A Computer-Based Audio Challenge and Response Cardiopulmonary Bypass Checklist System

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Key words: Checklist, audio, CPB

ABSTRACT

Comparisons continue to be made between perfusion and aviation. Although similarities exist there are important differences. One substantial dissimilarity is in the area of safety where commercial aviation has a dramatically lower accident rate than perfusion. Extensive safety systems, including the routine use of checklists, are a major factor in safe air travel.

Experience with the use of a checklist for cardiopulmonary bypass has proven useful for managing risk and assuring quality. Recent publications on cardiopulmonary bypass standards and safety mandate the use of checklists.

We borrowed from the aviation industry an audio checklist management system which employs digital speech technology. A small, mast-mounted, battery operated device with a lifelike voice challenges the perfusionist with a cardiopulmonary bypass checklist. After being challenged with a checklist item, the perfusionist responds verbally and advances to the next checklist item, by pressing a remote button. The device records the time that an item is checked and upon completion of the checklist prints a document for inclusion in the record.

The audio checklist includes pre-bypass set-up, pre- and post-initiation, cardioplegia, pre-termination, and post-bypass checklists. Emergency procedure checklists, for common perfusion incidents, may be called-up by the perfusionist. The computer may be programmed to generate custom checklists to meet an individual perfusionist's need.

The audio checklist device assures consistency and frees the perfusionist from a more cumbersome paper checklist system. Use of the audio checklist device minimizes the diversion of the perfusionist's eyes and attention from cardiopulmonary bypass equipment and events.

INTRODUCTION

Cardiopulmonary bypass (CPB) is a complex procedure that involves multiple mechanical, physiological, and pharmacological manipulations and is associated with a rate of accidents[1,2] higher than desirable. Current information indicates that there is *at least* one "perfusion related" accident in every 300 CPB cases and that once in every 1,000 cases there is a "perfusion related" accident that results in permanent patient injury or death.[1,2] At this accident rate, perfusion accidents occur at a rate that is about 1,000 times higher than that for commercial aviation. Flying a commercial aircraft is much more complex from both a mechanical and a human interaction perspective than is perfusion management and yet it is significantly safer than cardiopulmonary bypass.

It is difficult to judge the true accident rate for CPB because only two (2) surveys of CPB accidents have been conducted in this country.[1,2] Both surveys were retrospective and probably underestimate the incidence of unfavorable circumstances or events.

Commercial air travel may be safer than CPB for a number of reasons, including: extensive training and retraining of pilots, often employing the use of simulators, a pilot and co-pilot on every flight, attention to mechanical condition of the plane before every flight, and the long standing use of checklists.

In the Kurusz Perfusion Accident Survey,[1] in anesthesia,[3] in aircraft accidents,[4] and accidents in general,[5] it is a common finding that 60%-80% of accidents are attributable to human error.

It is prudent to concentrate our efforts on the elimination of human error since it is the most common cause of accidents. Toward this end, we may learn from the success of the aviation industry and duplicate their techniques.

One important accident prevention tool used by pilots is the checklist. The purpose of a checklist is to minimize the human error component of complex tasks. It is significant that failure to properly perform the checklist has been cited as a "contributing factor" in over 60% of airline crashes (Heads-Up Technologies Inc. compilation of Flight Safety Foundation computerized database records in 1986).

Our eleven year experience with a checklist for cardiopulmonary bypass in over 73,000 cases has led us to require its use. The acceptance of a checklist has not been difficult because perfusionists have a strong desire to conduct perfusion in the safest possible manner.

The purpose of this paper is to present an improved format for a CPB checklist.

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AUDIO CHECKLIST COMPUTER

In October of 1988, PSICOR entered into a joint venture with Heads-Up Technologies Inc. to develop an audio checklist computer which makes use of digital speech technology. Heads-Up Technologies Inc. is the market leader in audio checklist systems for private and commercial aircraft.

The audio checklist computer consists of an injection molded plastic case with integral Radio Frequency shielding. The nominal dimensions of the unit are 4" high by 11.5" wide by 8" deep. The front panel is a polyurethane coated membrane with "positive action" switches. The unit is battery operated with either 4 'D' size alkaline disposable or rechargeable Ni-Cad batteries. The screen is a 4 line by 40 character supertwist liquid crystal display (LCD). A replaceable cartridge contains the circuitry for checklist speech production, computer diagnostics, and clock and timer batteries. The unit contains a small printer with easy access for paper replacement. There is a one watt speaker and an external earphone jack. There is a remote "go" button used for the majority of checklist functions. The unit is dust and water resistant and may be cleaned with the usual anti-bacterial and anti-viral cleaners used in the operating room.

The checklist can be customized to a given operating room's equipment and disposables used and has a number of unique features.

• *Challenge and Response Format.* The checklist computer issues an audio challenge on each checklist item; the challenge and the appropriate response appear on the LCD screen. The perfusionist voices the simple response, as prompted on the screen, and pushes a remote "go" button and the computer then moves on to the next checklist item. If a checklist item is not finished or is inappropriate at that time, the skip button is pressed and that checklist item moves to the end of the appropriate checklist section, to be checked off later. If the item is not applicable, the cancel button is pushed. At the end of the case, all the "not applicable" items are noted on the printout. Essential items must have a written justification, on the printout, for marking that item as "not applicable" (for example, a safety device was found to be broken at the beginning of the case, and therefore could not be used).

• *Audio.* The audio capability of the checklist can be extremely helpful, but it could also be distracting in an active way (the written checklist could be distracting in a passive way). The perfusionist can eliminate this potential problem by choosing from three options: 1) a volume control which easily changes the volume of the internal speaker; 2) the operator may choose the silent feature from the checklist menu, and 3) the external earphone jack allows the perfusionist or perfusion assistant to disable the internal speaker while using an earphone.

Although the audible checklist is safer than reading the screen, it may be difficult or impossible to use the audible feature in some circumstances. How the audio feature is used will depend on individual circumstances and will be within the control of the perfusion team.

• *Checklist Configuration.* Prior to the case the operator may select the equipment that he/she will use. The computer will not include checklist items relating to equipment not used. The order of the set-up subchecklists may also be rearranged in some circumstances. For example: a member of the perfusion team wants to do the lab equipment checklist followed by the autotransfusion checklist before setting up the pump; they will have that flexibility. It is a good idea to occasionally change the order of some of the set-up checklists to minimize the ritual associated with performing the checklist in the same way, day after day. (Please refer to the schematic of the checklist.)

• *Help Screens.* Pressing the "HELP" button in the upper left-hand corner of the front panel will provide information about the operation of the computer as well as instructions for performing the checklist.

When the computer is displaying a menu, pressing the "HELP" button brings up a help screen that explains the menu and how to use it.

When the computer is in a checklist, the "HELP" button brings up a screen which explains what needs to be done to correctly perform a checklist item. The help screens become the instructions for the computer and the checklist and are a self-contained manual or reference handbook. The checklist instructions provide an opportunity to teach and reinforce protocol standards.

• *Recursive Checklists.* A recursive checklist calls, displays, and announces itself at perfusionist specified time intervals, until canceled.

There are two recursive checklists: 1) the cardioplegia checklist, which comes back periodically (default time 20 minutes, the time can be set by the perfusionist) and 2) a "chart check" (the chart check comes back with a default time of every 15 minutes).

The cardioplegia checklist serves to remind the perfusionist when it is time to give cardioplegia, and which tasks must be done to safely administer cardioplegia while continuing to monitor CPB.

The "chart check" checklist time starts with the initiation of the bypass. At user defined intervals, the perfusionist will be reminded to chart. At every other "chart check", or at half hour intervals after the first laboratory samples are drawn, the "chart check" reminder will include a reminder to send appropriate laboratory samples.

• *Timers.* The computer keeps track of the cardiopulmonary bypass time, cross clamp time, and elapsed time between cardioplegic solution doses. This feature eliminates the need to remember to turn timers on and off and use a separate timer. The checklist printout will record on, off, and total times for bypass and cross clamp.

• *Bypass Checklist.* Our previous checklist was only a pre-bypass checklist. This checklist includes checklists during and after bypass to allow for safer conduct of perfusion. We consider the expansion of the checklist (to include areas or times during and after bypass when one can make judgmental errors or neglect to do certain tasks in a required order) to be a substantial improvement over a simple setup checklist.

• *Post Bypass Checklist.* This checklist will remind the perfusionist of important parameters. These include items such as checking the aortic cannula for air before transfusing at the end

of a case.

Protamine reaction is reported to be the number one cause of patient mortality and morbidity associated with the use of cardiopulmonary bypass.[1] Post protamine checklist items remind the team to be aware of hemodynamic parameters and vigilant for the occurrence of post bypass hypotension. The use of the checklist may increase early recognition of the problem, provide documentation, and increase awareness of the event.

• *Emergency Checklists.* At any time during the procedure the operator will be able to call up a menu of emergency procedures. The most common emergencies will be listed in order of their likelihood of occurring. The emergency procedure checklists can be helpful in a number of ways. For example, if the perfusionist thinks that the oxygenator is failing he/she may select the oxygenator failure checklist and choose the diagnostics sub-checklist. This checklist will run through a list of things which could contribute to failure to oxygenate such as blender failure or failure to connect the gas source, etc. The diagnostic checklist will also include the formulae for calculating gas transfer and help the perfusionist make, or rule out, the diagnosis of oxygenator failure. If the diagnosis is confirmed then the computer will outline the steps to safely change out the oxygenator.[6] This can be performed as a "do checklist" or a "done checklist". The computer will then document that you performed the diagnostic and/or corrective steps.

• *Documentation.* The computer displays the printer menu at the end of the case and allows the perfusionist to print a copy (or two) of the checklist. The checklist is time stamped so that the perfusionist knows how long it took to do an individual checklist item, or a section of the checklist.

There are places on the checklist for perfusionist and perfusion assistant signatures, as well as hospital, surgeon, and patient information.

DISCUSSION

Safety is not the ultimate goal of perfusion. Safety is the minimum standard for cardiopulmonary bypass. The patient comes to surgery to have his/her condition improved by the surgery and not to be injured. It must be our goal toeinsure that no patient is injured as a result of a preventable event while on bypass. An accident, by definition, is preventable.

Joseph Juran[7] states that "quality problems are largely traceable to deficiencies in the methods used to plan for quality." The use of a checklist is part of the essential planning effort to assure patent safety.

Richard Collins, author of the classic book *Air Crashes*[4, 11-17], says that in addition to planning, a safe pilot needs discipline. Performing the checklist correctly requires discipline and discipline requires performing the checklist correctly. Perfusion that is safe for the patient minimizes stress on the perfusionist, decreases liability exposure, and enhances the position of the perfusionist as a professional — one definition of a professional is someone who is self-correcting.

In the Perfusion Accident survey Kurusz reports that only 29.9% of perfusionists used a written checklist and that only 49.3% of perfusionists had written protocols[1].

We have been told "that the difference between a wish and a goal is numbers and dates". So-called "mental checklists" are "wishlists" and not checklists. A checklist cannot be mental, in order to be effective and reproducible. The same can also be said for protocols.

Written checklists are not perfect. The use of a written checklist requires the attention of a person to be diverted away from the task at hand (setting up or operating the pump) in order to read the checklist and to document performance of the checklist.

We anticipate that the audio checklist will be an improvement over a written checklist because it does not have the drawbacks of a paper checklist. The computer can become more than just a device to free the perfusionist from a written checklist and document checklist performance.

The checklist script and help screens are undergoing pre-clinical evaluation and will shortly have extensive clinical evaluation using a computer simulation program. Streamlining of the checklist and improvement of the help screens will be accomplished while the prototype units are being built.

Ten prototype units will be available for clinical trial in selected PSICOR client hospitals in June. Following extensive evaluation and refinement of the hardware and software by clinical personnel, it is anticipated that the Perfusion Management System will become part of the routine for all PSICOR CPB cases.

The reasons we view use of the Perfusion Management System as an improvement over a written checklist include the following: the audio capability of the computer, the expansion of the checklist, the interaction required in the challenge and response format, the availability of help screen reference, the documentation provided by the printout, and the possibility of planned expansion of the system.

Even the best checklist is only part of the solution to patient safety, but it is an essential part. A comprehensive perfusion safety program must include improved selection of perfusion students, better training of both students and instructors, effective continuing education, and periodic additional training using simulators (i.e., for new equipment or drills for emergencies). The effort must also include, at the institutional, if not the national level, written standards/protocols that are reviewed and updated, effective peer review, incident review and analysis, and a relentless effort to prevent accidents of both human and mechanical origins.[8]

In the last year-and-a-half, the use of a checklist for cardiopulmonary bypass has been recommended in two publications, one on safety [9], and one on standards of practice.[10]

PERFUSION CHECKLIST SCHEMATIC

SETUP
Pump
Safety Devices
Temperature Control Unit
Disposables Inspection
O_2 and CO_2 Equipment
Accessories
Cardioplegia Delivery System
Intra-Aortic Balloon Pump
Centrifugal Pump
Bubble Oxygenator
Autotransfusion System
Drugs and Supplies
Heart Valves
Lab/Support Equipment

CIRCUIT
SAFETY DEVICES CHECK
PRE-INITIATION (DOUBLE CHECK)

INITIATION
(Bypass timer on)
(X clamp timer on)

CARDIOPLEGIA
CHART CHECK
PRE-WARMING
(X clamp timer off)

PRE-TERMINATION
BYPASS TERMINATION
(Bypass timer off)

PRE-TRANSFUSION
STATUS

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