J Extra Corpor Technol. 2019;51:38–40
The Journal of ExtraCorporeal Technology

Establishing a Ventilator–Heart Lung Machine Communication Bridge to Mitigate Errors when Weaning from Bypass

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This work was presented as a podium presentation at the AATS Patient Safety Course, Boston, Massachusetts, June 29–30, 2018.

Abstract: If a perfusionist weans a patient off the heart lung machine (HLM) and the anesthesiologist has not re-started the ventilator, the patient will become hypoxic. The objective of this project was to create a redundant safety system of verbal and electronic communication to prevent failure to ventilate errors after cardiopulmonary bypass. This objective could be realized by building an electronic communication bridge directly between the HLM and ventilator. A software application was created to retrieve and interpret data from the pump and ventilator and trigger a programmed smart alarm. The software is able to interpret data from the pump and ventilator. When both are off simultaneously (defined as a pump flow of 0 L/min with a respiratory rate of 0 breaths/min), the application will raies an alarm. Communication between a pump and ventilator is possible, enabling the deployment of a safety system that could exist in the operating room (OR) as a standalone alarm. A device dataset can be used to optimize clinical performance of the alarm. The application could also be integrated into smart checklists and computer-assisted OR process models that are currently in development. **Keywords:** cardiopulmonary bypass, ventilation, perfusion, patient safety. *J Extra Corpor Technol. 2019;51:38–40*

OVERVIEW

The operating room (OR) is an extremely complex and vulnerable socio-technical system. When this system fails, it is often because of entirely preventable human errors. Preventable adverse events typically occur during the most distraction-sensitive periods in the intraoperative process. Most of these events in the cardiac intraoperative process occur in the narrow window from post–cross-clamp to the weaning off from bypass phase (1). Specifically, if the perfusionist begins weaning the patient off the heart lung machine (HLM) and the anesthesiologist has not turned on the ventilator, the patient will become hypoxic. Cardiac teams rely completely on effective verbal communication to ensure that the ventilator is turned on before initiation of the weaning phase. However, it has been established that relying on a single intervention to prevent accidents in a high-consequence industry is not sufficient and a safety-redundant system is preferable (2). The objective of this project was to create an electronic mode of communication that adds redundancy to standard verbal communications to prevent failure to ventilate errors after cardiopulmonary bypass (CPB).

DESCRIPTION

This objective could be realized by building an electronic communication bridge directly between perfusionist's HLM and anesthesiologist's ventilator (Figure 1). First, live

Received for publication September 19, 2018; accepted January 25, 2019.
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This material is based upon work supported by the National Institutes of Health (NIH) under Grant 1R01HL126896 awarded to Dr. Zenati. Any opinions, findings, and conclusions or recommendations expressed in this publication are those of the authors and do not necessarily reflect the views of the NIH.
The senior author has stated that the authors have reported no material, financial, or other relationship with any healthcare-related business or other entity whose products or services are discussed in this paper.

Article available at https://ject.edpsciences.org or https://doi.org/10.1051/ject/201951038

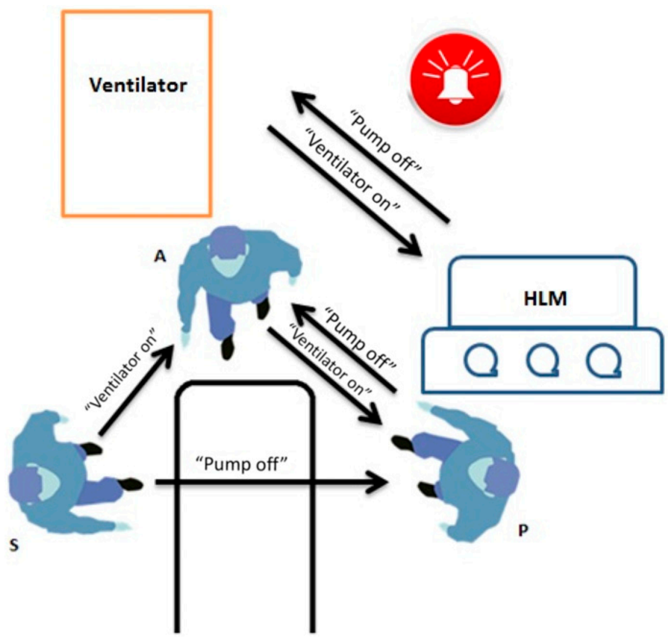

Figure 1. Redundant flow of verbal and electronic communication in the OR. Ventilator on/pump off demand originates from the surgeon. The anesthesiologist confirms that the ventilator is on, and the perfusionist then confirms that the pump is off. The ventilator will also confirm it is on, and the pump confirms it is off. If the pump and ventilator are off at the same time, the smart alarm will trigger. A, Anesthesiologist; P, Perfusionist; S, Surgeon.

data from an S5 HLM (Liva Nova, London, England) and an Apollo ventilator (Draeger, Lubeck, Germany) were captured via the serial data outputs on both devices. A dedicated software application was then created to retrieve and interpret these data. Medical devices generally use proprietary interfaces and terminology which are only documented in technical manuals that are not openly available (3). Therefore, the data retrieved from the HLM and ventilator had to first be translated into terms the application could understand. This was accomplished using the OpenICE platform (Medical Device Interoperability & Cybersecurity Program, Massachusetts General Hospital, Boston, MA), which translates each device's proprietary communications protocol and data representation to a standardized format and communications middleware (4).

Once the software was able to recognize the live data it received, parameters were established to trigger a programmed smart alarm. Specifically, when both devices are off simultaneously (defined as a bypass pump rate of 0 L/min with a respiratory rate of 0 breaths/min), the application will respond with both a visual and audible alert (Figure 2).

DISCUSSION

A redundant system of communication occurring directly between the HLM and ventilator will increase the reliability and safety of the complex process of weaning a patient off bypass. Currently, most devices in the OR suffer from a lack of interoperability. Availability of interoperable medical devices would lead to safety interlocks that enable more resilient systems (5). Our team has been able to successfully integrate industry standards of ASTM F2761 and Integrated Clinical Environment (ICE) concepts of interoperability from theory to a fully functioning model in a real OR environment (6).

This model is important because communication errors will inevitably occur in the OR between the surgeon, anesthesiologist, and perfusionist. These miscommunications are what can ultimately lead to ventilation errors. Some may argue that ventilation errors while weaning from CPB are too rare to justify the implementation of safety systems such as the one developed here. However, this error is common enough to be acknowledged in literature as a major adverse event, particularly when patient monitor alarms have been silenced (7). Furthermore, the likelihood of a communication error resulting in a ventilation error only increases beacuse of the lack of standardization of the weaning process and command language (8).

Proving that this bridge of communication can be established will drive the development of more advanced systems that will recognize and mitigate a host of similar errors. In the future, the system developed for this project will be fine-tuned to not only raise an alarm when the HLM and ventilator are both off at the same time, but to also recognize when the perfusionist starts the weaning from the bypass process. An alert could be triggered if a perfusionist has come to partial flow and the ventilator is not on. A device dataset could be used to optimize clinical performance of the alarm (9). This tool could exist in the OR as a standalone alarm. The application could also be integrated into smart checklists and computer-assisted OR process models that are currently in development.

The potential application for this technology is not limited to communication between a HLM and ventilator. The software can be used between any pieces of hardware that output the necessary data, and for which we have written a ICE equipment interface that translates the device's proprietary protocol and data representation into our open standards–based data model. Realistic examples of future applications include communication between extracorporeal membrane oxygenation circuits and ventilators in the surgical intensive care unit, or between a HLM and heater–cooler to help maintain safe heat gradients during patient warming.

Limitations of this technology include the necessity of the perfusionist using the application to manually activate it when appropriate. Just as the perfusionist has to remember to activate the bubble and level detectors, or initiate the bypass or cardioplegia timers, he or she would also have to remember to activate the ventilation communication application. This action could be added into the perfusionist's pre-bypass checklist. There may also be times where having the ventilator and pump flow off simultaneously is appropriate, such as during deep hypothermic circulatory arrest or the sternotomy. To compensate for this, an alarm

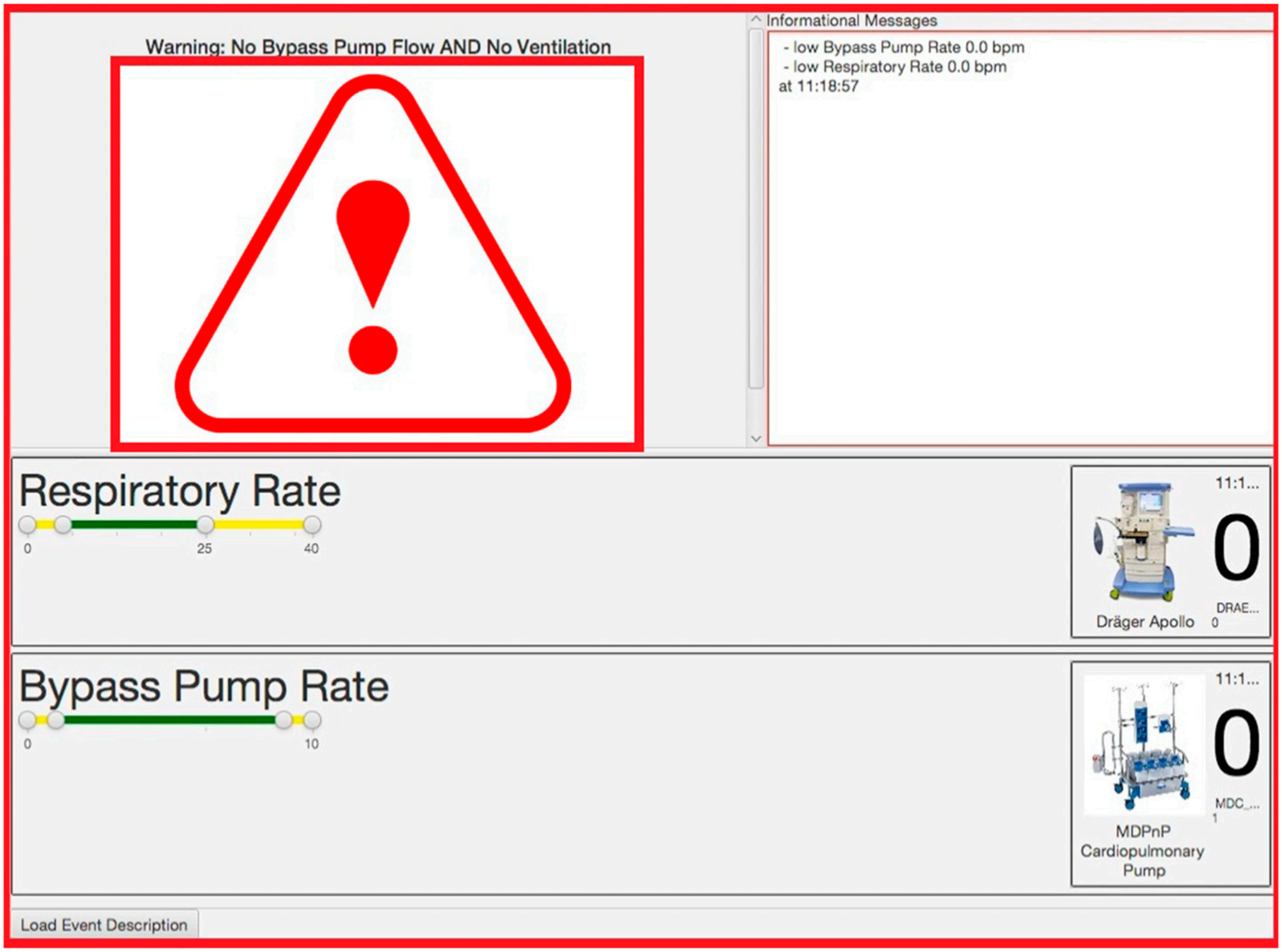

Figure 2. Software application screenshot. When the software application detects no bypass pump flow (bypass pump rate = 0 L/min) and no ventilation (respiratory rate = 0 breathes/min), the application will respond with both a visual and audible alarm.

standby button has been added to the application, which allows the user to manually silence the alarm system. When in standby mode, a large visual indictor will remain on the screen and the application will audibly chirp every few minutes to remind OR personnel that the alarm is silenced.

ACKNOWLEDGMENTS

This project is funded by NIH/NHLBI R01HL126896-01A1, Developing Standardized Intraoperative Process Models to Enhance Surgical Safety.

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