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ATTN: MCMR-CDT-N
3100 Ricketts Point Road
Aberdeen Proving Ground, MD 21010-5400

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3100 Ricketts Point Road
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Computer-Assisted Communication Device for botulinum-intoxicated patients

Michael Adler*

Neurobehavioral Toxicology Branch,
Analytical Toxicology Division,
US Army Medical Research Institute of Chemical Defense,
3100 Ricketts Point Road,
Aberdeen Proving Ground, MD 21010-5400, USA
Fax: 410-436-2750
E-mail: Michael.adler2@us.army.mil
*Corresponding author

Richard E. Sweeney

RESECO Research Engineering Consultants,
PO Box 554, Nottingham, PA 19362, USA
Fax: 410-436-8377
E-mail: Reseco@rcn.com

Abstract: A Computer-Assisted Communication Device (CACD) was developed for patients paralysed by botulinum neurotoxin (BoNT) who are unable to speak due to toxin-induced dysphonia or obstruction from an endotracheal tube for assisted ventilation. The system uses pre-programmed menus and synthetic speech to allow for patient-initiated communication. The CACD was designed to meet the needs of patients who possess normal cognition and hearing, but impaired vision, and who are extensively paralysed but still able to press a switch to make menu choices. The CACD will allow patients to interact more effectively with their health care providers which should aid in their recovery.

Keywords: BoNT; botulinum neurotoxin; dysphonia; paralysis; intensive care; text-to-speech; patient care.

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Biographical notes: Michael Adler is a Research Pharmacologist at the US Army Medical Research Institute of Chemical Defense (USAMRICD), located at Aberdeen Proving Ground, Maryland. He received his PhD Degree in Medical Pharmacology from the State University of New York at Buffalo. His current research has focused on the development of small molecule therapeutics for botulinum neurotoxin and on the development of nerve agent pretreatments and therapies. He has published over 100 peer-reviewed papers and book chapters and holds several patents.

Richard E. Sweeney earned a BS in Engineering from Widener College and has provided custom application programming, hardware/software engineering, molecular modelling, statistical theory and database services to the USAMRICD for the past 23 years. He has authored or co-authored over 20 peer-reviewed journal papers, book chapters, and technical reports and holds a US patent for an automated method of identifying nucleic acid sequences.

1 Introduction

The botulinum neurotoxins (BoNTs) comprise a family of seven distinct neurotoxic proteins (A-G) that are the most lethal substances in nature (Simpson, 1981; Gill, 1982; Ruthman et al., 1985; Middlebrook and Franz, 1997; Jankovic and Brin, 1997). Exposure to BoNT results in botulism, a transient neuroparalytic disease caused by inhibition of acetylcholine (ACh) release at peripheral cholinergic sites: the neuromuscular junction, autonomic ganglia and parasympathetic synapses (Simpson, 1981, 2004; Jankovic and Brin, 1997; Sobel, 2005; Adler et al., 2007). The clinical manifestations of botulism consist of blurred vision, diplopia, dizziness, dry mouth, dysphasia, dysphonia, fatigue and a bilateral descending muscle weakness (Simpson, 1981; Gill, 1982; Mann, 1983; Shapiro et al., 1998; Sobel et al., 2004; Penas et al., 2005).

Severe intoxication, following high dose exposure to BoNT, leads to respiratory collapse and death unless patients have access to intensive care and mechanical ventilation (Shapiro et al., 1998). Infusion of botulinum antitoxin can reduce the duration and severity of the disease if given within 2–3 days of exposure (ideally within 12 h of presentation), and is less effective if administered outside this window (Tacket et al., 1984; Chang and Ganguly, 2003; Chertow et al., 2006). Since BoNT acts selectively on peripheral cholinergic nerve terminals, patients intoxicated with BoNT retain normal sensation, and mental acuity (Cherington, 1974; Middlebrook and Franz, 1997; Maselli and Bakshi, 2000).

Mildly intoxicated patients, defined as those with only ocular or cranial nerve involvement, generally require a brief period of hospitalisation (~1 week) and appear to make a complete recovery (Mann, 1983; Tacket et al., 1984). Severely intoxicated patients, however, may require several months of intensive care and exhibit residual symptoms of intoxication for five years or more after exposure (Cherington, 1974; Mann, 1983; Schmidt-Nowara et al., 1983; Shapiro et al., 1998). Treatment of such patients is challenging due to their lack of mobility, impaired autonomic reflexes and reliance on tube feeding and mechanical ventilation for survival (Cherington, 1974; Maselli and Bakshi, 2000).

During much of their treatment, severely intoxicated patients have difficulty speaking due to BoNT-mediated paralysis of the vocal cords, diaphragm muscle, tongue and facial muscles and obstruction from the endotracheal tube required for artificial ventilation. Although speech is impaired, BoNT-intoxicated patients have been able to respond to yes or no questions by squeezing the examiner's hand (Maselli and Bakshi, 2000) or by moving an extremity (Kobayashi et al., 2003; Souayah et al., 2006). Small movements in the hands or feet in response to caregiver queries should be possible for most patients, and these could allow for simple communication (Maselli and Bakshi, 2000; Kobayashi et al., 2003; Souayah et al., 2006).

In the event of a large outbreak of botulism, this form of communication would be impractical, since it is inherently error-prone and would place excessive time demands on hospital personnel. However, communication in which the patient's response is limited to small movement of an extremity could be incorporated in a Computer-Assisted Communication Device (CACD). The CACD described in this report would allow patients to initiate communication and verify the accuracy of messages prior to presenting it to the staff.

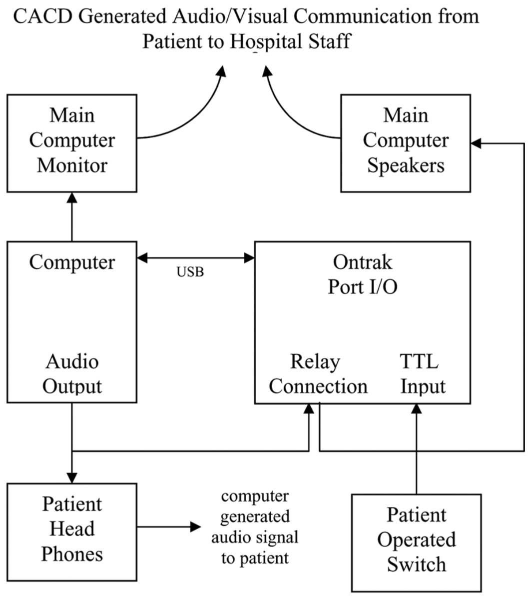
To construct the CACD, we employed a principle similar to that used in serial audio menu presentation schemes in automated call routing systems. The typical operation of those systems involves audio presentation of menu options, followed by a selection of available response channels. To develop an interactive menu-based CACD for patients lacking speech, vision and normal movement, we selected a basic press-plate switch as the input, computer-generated synthetic speech as the patient's output, and both synthetic speech and a visual display as outputs for the caregivers. This report describes the construction and operating principles of the CACD; tests of the device in human volunteers will be reported in a subsequent communication.

2 Prototype development

A prototype CACD system was developed in which pre-programmed menu options are presented to the patient by a computer-generated voice. The prototype consists of a computer (Dell Optiplex GX270 running Microsoft Windows XP Professional® and Microsoft Office Excel® 2003 SP3), with external speakers and headphones, a Universal Serial Bus (USB)-based relay Input/Output (I/O) interface (Ontrak Control Systems ADU208), and a relay circuit that allows the computer audio output to be directed to the headphones only, or to both headphones and speakers (Figure 1). Microsoft Excel was selected to implement this prototype because it provides a spreadsheet format suitable for storage of the menu commands, the ability to program the menu delivery using Microsoft Visual Basic®, the capacity to produce computer-generated voice messages using the text-to-speech engine and the ability to modify menu selections by changing the text in the spreadsheet cells associated with menu commands.

Menu options are selected by activation of the patient operated switch. Computer-generated verbal menu prompts are delivered to the patient through headphones (Figure 1). For patients unable to use headphones, pillow speakers can be substituted. The hospital staff would both hear the patient's computer-generated speech messages on the main computer speakers and also read them on the main computer monitor. In a final version of the product, it is envisioned that the I/O interface, speakers, and monitor will be included internally in a small computer device (perhaps mounted with the ventilator), with only the switch and headphones residing with the patient.

Figure 1 A block diagram of the CACD. Audio output of menu options is delivered through the patient's headphones (or pillow speakers). Menu selections are made by pressing the patient-operated switch at appropriate times, which the computer detects using the Transistor-Transistor Logic (TTL) input channel. The relay is activated at appropriate times to route the audio output to the caregiver. The computer display provides visual messages for the caregiver



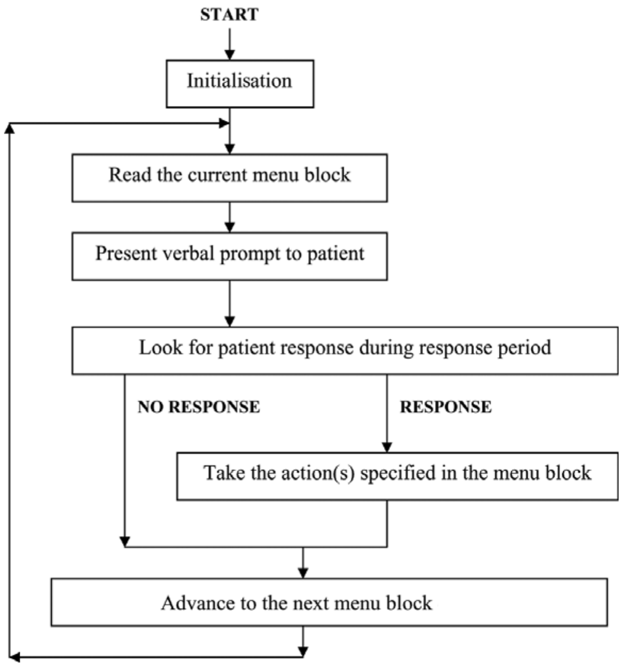
3 System configuration

The basic operation of the CACD is presented by the flow chart in Figure 2. The program starts automatically when the computer is turned on and will run continuously. The program first performs initialisation of hardware and selection of the initial menu item, and then begins a repeating loop. Each pass through the loop processes a single menu option. Processing consists of

- reading the information associated with the menu option from the spreadsheet
- presenting the verbal prompt portion of that information to the patient using the text-to-speech engine
- generating a short delay (adjustable) during which the patient may respond to the prompt
- carrying out the 'actions' defined for the menu option if the user responds
- progressing to the next menu option.

The new menu option is then made current, and the cycle repeats. Note that the *next* menu option depends or whether or not a patient responds to the *current* menu option. Only a power failure will cause the CACD to stop. An automatic reboot of the computer coupled with an automatic restart of the program on computer start-up will ensure that the patient is never without the ability to initiate communication.

Figure 2 A flow chart of main program loop is presented. Once started, the system will initialise and start a repeating loop. On each pass through the loop, information from the current menu block is read and the audio prompt for the block is presented to the patient



3.1 Menu selections

The menus for our CACD prototype were stored on an Excel spreadsheet to allow the system to be readily adapted to match the patient's needs. The verbal prompts are shown in Table 1. Once started, the system loops from left to right through the top menu row. When an item is selected, the system cycles vertically though the submenu under the selected item. Menu options linked to submenus are shown in bold typeface. The PLAY and REPEAT main menu options are used to play a previously composed message for the hospital staff. The YES and NO options allow the user to make rapid responses to questions from the staff. STOP is included so that the patient can request the staff to stop whatever procedure they are currently doing. NURSE, PAIN and FEELING allow the patient to request the nurse to perform an action, identify and localise pain and its severity and describe his or her emotions and sensations, respectively. CHECK allows the patient to request that specific items be looked at by a caregiver. The ASK option enables the patient to select questions from a list. The OPTIONS menu permits the patient to review the current message, to play the message or to enter the silent or spelling modes. In silent mode, the system becomes quiescent; however, any response in this mode will resume operation. In the spelling mode, patients can build messages one letter at a time to allow unique statements to be composed. The spelling feature also enables the patient to create and add new messages to the system. Since the spelling mode requires patients to keep track of words and phrases, those unable to accomplish this would still benefit from use of the preprogrammed menus.

Table 1 Menu structure for the prototype CACD[§]

OPTIONS	**PLAY**	**REPEAT**	**YES**	**NO**	**STOP**	**PAIN**	**NURSE**	**HELP**	**FEELING**	**CHECK**	**ASK**
Silent mode						Right leg	It is urgent	Move right arm	Bad	Catheter	Who
Review message						In back	Go back	Move right leg	Nausea	Heart rate	Why doing
Play message						Right arm	Request 1	Move left leg	Scared	Blood pressure	When doing
Spelling mode						Left arm	Request 2	Adjust pillow	Sad	For infection	Question 1
End spelling						Head	Request 3	Light off	Depressed		Question 2
Review spelling						All over	Request 4	Light on	Drugged		Question 3
"A" to "M"						Go back	Request 5		Tired		Question 4
"N" to "Z"						**Level**	Request 6		Cold		Question 5
Space						Go back	Request 7		Warm		Question 6
Erase						1	Go back	Go back	Go back	Go back	Go back
"A" to "G"	**"N" to "T"**					2					
"H" to "M"	**"U" to "Z"**					3					
Go back	Go back					4					
A	N					5					
B	O					6					
C	P					7					
D	Q					8					
E	R					9					
F	S					10					
G	T					Exit pain					
Go back	Go back										
H	U										
I	V										
J	W										
K	X										
L	Y	Time									
M	Z	Date									
Go back	Go back	Exit									

[§]Each rectangle represents a single menu block. Each menu block is stored as a stack of 15 cells in the Excel spreadsheet. When the system starts, the program cycles through the top menu choices in a repeating loop. When the patient responds, the action defined for the option is taken. Most of the top-level options will lead to a submenu, stored in a column directly under the top level choices. As with the main menu, options for a selected submenu are presented repeatedly. Some submenu options will lead to lower level, more detailed submenus when chosen, but most will take an action such as adding a phrase to a message being built. Menu options that cause a submenu to be entered are shown in bold. Once a message has been completed, the PLAY option presents it for the caregiver. The YES, NO, REPEAT, and STOP options are included on the top-level menu for rapid responses. The OPTIONS choice enters a submenu that allows the patient to silence the system, review messages being built or spell out messages. Requests 1–7 under NURSE and questions 1–6 under ASK are for future programming.

3.2 Menu structure

Information associated with a menu option is grouped conceptually into a menu block. The information contained in a block describes the audiovisual presentation for a menu option and the actions that are to be taken when that menu option is selected by the patient. The organisation of the menu system is controlled by links that define the next menu option to be presented for both the patient-response and no-response cases. Text fields in each menu block contain phrases that are converted to an audio presentation for the patient using the text-to-speech engine. Other fields in the menu block contain text that is added to messages being built by the patient.

By appropriate selection of the menu options, a message can be built by the patient and presented on the device's visual display for the caregiver, along with a text-to-speech audio playback of the message and an enunciator tone to indicate that a message is available. When the caregiver has responded, it is anticipated that the quick response menu options YES or NO will be used to answer caregiver questions. The format of each menu block is identical, but the actions that are implemented can vary widely.

Table 2 Action codes in Visual Basic 6.5 used in the prototype system[§]

PLAYFORME
Plays the current audio message on the patient's headphones
PLAYLETTERSFORME
Plays the letters in the current spelling mode message, one letter at a time, on the patient's headphones
PLAYFORALL
Puts the current video message on the display screen, turns on the external speakers, and plays the current audio message on the main speakers so that the hospital staff can hear and read the patient's message
PLAYLASTFORALL
Plays the last message again for the hospital staff
ERASECHARACTER
Erases the last character in the string in the spelling mode
ADDSPACE
Adds a space as a word separator in the spelling mode
DELETEMESSAGE
Allows the patient to erase the message currently being built
DATEANDTIME
Plays the date and time for the patient

[§]Other action codes are envisioned. For instance, the addition of a second computer controlled relay switch would allow the patient to activate the 'call' button for the nurse.

One field in the menu block contains the text specifying the verbal prompt presented to the patient. Only the patient will be able to hear the verbal prompts (through headphones or pillow speakers) because the main speakers are usually disconnected by the speaker relay. After the verbal prompt has been presented, the program looks for switch activation by the patient for a convenient period (default time, 3 s). The end of the response period is marked by a brief tone. Switch activation at any time during the response period causes selection of the presented menu option, while absence of a response advances the program to the next choice.

Currently, each menu block allows up to three 'actions' to be implemented by the software when the patient responds to the menu item. The specific actions are defined by action codes stored in the OPERATIONS elements of the menu block. The eight action codes used in the prototype system are described in Table 2. The patient need not be concerned with these codes, but they would be used by a programmer to modify a menu system to match a particular patient's needs.

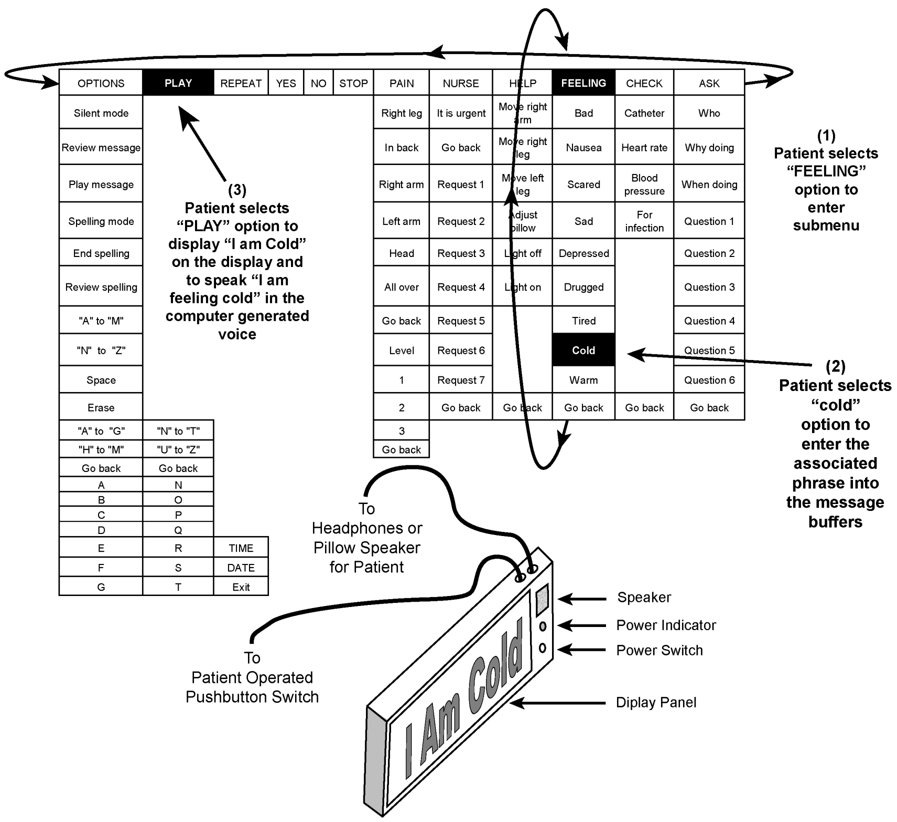
The PLAYFORALL code is of particular importance. When the user responds to a menu option that contains this action code, the speaker relay is activated so that audio output from the computer is directed to the main speakers and the message that has been built by the patient is both displayed on the computer monitor for visual output and played using the text-to-speech feature for audio output to the caregiver. A similar PLAYFORME action code allows the patient to review the current message before playing it for caregivers. Other action codes cause phrases or letters to be added to an incipient message or control aspect of the patient's environment. Although not implemented in the prototype, the authors envision actions such as 'read my e-mail' or 'select music channel' as eventual possibilities to allow an improved quality of life.

4 System operation

Figure 3 shows a schematic of the system operation. The sequence of menu presentations are indicated by the arrows, and the current patient-selected menu entries are indicated by highlights. In the example illustrated, the patient has selected FEELING from the top-level menu to enter the associated submenu. From that submenu he or she has selected 'cold' to add the phrase 'I am feeling cold' to the current message buffer. Finally the patient has selected the PLAY option to cause the verbal message 'I am feeling cold' to be announced on the main speakers and the text message 'I Am Cold' to be displayed on the monitor. The CACD does not rely on visual interactions with the patient, since BoNT-intoxicated patients generally have impaired vision, which may persist during much of their hospitalisation (Penas et al., 2005).

The ability to initiate communication would be expected to relieve some of the anxiety and frustration of severely intoxicated botulinum patients. Furthermore, the two-way communication made possible by the interactive features of the CACD is expected to improve the level of care by allowing hospital staff to assess the patient's subjective responses to treatments and procedures.

Figure 3 Schematic of the CACD system operation



5 Benefit to patient

Based on data from large outbreaks, patients severely intoxicated by BoNT/A spend an average of three months in intensive care, and a significant fraction of such patients (~30%) require mechanical ventilation for most of their hospitalisation (Mann, 1983; Schmidt-Nowara et al., 1983; Shapiro et al., 1998; Sobel et al., 2004; Ungchusak et al., 2007). The long-term care of such patients presents unique difficulties, physically as well as psychologically. With regard to the former, severely intoxicated patients appear to be comatose due to their inability to move or speak, which may result in sub-optimal care by hospital personnel. BoNT-intoxicated patients also lack the ability to communicate by alternate means such as writing, hand gestures or facial expressions, thus intensifying their isolation. These patients, however, are mentally alert and can feel pain and tactile stimuli (Maselli and Bakshi, 2000). The psychological problems stem, in part, from the loss of control over their environment, especially from the inability to communicate their feelings and status or to make requests. Psychological disorders such as depression and anxiety often develop in this group of patients and persist long after they recover muscle function (Hardin and Cohen, 1988).

The concept for our CACD was developed in response to reports of BoNT-intoxicated patients whose only means of communication was moving a hand or foot in response to questions. This form of communication is difficult since it requires the presence of dedicated personnel who must anticipate the needs of the patient. It is also subject to misinterpretation and deprives the patient of the ability to initiate communication. To translate the concept to a practical device, we chose components (computer and peripheral devices) that are inexpensive and readily available.

Interaction of the device was by means of a switch (input) and audio signals (output) in accordance with the expected abilities of the target patient population. The rationale for the use of a switch was based on reports that BoNT-intoxicated patients often retain some degree of volitional movement in the hand or foot and can therefore carry out the required task (Cherington, 1974; Maselli and Bakshi, 2000; Kobayashi et al., 2003; Souayah et al., 2006). Switches can be selected to suit the abilities of the patient in terms of size, effort and travel. Pressing of the switch may also be accompanied by an audible click to ensure that the actions are completed. Audio signals were selected on the basis that hearing is normal in BoNT-intoxicated patients, while vision is compromised due to the presence of ptosis, extraocular muscle weakness, reduced tear production, problems with accommodation and impaired pupillary responses (Penas et al., 2005).

The menus for our prototype system were based on extensive discussions with a patient who was accidentally injected with a >40 human LD50 dose of BoNT/A during a cosmetic procedure, and additional input was obtained from her primary emergency care physician (Chertow et al., 2006; Souayah et al., 2006). This patient spent 3.4 months in intensive care followed by additional time in physical rehabilitation and over 5.5 months on assisted ventilation (Chertow et al., 2006). Issues that were important in her treatment were incorporated into the program menus, such as requirement for pain medication, questions regarding diagnostic procedures or the need to adjust body position (Table 1). Many of these issues are applicable to botulism cases in general, as well as for other neuroparalytic conditions such as myasthenia gravis, Lambert-Eaton myasthenic syndrome, Guillain-Barré syndrome or amyotrophic lateral sclerosis, especially if mechanical ventilation is required.

6 Comparison with implanted devices

A number of Brain-Computer Interface (BCI) or Brain-Machine Interface (BMI) devices have been described recently. These use signals from implanted electrodes, EEGs or electrocorticograms to stimulate muscles or to operate external devices or computers. BCI/BMI devices are generally intended for aiding patients who are paralysed as a consequence of spinal cord injury or stroke (Birbaumer and Cohen, 2007).

These devices may be useful for some paralysed individuals, but they are not suitable for botulism patients for the following reasons:

- BoNT-mediated paralysis is due to block of transmitter release at the final synapse between the motor nerve terminal and motor endplate; these terminals are incapable of responding to electrical stimulation of the spinal cord or peripheral motor nerve via signals from BCI/BMI devices (Maselli and Bakshi, 2000).
- BCI/BMI devices require extensive training (Lebedev and Nicolelis, 2006; Kubler et al., 2001), while most BoNT-intoxicated patients recover speech within three months of hospitalisation (Sobel, 2005).

- BCI/BMI devices generally require visual feedback (Kubler et al., 2001), whereas vision is invariably compromised in BoNT-intoxicated patients (Penas et al., 2005).
- In the event of a large-scale natural outbreak (Ungchusak et al., 2007) or bioterrorist event (Arnon et al., 2001), the number of BCI/BMI devices would be limited, whereas the CACD can be stockpiled and available since it can be produced at a small fraction of the cost of the former.

Although patients could learn to manipulate a BMI to mimic the functionality of a simple switch, the expense and complexity of such systems make them impractical for use in a mass casualty incident. In situations where the botulism patient lacks all voluntary movement, however, the BMI (as the input to the CACD) may be the only option available for communication.

7 Conclusions

The concept of a computerised assistant to aid in patient-initiated communication is a logical extension to the manually assisted method already in use. With improvements such as a network connection, the device would allow patients to compose, send or receive e-mails to stay in touch with their surroundings, to control a heating blanket (and other devices), to make radio or music library selections and even to perform some limited job-related functions in spite of being in a state of near complete muscle paralysis.

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Abbreviations

BoNT	Botulinum Neurotoxin
CACD	Computer-Assisted Communication Device
BCI	Brain-Computer Interface
BMI	Brain-Machine Interface