, I want ice, pull me up in bed/position change. Participants provided descriptions and/or drawings that were used to revise the original template. After these revisions, no other changes were recommended by the rest of the participants in the study (n=7). The last group of participants (n=7) used a revised template.
Pilot Study 2

Sample Characteristics

A total of 24 subjects consented for participation in the study. Three subjects (12.5%) completed only one day of the study due to declining health. Seven consented subjects did not participate in the study due to: discharge to a rehabilitation hospital (n=1; 14.3%); declining health status (n=1; 14.3%); effective use of Passy Muir speaking valve (n=1; 14.3%); presence of delirium (n=1; 14.3%); surgery cancellation (n=1; 14.3%); no interest to participate (n=2; 28.6%). The final sample consisted of 11 participants (completing all measures included in the study for day one, and at least one satisfaction questionnaire) with an age range of 40-72 years (Z=13.27 ±2.90). Demographic and clinical characteristics are included in Table 4-4. Participants were mostly male (81.8%), white (90.9%), had more than 8 years of education (91%), became SS as a result of airway intubation (100%). Approximately 73% of the participants had head and neck cancer and were recovering from a surgical intervention that resulted in SS (laryngectomy [n=5]; floor of mouth [n=1]; base of tongue [n=1]; skin cancer with extensive involvement and oral-facial defect [n=1]). The average number of days in the study was 6 days (range 1-10; SD=2.75).

Presence of Delirium, Agitation or Sedation

All participants were pre-screened with the CAM and the RAS instruments prior to consent and/or daily data collection. Initial RAS and CAM evaluation conducted prior to providing communication device to participants demonstrated that 91% of participants were not experiencing behaviors consistent with delirium, restlessness or sedation. One participant (9%) demonstrated light sedation (RAS= -2) and acute changes in mental status upon initial evaluation. As a result, a demonstration about how to use the
communication device was not provided until resolution of symptoms over a period of 24 hours. Another participant demonstrated acute changes in mental status while the study was in progress (day 6), with appropriate recovery and completion of study.

**Independent Activation of Communication Strategies**

Study participants demonstrated ability to activate strategies integrated in the communication system including activation of pictorial hot-buttons (illustration associated with a spoken message), handwriting and typing screens.

**Hot buttons**

At a minimum, 73% of study participants (range=72.7%-100%) were able to independently activate five hot-buttons on command on day 1, after a brief 10 minute review about how to use the communication system. Consistent independent performance was observed throughout the study with a minimum of 88% of the participants reaching independence in activation of hot buttons by day 5 and 100% of participants demonstrating independence by day 10 (Figure 4-1). One participant was unable to physically push one out of five hot buttons at two different points of data collection, requiring significant assistant from research staff. For a small number of participants (n=3), the evaluation of their ability to activate messages on command was not possible for a range of 1-2 data collection points due to the following reasons: off the unit for procedure and/or transfer (n=1); participant experiencing drowsiness (n=1) or fatigue (n=1).

**Handwriting and typing**

From a total of 48 data collection points, the handwriting screen was accessed independently 92.3% of the times (n=48). The typing screen was accessed independently 94.4% of the times (n=34 of 36 data collection points). Minimal
assistance was needed to activate the typing function during day 2 by one participant. Minimal assistance to activate the handwriting function was required by two participants on day 1 and one participant on day 5.

**Use of the urgent button**

From a total of 63 data collection points, the urgent button (UB) was independently activated 83% of the times by study participants. The most common difficulty experienced by participants (n=3) related to temporary inability to locate the UB for activation. On Day 1 of the study two participants (18%) required minimal assistance (less than two prompts) to activate the UB and one participant required considerable assistance (more than 2 prompts) to locate the UB for activation. One participant (9.0%) activated the emergency hotbutton instead of the UB. A review about where the UB was located and procedure to activate the UB was provided every time participants required minimal or considerable assistance to activate the device. One participant required assistance to locate the UB for 3 consecutive days followed by independent activation during the rest of the hospitalization. Another participant required considerable assistance to remember the location of the UB throughout the study, on days 2, 3, 5 & 9.

**Difficulties Encountered by Participants with the Communication System**

Difficulties experienced by participants (n=11) when use of the SGD was requested included: inability to physically push requested hot buttons (n= 2; 18%); eyeglasses not available limiting visual acuity (n=2; 18%); level of sedation impaired the correct use of device (n=1); illegible writing (n=2; 18%). Two participants able to identify hot buttons independently upon request experienced difficulty with the use of a stylus to activate the correct hot buttons. Difficulty with activating the hot buttons was
associated with having a pulse oximeter on the dominant hand (n=1; 9%), and/or wrist restraints (n=1; 9%), and resulted in the activation of the hotbutton next to the one requested.

Re-teaching of device use was needed by three participants (27%). The need for a review was necessary due to difficulty to activate three hot buttons on command (n=1; 33%); difficulty to locate the urgent button (n=2; 66%), or the need to reinforce information as a result of acute mental status changes (n=1; 33%).

**Accessibility of Communication System**

Data about accessibility of the communication system was collected daily. During the study, the SGD was accessible in the participants’ room when data were collected approximately 96% of the time (n=66). The SGD was accessible within participants’ arms reach 52% of the time (n=34). Approximately 44% of the time (n=29), the device was in the room but not reachable by the participant. Rationale for not having the SGD within arm’s reach of participants included: device moved by nurse, physical therapist or relative, and not returned close to participant (n=12); unknown rationale (n=11); device moved by study participant (e.g. ambulatory participant) and relocated as needed (n=4); participant’s request (n=2). During the study, the device was not transferred with two patients from the intensive care unit to a medical surgical floor (3%) at one data collection point (e.g., day of transfer). Additionally, one participant’s device was stored at the nurses’ station after the patient was extubated within 24 hours of initiation of the study (1.5%).

**Usability of Communication System**

Usability of the SGD was evaluated by determining if the device was functional at 66 data collection points. The device was on and functional at capacity 68% of the time.
The SGD was found non-functional (powered off) for the following reasons: found unplugged and off for unknown reasons (n=10; 62.5%), device not set up after a procedure or transfer to another unit or room (n=3; 18.75%), participant accidentally pulled device from dock resulting in automatic shut-off (n=1; 6.25%), and device moved in the room and left unplugged (n=2; 12.5%). Additionally, the SGD’s did not produce speech (n=2; 3%) hot buttons froze (n=2; 3%), and/or both speech and hot buttons were non-functional (n=1; 1.5%) due to unknown causes. Re-boot of the communication system made devices operational within the same data collection visit each time usability issues were identified.

The UB functionality was evaluated by activating the device at 66 data collection points. The device was functional 95% of the time data were collected (n=63). The UB was dysfunctional and required battery replacement at three data collection points (4.5%), involving two participants during the study.

**Clerks’ understanding of message via nurse call button**

Participants transferred to medical surgical units where the hospital call system was in use (n=10) activated the system at 40 different data collection points, and upon response from the clerk, proceeded to activate a message from the device. Ninety-five percent (n=38) of the messages generated by participants via the hospital call system were understood by the clerks.

**Level of importance and satisfaction with the use of the communication system**

Participants rated their importance and satisfaction level by using The Patient Satisfaction and Usability Instrument (1 = strongly agree, 2 = agree, 3 = neither agree nor disagree, 4 = disagree, 5 = strongly disagree). Six items measured satisfaction based on use of device functions, ease of device use, and ability to report symptoms
and/or improve communication with nursing staff. The mean score for all satisfaction items was 1.5 (n = 11; SD = 0.29; range=1.16-2.0), indicating that participants were satisfied with use of the SGD during their hospital stay. One participant strongly disagreed that the prototype device was easy to use, based on the size (“too big, in the way”).

Four items measured importance specific to availability of the SGD for use by SS patients and importance of device functions. The mean score for all importance items was 1.61 (n=11; SD=.55; range 1-3.00), indicating that participants considered the use of the SGD and its functions of importance while experiencing SS. One participant strongly disagreed that having picture hot buttons was an important function, indicating his/her preference to “write fast” and thus assigning a higher importance to writing as a function included on the device.
Table 4-1. Demographics and clinical characteristics – pilot study 1

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>46-55 years</td>
<td>5 (45.4%)</td>
</tr>
<tr>
<td>56-65 years</td>
<td>2 (18.0%)</td>
</tr>
<tr>
<td>66-75 years</td>
<td>3 (27.2%)</td>
</tr>
<tr>
<td>76-85 years</td>
<td>1 (9.0%)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>8 (72.7%)</td>
</tr>
<tr>
<td>Female</td>
<td>3 (27.2%)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>7 (63.6%)</td>
</tr>
<tr>
<td>Black</td>
<td>1 (9.0%)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1 (9.0%)</td>
</tr>
<tr>
<td>American Indian</td>
<td>1 (9.0%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (9.0%)</td>
</tr>
<tr>
<td><strong>Years of education</strong></td>
<td></td>
</tr>
<tr>
<td>10-12 years</td>
<td>7 (63.6%)</td>
</tr>
<tr>
<td>14-16 years</td>
<td>2 (18.0%)</td>
</tr>
<tr>
<td>18-20 years</td>
<td>1 (9.0%)</td>
</tr>
<tr>
<td>&gt;20 years</td>
<td>1 (9.0%)</td>
</tr>
<tr>
<td><strong>Diagnosis leading to SS</strong></td>
<td></td>
</tr>
<tr>
<td>COPD</td>
<td>7 (63.6%)</td>
</tr>
<tr>
<td>H &amp; N cancer</td>
<td>4 (36.3%)</td>
</tr>
<tr>
<td><strong>Classification of SS</strong></td>
<td></td>
</tr>
<tr>
<td>Temporary</td>
<td>9 (81.8%)</td>
</tr>
<tr>
<td>Permanent</td>
<td>2 (18.0%)</td>
</tr>
<tr>
<td><strong>Presence of delirium</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>No</td>
<td>11 (100%)</td>
</tr>
<tr>
<td><strong>Presence of agitation-sedation</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>No</td>
<td>11 (100%)</td>
</tr>
</tbody>
</table>
Table 4-2. List of needs generated by suddenly speechless patients (original list)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Needs</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychosocial Need</td>
<td>Leave me alone</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td></td>
<td>Take it easy</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td></td>
<td>How I am feeling</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td>Basic Care Need</td>
<td>I want water</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td></td>
<td>I want ice/ice chips</td>
<td>3 (8.82%)</td>
</tr>
<tr>
<td></td>
<td>Make me more comfortable in</td>
<td></td>
</tr>
<tr>
<td></td>
<td>bed/reposition in bed /pull me up in bed</td>
<td>4 (11.7%)</td>
</tr>
<tr>
<td></td>
<td>Drink</td>
<td>2 (18.1%)</td>
</tr>
<tr>
<td></td>
<td>Tired</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td>Immediate Need</td>
<td>Can’t breathe</td>
<td>2 (18.1%)</td>
</tr>
<tr>
<td></td>
<td>I am hurting</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td></td>
<td>Pain</td>
<td>3 (8.82%)</td>
</tr>
<tr>
<td></td>
<td>Can’t breathe</td>
<td>2 (18.1%)</td>
</tr>
<tr>
<td></td>
<td>Dry mouth</td>
<td>2 (18.1%)</td>
</tr>
<tr>
<td></td>
<td>IV hurting</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td></td>
<td>Suction</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td></td>
<td>Headache</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td>Clarifying / Informational Needs</td>
<td>Where is my family</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td></td>
<td>When will I go home?</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td></td>
<td>When will the tube in his nose be removed?</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td></td>
<td>How well am I doing?</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td>General</td>
<td>Hot</td>
<td>2 (18.1%)</td>
</tr>
<tr>
<td></td>
<td>Thank you</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td></td>
<td>Stop</td>
<td>1 (2.94%)</td>
</tr>
<tr>
<td>Messages on template</td>
<td>Not on original list, wanted (%)</td>
<td>Not on original list, not wanted (%)</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>----------------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td><strong>Immediate needs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stop</td>
<td>90.9</td>
<td></td>
</tr>
<tr>
<td>I have pain</td>
<td>72.7</td>
<td></td>
</tr>
<tr>
<td>I need a nurse now</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>I am nauseated</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>I am having breathing problems</td>
<td>81.8</td>
<td>18.2</td>
</tr>
<tr>
<td>I have trouble sleeping</td>
<td>81.8</td>
<td>18.2</td>
</tr>
<tr>
<td>I need suction</td>
<td>81.8</td>
<td>9.1</td>
</tr>
<tr>
<td>I want to rest now</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Help</td>
<td>81.8</td>
<td>18.2</td>
</tr>
<tr>
<td>Emergency</td>
<td>90.9</td>
<td>9.1</td>
</tr>
<tr>
<td><strong>General responses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thank you</td>
<td>72.7</td>
<td>18.2</td>
</tr>
<tr>
<td>Yes</td>
<td>90.9</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>90.9</td>
<td></td>
</tr>
<tr>
<td><strong>Basic care</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I need to go to the bathroom</td>
<td>72.7</td>
<td>18.2</td>
</tr>
<tr>
<td>I need the bedpan.</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>I need the urinal</td>
<td>81.8</td>
<td>18.2</td>
</tr>
<tr>
<td><strong>Clarification information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How am I doing?</td>
<td>81.8</td>
<td></td>
</tr>
<tr>
<td>Can you tell me more? about that?</td>
<td>90.9</td>
<td></td>
</tr>
<tr>
<td>What is happening?</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>I am doing OK</td>
<td>90.9</td>
<td>9.1</td>
</tr>
<tr>
<td><strong>Psychosocial needs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Could you call my relative?</td>
<td>72.7</td>
<td>9.1</td>
</tr>
<tr>
<td>How I feel today</td>
<td>81.8</td>
<td>9.1</td>
</tr>
<tr>
<td>I love you</td>
<td>90.9</td>
<td>9.1</td>
</tr>
<tr>
<td><strong>Other needs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am cold</td>
<td>90.9</td>
<td></td>
</tr>
<tr>
<td>I am hot</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>
Table 4-4. Demographics and clinical characteristics – pilot study 2

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>40-50 years</td>
<td>3 (27.3%)</td>
</tr>
<tr>
<td>51-60 years</td>
<td>4 (36.4%)</td>
</tr>
<tr>
<td>61-70 years</td>
<td>3 (27.3%)</td>
</tr>
<tr>
<td>71-80 years</td>
<td>1 (9.0%)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>9 (81.8%)</td>
</tr>
<tr>
<td>Female</td>
<td>2 (18.2%)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>10 (90.9%)</td>
</tr>
<tr>
<td>Black</td>
<td>1 (9.1%)</td>
</tr>
<tr>
<td><strong>Years of education</strong></td>
<td></td>
</tr>
<tr>
<td>8-10 years</td>
<td>2 (18.2%)</td>
</tr>
<tr>
<td>11-13 years</td>
<td>3 (27.3%)</td>
</tr>
<tr>
<td>14-16 years</td>
<td>5 (45.5%)</td>
</tr>
<tr>
<td>17-20 years</td>
<td>1 (9.0%)</td>
</tr>
<tr>
<td><strong>Diagnosis leading to SS</strong></td>
<td></td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>3 (27.3%)</td>
</tr>
<tr>
<td>H &amp; N cancer surgery</td>
<td>8 (36.3%)</td>
</tr>
</tbody>
</table>

Figure 4-1. Activation of hot buttons days 1, 5 and 10.
CHAPTER 5
DISCUSSION

Summary of the Study

The overall purpose of this research was to refine proof-of-concept communication intervention prototype software (GatorVoice) and test its feasibility and usability in the clinical setting. Two observational descriptive pilot studies were proposed. Pilot study 1 focused on refining and confirming the completeness of direct selection of pre-recorded messages with their respective illustrations, to communicate safety, care and comfort needs of hospitalized SS patients. Pilot study 2 focused on evaluating the feasibility and usability of a multi-functional prototype communication system tailored to the needs of hospitalized SS patients. Eleven participants were recruited for each pilot study from a tertiary care institution in the southeast region of the United States.

Messages and illustrations incorporated in the proof-of-concept prototype communication device were representative of the needs of hospitalized SS patients completing the study. Minimal adjustment was required to incorporate five new messages as recommended by study participants. Participants experiencing sudden speechlessness, admitted to the critical care setting, demonstrated ability to independently activate functions integrated in the prototype communication system on command to communicate safety, care and comfort needs. Participants considered the communication system important during an SS period, and reported a high level of satisfaction with use of the communication system.

Discussion of Findings

Eleven subjects agreed to participate in each study and met criteria for participation. Enrollment during pilot study 2 was influenced by factors characteristic of
acutely ill individuals admitted to the critical care setting such as changes in cognitive and health status, surgery cancellation, and recovery of ability to speak.

Study participants were cognitively functional over the majority of the time enrolled in the study. Consistent with literature findings, barriers such as the need to adapt to a challenging acute care environment and limited familiarity with the communication system did not limit participants’ ability to use the device. However, this study excluded individuals experiencing delirium and agitation/sedation, conditions often experienced by SS patients, beyond a set criteria (RASS measure greater or equivalent to 2 or -2). Additionally, sample limitations that constrain the ability to generalize study findings include sample size, minimal representation of minority and/or participants with lower education, and the inclusion of subjects from only one geographic area. Future research endeavors should focus on evaluating the use of communication interventions with a more diverse sample and with individuals with lower literacy levels.

Difficulties encountered by study participants were consistent with those documented in the literature, including neurocognitive factors such as the presence of delirium and issues with coordination of the upper extremities. The protocol established to assess cognitive status prior to consenting participants, as well as daily pre-screening prior to data collection, effectively identified participants with acute cognitive changes. Likewise, daily evaluation of participants’ use of device and technology function helped to identify participants who exhibited occasional difficulty with the communication system. Consistent re-assessments of study participants’ skills and device functionality must be considered when conducting studies exploring the use of technology based communication interventions for SS patients.
The evaluation of alternate methods to provide consistent accessibility of communication devices requires examination in future studies. Frequent removal of the communication device after daily care or placement at a difficult to reach location has been a challenge documented on research exploring the use of SGDs in the acute care setting.47, 49 Mounting the communication system on a mobile unit facilitating access for study participants was, to some extent, of assistance. However, maintaining the device at a reachable distance and functional at capacity (plugged in/charged) was a challenge observed with some participants. Strategies to provide consistent accessibility of communication devices in the acute care setting must be considered, in particular, attaching the device to an area closer to the patient rather than to a mobile unit. Similarly, integrating healthcare staff and relatives during educational sessions provided to study participants should be considered to facilitate understanding about the importance of keeping communication devices within reach for SS patients.

Most participants required minimal instruction to activate an independently functioning call button (UB) that enunciated the need for assistance until reset by the nursing staff. Anecdotal findings shared by participants validate the role of the communication system (including the UB) to summon help during urgent situations via the nurse call system. However, further testing of the communication system (GatorVoice and the UB) will be of assistance to determine the potential benefit and usefulness of each device in assisting hospitalized SS patients to communicate their needs.

Preliminary tests associated with the use of the communication device via the unit’s call system are encouraging. Participants demonstrated ability to activate the
nurse call button and communicate comfort/care/safety needs by using the
communication system associated with the study. Future investigations should
incorporate an evaluation of the potential benefit of this function and potential impact in
the communication process of SS patients.

The inclusion of a larger sample of SS patients will be of assistance to overcome
study limitations related to the selection of a convenience sample and generalization of
findings. Continuing the development and refinement of the communication intervention
is consistent with the goal of improving the standard of care for SS patients. Future
studies should incorporate a design that allows for a comparison between a
control/standard of care group and an intervention group, as well as evaluating the
impact of the intervention on enhancing the communication process between SS
patients and healthcare staff.

Successful use of the communication system by acutely ill participants supports
the use of strategies to enhance the communication process for SS patients despite the
complexity associated with an admission to the critical care setting and limited time to
learn the system. Testing the intervention beyond the realms of the critical care setting
will facilitate the evaluation of the intervention with other SS populations.

Further development of technology associated with this study is necessary. Future
studies should focus on evaluating communication intervention with other SS
populations, including individuals experiencing SS who are non-English proficient, other
age groups, and individuals experiencing SS as a result of health conditions not
included in this project.
Nurses' active involvement in the development of interventions tailored to the needs of SS patients is a priority. Nurses as bedside providers of care have a unique perspective that is of essence to tailor strategies to the specific needs of the SS population. Involvement of nursing staff is necessary to inform changes that will impact clinical practice and the quality of care of SS patients.
REFERENCES


BIOGRAPHICAL SKETCH

Carmen S. Rodriguez was born in Caguas, Puerto Rico. She graduated from Gautier Benitez High School, Caguas, Puerto Rico in 1973. Carmen attended the University of Puerto Rico, Rio Piedras, Puerto Rico and received a Bachelor of Science in Nursing in 1978. A Master of Science in Nursing was received from the University of Miami, Miami, Florida in 1988. Her Ph.D. was received from the University of South Florida, Tampa, Florida in 2003. Carmen's dissertation research focused on individuals experiencing head and neck cancer and sudden inability to verbalize their needs. Upon completion of her doctoral degree, Carmen's research focus was directed at developing communication interventions to facilitate the communication process of hospitalized patients experiencing sudden speechlessness.

Carmen has been a certified Adult Nurse Practitioner since 1994. Carmen's nursing specialties include adult health and adult oncology. Post-doctoral awards that have been instrumental in the development of her research program included the John A. Hartford Foundation (Building Academic Geriatric Nursing Capacity Scholar Award Program Coordinating Center at the American Academy of Nursing; 2004) and the Clinical and Translational Science Institute KL2 award (Multidisciplinary Program for Junior Faculty; 2009), through which she received her Master of Science with a concentration in clinical and translational science in 2012. Carmen is currently an assistant professor in the University of Florida's College of Nursing in Gainesville, Florida.