Guest Commentary

The Big Picture: Intelligent Solutions for Ventilator Safety

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Error reduction, patient safety and risk reduction are hot topics of discussion in the medical community. Who is not concerned about the safety of a loved one when they enter the health care system? Commercial aviation, with all its potential risks, is classified as one of the safest industries today. What can the medical community learn from their success?

Imagine your reaction if, sitting on an airplane, ready to depart you heard this. "Ladies and Gentlemen, this is your Captain speaking. I want to inform you today of a common occurrence called Aircraft Induced Passenger Injury. We know that if you stay on this flight long enough, it will happen. There is nothing wrong with the aircraft, but there is a high probability that we will not set the flight controls properly and you may be hurt in the process." Can you imagine the public outcry?

Here is a challenge for the medical community. Eliminate ventilator induced lung injury. Despite healthcare professionals working tirelessly every day, this is a fact of placing someone on a mechanical ventilator. If lung protective ventilation is not a constant focus, the ventilator will do damage. Remember, "First, do no harm."

Comparisons between the safety records of health care and commercial aviation are not new. One of the more recent comparisons was from the October 31, 2006 issue of the New York Times, "What Pilots Can Teach Hospitals about Patient Safety". This article discussed how many hospitals are using pilots as consultants to help them address patient safety and error reduction. Another example, Jean-Louis Vincent, MD, in an editorial to ICU Management 6:1:2006 said it best. "Over the years, healthcare services have developed a 'cover-up' culture where mistakes have been hidden … However, this traditional attitude is beginning to change as we learn from other industries where great harm is possible, e.g. aviation and nuclear power, which approach the concept of safety with a no-fault or limited fault approach."

Once an industry accepts that certain risks are present, correction can be implemented. Many airline pilots have had the opportunity to participate in no-fault or limited fault disclosures that have resulted in great strides in passenger safety. Want proof? In 1999, the American Hospital Association reported that there were somewhere between 44,000 and 98,000 deaths every year due to medical errors. Compare this to National Transportation Safety Board statistics for 2004, where there were 11 fatalities due to commercial aviation. Despite the recent focus on safety statistics, experts assure us that the health system in the United States is safe. But its safety record is a far cry from the record of the similarly complex aviation industry, which is being held up as an example for the medical community. A person would have to fly nonstop for 438 years before expecting to be involved in a deadly airplane crash, based on recent airline accident statistics. The Institute of Medicine has stated that health care is at least a decade behind aviation in safeguarding consumers' lives and health. Of course there are dramatic differences between commercial aviation and health care, and there is not a "one size fits all" solution. It is, however, hard to argue with the fact that improvement is needed.

Human error is still the leading cause of accidents. At the airlines, we addressed this with Crew Resource Management (CRM), and aircraft-type specific training, conducted with advanced simulations. Airline crews have procedures, profiles and flows to address each element of routine, abnormal and emergency situations in a

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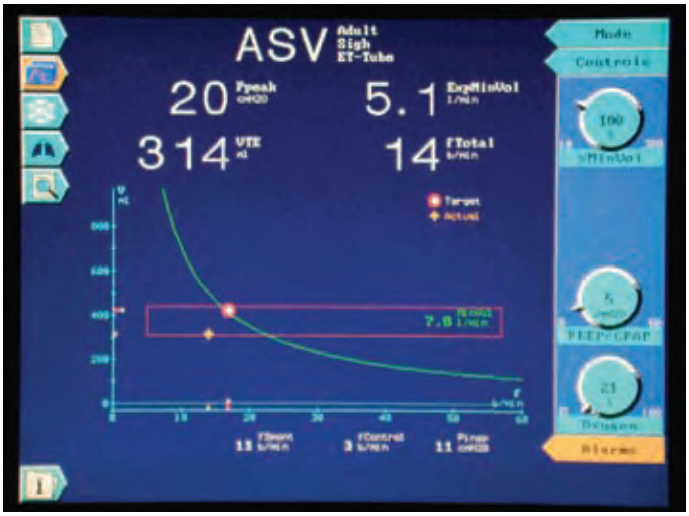
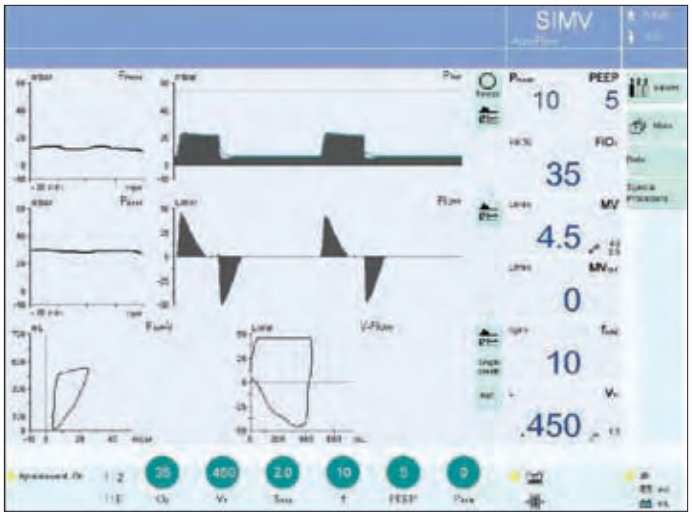
standardized fashion. Medical device companies offer little, if any, of this kind of training, and hospitals are rarely offering it either. With literally thousands of jet engine starts in my flying career, I still use a checklist. I use a checklist for safety and to eliminate mistakes. Is there a checklist for immediate actions to take in the event of a suspected ventilator malfunction? The Federal Aviation Administration requires any pilot flying a turbojet aircraft to have type-specific training and certification before they may act as the pilot in command. How many different types of medical instrumentation does the average healthcare professional come in contact with on a given day? Is current training provided by sales people and clinical support representatives really adequate? Look at the facts. The Joint Commission on Accreditation of Healthcare Organizations published a Sentinel Event Alert 26.2.2002, "Root Cause Analysis of 23 deaths or injuries related to long term ventilation," where inadequate orientation/training was found to be a factor in 87% of these cases. The second leading factor in this study was "communication breakdown among staff members." These are issues that can improve with more effective training, what is being done today is simply not working.



Every pilot knows that flying is extremely dynamic. Weather, air traffic control, the aircraft and many other factors require the pilot to assemble a "big picture" regarding the status of their flight - constantly and correctly. The same can be said for patient care in the ICU where the situation is also extremely dynamic. This is precisely why airline pilots are trained in simulators before ever carrying passengers. Were you aware of the fact that an airline pilot essentially puts their job on the line every six months? Standardization, procedures, immediate action items, etc. are so important to safety that crews are given practical examinations on a routine basis. Safety issues can be addressed before something goes wrong. Hospitals can no longer afford the costs of medical errors and increased lengths of stay due to improper actions by staff, yet the investment in advanced training is inadequate.

A safe operation has three elements

Safety is predicated upon three basic elements. These are the operator, the machine and the environment. Imagine a three-legged stool. If any one of these elements is weak then the entire system can fall apart.



The Operator (pilot or clinician) needs to be in good physical and mental condition to perform safely. Errors are much more likely when the Operator has worked long hours or needs to function with a team that has little standardization. Most importantly, Operators must maintain what pilots refer to as "situational awareness" (SA). Situational awareness is defined as, "the degree of accuracy by which one's perception of his current environment mirrors reality." Pilots simplify this definition: aviate, navigate and communicate. The ability to maintain situational awareness is a major factor in determining the skill level of a pilot. Manipulation of the flight controls is often the easiest aspect of good piloting skills. Getting a pilot to the point where they exhibit a high degree of situational awareness skills and can anticipate what will happen next is what separates the average pilots from those most able to conduct safe flight operations under all conditions. This also relates very closely to health care within the ICU. There are many inputs and many decisions that need to be made. The clinician must keep the big picture of appropriate care, patient safety, and effectiveness while responding correctly to minor deviations. Those teams who do this with consistency generate the best patient outcomes.

Research into situational awareness has uncovered some compelling information. A pilot's perception of reality is often influenced or degraded by internal (mental) and external (environmental) forces. The pilot's ability to process incoming information is subject to certain expectations and biases. Problems are most likely to emerge when expectations distort, conflict with or mute incoming information.

Does this kind of statement sound familiar? It should. Clinicians in the ICU are under the same kind of influences. The problem is, that until recently, clinicians have rarely been given any training in situational awareness, much less evaluated on their ability to handle complex and dynamic environments. Developing and maintaining situational awareness is clearly important, but where to start? Pilots learn that situational awareness is not easy to keep, so they develop their own method of developing and maintaining it.

For you or that pilot to have any chance of seeing the big picture, you must always, at any time be able to answer 5 simple questions:

Where have I been?
Where am I?
Where am I going?
What should I be doing?
What might impact my plans along the way?

If at any point in the cockpit or during the care for your patient you cannot answer these five questions, situational awareness is not possible. With the correct answers to these questions (note: correct answers) situational awareness can be rebuilt.

Fortunately pilots and clinicians do not have to do this all on their own. There are lots of tools, some obvious, some not – that can assist in developing and maintaining situational awareness. Aviation uses the term CRM (Crew Resource Management), because time and time again it has been proven that it is people *not* working together that is a major factor in losing situational awareness and creating unsafe conditions.

Open channels of communication allow individuals to express opinions. There have been plenty of aviation accidents that could have been prevented if the cockpit crew had communicated more effectively. In fact, an NTSB study of 37 accidents found that 31 could have been prevented if one or more crewmembers had spoken up about errors and/or situational awareness concerns. This holds true in clinical practice as well. This is exactly why the Joint Commission listed "communication breakdown" as the number two reason for ventilator injuries or deaths in the report cited earlier.

Another supportive tool for a pilot is a checklist. Use of checklists, even for very simple tasks, are excellent outlines that

guide pilots through problems or routine procedures in a methodical way, which, in turn, allows their focus to remain on the big picture, not the routine or rote. Hospitals are now trying to utilize this idea as well, but still many procedures or "protocols" are performed from memory, not by direct reference to a printed card, graphical user interface on the instrumentation, etc.

The second element to safety is the machine (aircraft, ventilator or other instrumentation). Modern mechanical ventilators are all very manual devices. Equipment reliability from all manufacturers has improved over the years and the equipment is designed to protect the patient in the event of a failure. But Ventilator Induced Lung Injury does not normally result from an equipment failure, but rather from incorrect ventilator settings that were set by a human operator. Until very recently, the mechanical ventilator even with so called "dual modes" relies on the clinician to select a mode, and make static settings. The modern mechanical ventilator, with rare exception is like having the pilot flying the airliner by hand all the time, in all kinds of weather. Not the best for safety. A mechanical ventilator is a potential killing machine. It is really a time machine. The ventilator does not heal, but mainly "buys time" for the patient to improve. So the fact that the ventilator causes harm to the patient very routinely, says little for what manufacturers have to offer the clinician.

Aircraft instrumentation has come a long way and safety has improved in line with those advances. The airliner cockpit used to be filled with dials and gauges, and progressed to digital displays. But, because situational awareness is so critical to the safety of the passengers on board a modern airliner, the aviation community is always exploring new ways to help pilots maintain it. The modern "glass cockpit" uses pictures rather than dials and numbers to help pilots formulate answers to those five questions mentioned before. Such displays can put contingency plans at a pilot's fingertips, while greatly simplifying many of the aspects of the flight. The goal of modern aircraft panels is to provide the pilots a clear, unobstructed view of the flight path regardless of time of day or severity of the weather. In stressful circumstances, the cockpit offers "intelligent" displays that allow the pilot to focus only on what is important to the task at hand.

We can see evidence that the medical community is venturing down this pathway as well, but with mixed results. Fancy "boxes" and displays only can help the clinician if they know how to use them effectively. Little time is spent with the clinician in training on this area of operation of each particular device. Operational errors or misunderstandings can destroy situational awareness very rapidly. High tech toys can sometimes lull pilots and clinicians into losing situational awareness. Serious concentration on these displays can distract from other required tasks. Take the trend in ventilator graphics for instance, an early attempt at giving a mechanical ventilator some kind of "picture" to help assess the patient. The respiratory therapist or physician will agree that waveform interpretation is not a simple task. What is needed is a display for the mechanical ventilator that gives instant confirmation that the patient is being treated appropriately. This is available today on a mechanical ventilator with much research being devoted to take ventilator displays to a whole new level.

The third key factor related to safety is the Environment (the weather or the patient and facility). The modern ICU is a flurry of activity. The patient is dynamic. The patient care team is diverse, dynamic and not always working as a team. The clinician is presented with a situation that is difficult or impossible to control. Despite these challenges, clinicians work long hard shifts to care for the patients that we all serve. Pilots learn to develop contingency plans to manage elements beyond their control. The clinician needs better tools to not only let them manage what is happening real time, but allow them to anticipate the elements that are not in their control. The goal is to anticipate not simply react.

How does this affect the next generation of mechanical ventilators?

Those three elements critical to safety (operator, machine, environment) must be considered together, to reach the goal of eliminating Ventilator Induced Lung Injury.

Tools and technology are not enough to ensure safety and situational awareness. Mental conditioning is required to keep your situational awareness in top form. You must eliminate any belief that you can always do everything yourself. Pilots and clinicians by nature are independent thinkers. When times are busy however, teamwork is essential. Dividing duties is critical to every type of operation – some should be flying the airplane, while another should be working on the other issues.

Pilots have one huge advantage over the clinician in the ICU. They rely on cockpit automation to maintain situational awareness and divide duties between the team. The autopilot has dramatically improved the safety of airline travel. We are just now seeing independent thinking medical device companies offering "autopilots" on their medical devices as well. The mechanical ventilator forces a breathing pattern on a patient, based upon manual settings by a clinician who may or may not have situational awareness of the current situation. The term Ventilator Induced Lung Injury should really be clinician induced lung injury. Patients don't fight ventilators, ventilators fight patients. There has to be a better way than sedation to allow the ventilator to do its work.

There is a very famous airline crash that is often used to demonstrate how the loss of situational awareness can have dire consequences. An Eastern Airlines crew of a Lockheed Tri-Star airliner crashed into the Florida Everglades due strictly to pilot error and loss of situational awareness. Everyone in the cockpit was focused on a landing gear problem, but nobody was watching the airplane. Actually, there was nothing wrong with the landing gear. A 29 cent light bulb had simply blown out. In this crew of three, not one had assumed responsibility to actually fly the aircraft. They all focused on the "perceived" problem and flew a perfectly good aircraft into the Florida everglades killing many people.

Mechanical ventilators, that do not employ advanced technology like an autopilot, offer almost no safety net for the clinician. In the hands of an appropriately trained clinician at the bedside at all times the ventilator can be readily manipulated. It is impossible for a clinician to be at the bedside all the time. There are common problems with mechanical ventilators however that the industry is ignoring. There are too many modes. Clinicians are rarely experts at all the modes on modern ventilators, not to mention the differences between how these modes operate

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Members of the Respiratory Therapy Department at Scripps Mercy Hospital.

it is advantageous." However, Brewer says, the respiratory therapists were eager to learn BiVent and to assist the physicians in using it in appropriate cases. Brewer is helping the hospital to write protocols for BiVent.

With the support of Maquet's clinical applications specialists, a select group of specialists and RTS were trained first and they, in turn, trained others, including the nurses, on the use of BiVent. Maquet provides continued support as needed. Scripps Mercy believes in collaborative healthcare and thus cross-trains its staff, which was easy to do in this case because the ventilators and BiVent operate with a touch screen, Tanaka notes. "BiVent is very user-friendly," he says.

The respiratory therapists favored the SERVO-I when the hospital was looking to provide new and more effective ventilation strategies. A committee had narrowed the choices on the recommendations of physicians and staff, Tanaka says.

"It is very important that the therapists appreciate the ventilator and are comfortable with all its modes because they are very closely involved with the equipment," Lichter says. The hospital has 70 respiratory therapists and staff.

Tanaka says that like with everything new, the physicians and staff had to be convinced that BiVent works, but it did not take long once they saw how easily it could be employed, and how beneficial it could be for their trauma and medical patients. "Going forward," Tanaka says, "we want to be able to provide the best care possible for our patients, and we believe that with BiVent, we can do that."

The views, opinions and assertions stated by Scripps Mercy staff are those of the clinicians and administrators, and don't necessarily reflect the views of Maquet. This article was provided to Respiratory Therapy by Maquet.

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between various models of ventilators. There is far too much complexity in the operation of a ventilator. There is a multitude of controls that all must be set by the clinician often using "best clinical judgment." These settings are static, while the patient and the environment are dynamic.

Imagine a mechanical ventilator with an autopilot with capabilities very similar to what is used as routine by airline pilots. The clinician can determine the relevant clinical parameters very easily and let the ventilator run the routine manipulations and provide for automatic patient safety parameters that are not alarms, but an actual lung protective strategy built right into the device. The operation of the ventilator would be hassle-free with not many modes, but a single non-mode. The ventilator would simply provide the appropriate gas delivery in a manner that the patient is most comfortable with.

What next? Imagine a completely modern graphical user interface that provides what a pilot would call, an "artificial horizon." Imagine being able to see what is actually happening to the lungs. Soon a clinician will be able to actually see a patient weaning from the ventilator, not by studying a list of data for various monitored parameters but with easy to understand graphics that interpret the data based upon established clinical principles. Training programs would make extensive use of advanced simulators so that scenario based training could reinforce the critical care protocols. There are already ventilation autopilots, but you will soon see this automation address more than ventilation but oxygenation, lung recruitment and setting appropriate PEEP. Ventilator electronic data will be more relevant to the clinical information systems as hospitals move toward the Electronic Health Record and automated care protocols.

Some in the health care industry are worried that their job may be lost to automation. Autopilots have been in commercial airliners now for over 50 years, and still there are two pilots up front. We are seeing robotic surgery, electronic ICUs, telemedicine and many more enhancements in medicine. The development of mechanical ventilators that are able to ventilate the patient independently will allow that RCP, nurse or physician more time to focus on the big picture, helping that patient get back home with their family as soon as possible. The best thing that could happen would be the development of preventative healthcare that would reduce or eliminate the need for mechanical ventilation in the first place. That would be truly best for the patient. If they must be intubated and placed on a device such as a mechanical ventilator, it is our obligation therefore, to at least do no harm. The need for qualified health care professionals is greater now than ever before. Advancements in instrumentation like the mechanical ventilator will free these clinicians to focus on patient care, rather than the instrumentation.

Now that you have been enlightened that there is a better way to ventilate patients, how can you continue to ventilate without automated lung protection, or without at least considering lung protection, and being able to validate it with each and every patient? The new standard of care in mechanical ventilation is here. Are you ready for it?