Will Real-Time Monitoring Technology be a Game Changer for Perfusion Safety?

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I want to take this opportunity to thank the program committee for inviting me. I was asked specifically to discuss if real-time monitoring technology will be a game changer for perfusion safety. Again, there are no conflicts of interest for this presentation. To begin, the American Recovery and Reinvestment Act of 2009 stipulated that by January 1, 2014, all public and private health-care providers must have adopted and demonstrated meaningful use of an electronic medical record.

This includes financial incentives for health-care providers who prove meaningful use through electronic health-care records. Meaningful use is defined by Health IT government as using digital, medical, and health records to achieve improved quality, safety, and efficiency, and reducing health disparities, engaging patients and family, improving care coordination and public health, and maintaining privacy and security of patients’ health information. In Figure 1, the adoption of the electronic health record among office-based physicians is about 78% for a basic system compared to the non-federated acute hospitals have a certified electronic medical record adoption rate of ~94%.

As of June 2014, more than 400,000 professionals representing 75% of the nation’s eligible professionals have received incentive payments through the electronic health incentive program, and more than 4,500 hospitals representing 92% of eligible hospitals, including critical access hospitals, have received incentive payments.

These payments have to be adopted and implemented in stages of meaningful use, and there are three stages. Stage 1 set the foundation for the EHR Incentive Programs by establishing requirements for the electronic capture of clinical data, including providing patients with electronic copies of health information.

Stage 2 expanded upon the Stage 1 criteria with a focus on ensuring that the meaningful use of EHRs supported the aims and priorities of the National Quality Strategy. Stage 2 criteria encouraged the use of health IT for continuous quality improvement at the point of care and the exchange of information in the most structured format possible.

In October 2015, CMS released a final rule that specifies criteria that eligible professionals, eligible hospitals and CAHs must meet in order to participate in the EHR Incentive Programs in 2015 through 2017 (Modified Stage 2) and in Stage 3 in 2017 and beyond. And you can see the maximum incentives are about $44,000.00 over 5 years for Medicare and about $63,000.00 for Medicaid.

This program will be extended to 2021, and this is an enormous amount of money. Billions of dollars are being spent. What I could not find in the literature was anything to tell me exactly how these monies are spent. So I decided to try to have a personal communication with Lucian Leape, MD. Dr. Leape is a thoracic surgeon who knows a great deal about cardiopulmonary bypass and cardiac surgery. And my question—I e-mailed him and asked him—was, is the field of perfusion and cardiopulmonary bypass important enough to record in a real-time electronic medical record, and what pressure should be placed on hospitals to accomplish this?

And, also, I had a good feeling that he might know through these incentive programs where these monies that are sent to hospitals nationally; I was wondering if there was any public record of the division, of the funds to the hospitals, or provisions of how they were able to spend these funds because that’s been one of the problems, especially in perfusion, to get hold of equipment for electronic medical record. It’s been very expensive. Of course I was disappointed, Dr. Leape didn’t answer me, so that was a little bit of an embarrassment. So if he ever sees this recording, maybe he’ll e-mail me back.
If we look at the advantages of electronic records, we’re supposed to provide accurate, up-to-date, and complete information about patients, and this information needs to be securely shared, effectively be able to diagnose patients and reduce medical errors, and provide safer care to our patients. It also improves communication, enables safer, more reliable prescribing for physicians, and helps to promote legible, which is very true, complete documentation and accurate streamline coding and billing.

It enhances, again, privacy and security of patient data, and helps the provider to improve productivity and work/life balance, so it should be easier for you at your job if you have an electronic medical record. This enables the providers to improve efficacy and meet their business goals, and, again, reduce cost. Let’s look at some of the disadvantages of medical records. There are high startup costs. The convenience and immediacy of an electronic record makes it easier to violate privacy. So identity theft could equal fraud. And if your computer crashes, you would have data loss, and it could wipe out the data, destroying the continuity of care of your patient.

There is lack of standardized terminology, system architecture, and indexing. Today, many vendors have just as many software applications as we little know. Data cannot be shared unless a gooey interface is written, and unfortunately these interfaces are not always accurate or dependable. And then there are legal issues, especially in the United States, taking the health-care industry to court, has in the past few decades been very, very lucrative. A very interesting app that I found outside of the health-care industry an an example of real-time monitoring, is an app that you can download free from the internet. I don’t know if any of you have this app, but as you face your camera on a phone, andas your heart beats, more blood is pumped to your face. This slight increase in blood causes more light to be absorbed, and hence, less light is reflected from your face. So using this sophisticated software that is on your iPhone, the front camera contracts any tiny changes in a reflected light and calculates your heart beat. Real-time alerts of LivSecure help ensure safety and security of your home. LivSecure lets you know if there’s a break-in alert. It lets you know if there’s fire or carbon monoxide rising in your home. It gives you video alerts, lights, and thermostats. So we can remotely monitor outside of our homes; why then cannot we do it inside of the operating rooms (OR) specific to perfusion-related procedures? Now, this was a paper that discussed the failure to recognize loss of incoming data in an anesthesia record-keeping system, and it may have increased medical liability (1).

And what happened during the procedure was relying on the physiologic monitor to assess the patient’s condition, and the anesthesiologist did not recognize the interruption of data transmission because he or she had an active medication window open, which was obscuring the graphical display of the vital signs. So we really need to make sure if the information we’re collecting is the entire recording of what happened and not intervals, and certainly not embedded in another record or a scanned copy of a paper document, which is what a lot of perfusionists are using today. This is a paper that discusses real-time continuous monitoring of cerebral blood flow (2). We heard about that topic all week at this conference.

And in conclusion, the monitoring of cerebral blood flow can be monitored continuously with near-infrared spectroscopy. In adult patients undergoing bypass in real time, cerebral autoregulation monitoring may have a role in preventing injurious hypoperfusion during cardipulmonary bypass, so again, real-time monitoring. This paper was from the Mass General discussing real-time alerts and reminders using information systems. They’re defining systems that analyze the data and report unexpected or abnormal conditions back to a clinician, at or near the moment that these data are available, are also known as real-time alert systems (3).

Real-time alert systems would be expected to be most useful in clinical situations, where patient’s conditions are anticipated to change on a second-to-second or minute-to-minute basis. And in my mind, that’s during cardiopulmonary bypass. But they stated that outside of the OR, the intensive care unit and emergency room are the other acute care settings where physiologic conditions change in a short timeline. Another example is that during cardiopulmonary bypass, a lack of a pulsatile flow triggers physiologic monitoring alarms to go off on the anesthesia monitor. And so what could happen then is the anesthesiologist turns off the alarm?

After coming off bypass, and prior to an intervention, the rate of the monitor alarm reactivation at one institution when calculated was 22%. Meaning after discontinuation from CPB the anesthesiologist is reactivating the alarm 22% of the time. So they decided to use an Analytics Integrated Monitoring System AIMS-based alert, and it
developed the capability of detecting post-bypass vital signs and notified the anesthesiologist to turn back on the alarm. And once they reactivated this, their situation changed by 63% in a positive direction. And after they had an education session, they were then able to turn their alarms back on 83% of the time.

This is a paper that looks at glycemic control in type I diabetes during real-time continuous glucose monitoring compared with self-monitoring of glucose. It was a meta-analysis. It determined the clinical effectiveness of real-time continuous glucose monitoring compared with self-monitoring. And they summarize that continuous glucose monitoring was associated with a significant reduction in HbA1C percentage, which was greatest in those with the highest levels at baseline and who most frequently used the sensors.

And exposure to hypoglycemia was reduced, and the most appropriate use of continuous glucose monitoring is likely to be targeted at people with type I diabetes who have continued poor control during intensified insulin therapy and who frequently use continuous glucose monitoring (4).

Now we come into an interesting perfusion paper that Jane Ottens wrote in the *Journal of ExtraCorporeal Technology: Improving Cardiopulmonary Bypass: Does Continuous Gas Monitoring Have a Role to Play?*. And she looked at CDI monitoring vs. controlled no monitoring. And basically what they found—you can see here; this is the control, and this is the CDI, that there was a significant decrease in variation when you’re looking at PCO₂ over 45 or pHs less than 7.35 (5).

And they did find something very interesting, and that was an isolated case where the PCO₂ was out of the range 80% of the case. So I think that it’s pretty clear that it’s important to have real-time monitoring. And what’s important for our electronic perfusion records? Well, it is consistent and intelligent record-keeping. We have to have alarms and alerts; eliminate errors by automatically identifying specific fields when they don’t meet electronic system entry requirements. These computers are highly intelligent and can constantly remind us in seconds of out of range conditions. And I might add here we need hard stops and record keeping for changes in personnel.

If you have one person on a case, and then another person takes over, a computer will recognize the hard stop and have that next perfusionist make sure that he or she has gone through all the parameters to confirm understanding of exactly where he or she is in that case by using a checklist. Out-of-range monitoring parameters can pop right up in your face, coupled with alerts and alarms that reveal events before you might realize it because you’ve been preoccupied with other issues; this automation is a step toward real safety.

Competency review, real-time or after the case, is extremely important. You know exactly if you are in or out of set ranges for that entire case. Problem-solving can be done in real time. Something happens during the case, you can still be collecting information, but stop and pause, and look to see what went on 10 minutes ago by virtue of an ability to look at a historical view in real time. And then data collection is also very important. So what do we have available to us today as perfusionists? One of the first programs that was used among perfusionist was JOCAP a data management system for heart lung machines, and that was in January 2008. And this OR computer could be directly connected to the hospital’s information system via Ethernet, allowing data for administration and archiving to be exchanged easily. And then the OR computer had manifold inputs for network USB. Data could be optionally saved to the CD-ROM or DVD.

About 30 years before this, Jostra had pump capable of an electronic medical record, and it was not as sophisticated as we have today. Next, we have Connect, from the Sorin, LivaNova Group. LivaNova announced their FDA clearance for the new Sorin Connect system. And this, again, is real-time data recording and trend visualization aimed to support clinicians and institutions in their perfusion management and documentation goals during and after cardiac surgery.

Post surgery, there are statistical tools that are easily available for queries and analyses supporting clinicians’ efforts toward hospital quality management and practice improvement programs. In fact, Connect was designed with goal-directed perfusion in mind, and you can see many new features. I have not used Connect clinically. Also, you can assign your choice of parameters for tracking and monitoring perfusion, the patient’s physiologic data. It’s an excellent approach to goal-directed therapy.

In addition, we have Terumo TLink. Your data can be collected and stored in an organized and accurate manner through TLink; it can easily transfer cases to hospital information systems; can centralize all case data; can enable quick data transfer via wireless, CD, LAN, or USB. Also Perfusion.com has an electronic medical record that you can purchase for use in your operating rooms that incorporates other compatible perfusion software called OnCloud. So these are all things that will help facilitate us toward an electronic medical record. You just have to make a decision which one you want to use.

Capsule Tech is kind of new to perfusion and perfusion technology. But this has the capability of taking any vital sign monitoring information, documentation, connectivity, and early warning scoring systems. It does everything all in one device. And you could use this on your perfusion circuit if you wanted to. You would just keep plugging individual things into the Capsule Tech and create yourself your own electronic medical record. Now some of the roadblocks besides monies available to purchase electronic systems for us in perfusion are as follows: outcome-based.
decision support that focuses on rewarding and incentivizing, and facilitating care that leads to better patient outcomes downstream.

But because the data sources that allow measurement of meaningful patient outcomes are downstream from the perioperative environment, efforts at implementing this type of decision support have been quite limited to date. I also had personal communication with the Epic sales force preparing for this presentation. The Epic Systems Corporation is a privately held software company. And according to the company, it uses software and holds medical records of 54% of all the patients in the United States, and about 2.5% worldwide. And the reason I mention Epic in this discussion is because many hospitals are beginning to buy the Epic software for patient physiologic monitoring in their operating rooms.

So I wanted to know how does Epic interfaces with perfusion? There is no support right now for a perfusion record in Epic. Perfusionists need additional workstations, which we will need anyway whichever system you buy. Hardware costs and space are considerations. And although they feel that perfusion is an important part of the patient’s clinical story, there’s no perfusion-specific encounter according to them. So their system does not support it. Epic cannot currently display a perfusion-specific record in the chart review, and the navigator solution is that the perfusionist uses a flow sheet–based smart form to capture his or her documentation, and then use his or her report to review device data through or from the anesthesia record.

So there were some limitations for Epic and the reasons that they did not work on a perfusion record per se, although they are looking toward working that into their repertoire now. For instance, one of them was medication administration. While EPIC does give the perfusionist access to one-step medication activity, it also bypasses many of the steps necessary for medication reconciliation.

Perfusionists can’t document or edit vitals because the system populates the vitals through the device integration into the anesthesia record. And if there is an error, then the perfusionist is going to have to keep going back to the anesthesiologists and ask them to change the record. It would be kind of fun to have anesthesiologists as our record-keepers though. Others are in read-only access, and it can affect communication between providers at times, and a single record for anesthesia and perfusion is not the right choice in my mind.

Perfusionists can change documentation in the anesthesia record; but if for instance, if both records separate lines for the same medication, the system cannot total, resulting in misleading information. And then there was difficulty in legal sign-off; difficult to separate and merge documents. So more to come on that. I did find this very interesting paper, a very good paper: Perfusion Electronic Documenta-
tion Using the Epic Systems Software. It’s Tom Steffens’ paper. And they have incorporated their perfusion record into Epic (6).

The things they said that they were concerned about were documenting on paper that doesn’t provide accurate assessment of patient real-time conditions usually recorded every 5–30 minutes. It’s a paper document, and subjective without the capability of electronic interaction. And the automated bypass records may only produce a paper printout, or upload to an electronic file format. And then, again, same problem. Software compatibilities with institution systems, as well as hardware requirements, and their interactions is a problem for hospital IT, and I think we all know that.

And so in an effort to have full communication with hospital electronic medical record, they decided to incorporate their perfusion record with the Epic Systems Software. And the choices were to incorporate with the nursing op-time document, document flow sheet, or the anesthesia module; and they chose the anesthesia module. They created a stand-alone perfusion document by integrating perfusion data within the anesthesia record already being recorded. And they moved from a silo in their perfusion record to an integrated information sharing within the anesthesia document.

They also postulated that a combined record could provide accuracy, reduce duplication of data, and improve safety to the patient. But one of their major concerns was that perfusion would be documenting in an anesthesia record that anesthesia owned. And then it had to go to legal, and legal’s decision was that neither the perfusionist nor the anesthesiologist owned the record, and that the patient owns his or her own record. So they decided to incorporate the anesthesia module to include perfusion parameters and created a document that provided a seamless record of events during cardiac procedures. And this is just a little of what it looks like, but it’s a time stamp—time stamp by perfusion in Epic anesthesia. So it’s not full continuous real-time monitoring.

Then I would be remised if I didn’t discuss Spectrum Medical because it’s what I have the most knowledge of, and what we adopted when I was working at NewYorkPresbyterian at Columbia University Medical Center. It’s really light-years ahead of everyone. They’re in their second generation production now. They will have a whole full heart/lung machine available in 2017. Key features of the Viper are data collection from all physiologic monitors and ancillary devices in the OR, or special settings, such as extracorporeal membrane oxygenation. It has the ability to capture electronically, everything. It’s real-time automated record-keeping every minute, every second. You can set how many seconds you want it to record.

Viper’s connectivity solution supports near-real-time transfer of data for remote trending analysis in patient alert.
systems, and the connectivity options include RS-232. You can plug anything into it. It's non-evasive for monitoring Wi-Fi and conventional wired networks. The study that I want to talk about is a study that was conducted at Columbia University by James Beck and colleagues. And you can see, here is—that's a Viper and the red bars on the monitor that you see are the compliance alerts that pop up when something is out of range once you've set it (7).

So if you set the PO2, to stay at 40 mm Hg, and it goes to 41 mm Hg, that compliance alert will pop up on the screen, as well as flows or any other conditions that you want to set to monitor. So it's immediate information. The study design contained two groups: group B, which was blinded to compliance alerts. They moved the screen away from the perfusionist, and they were unable to look at any compliance alerts. And group A has the compliance alerts screen displayed, and they were able to see it throughout their entire case. So B is the control group, and A is the compliance group (Figure 1).

The results were as follows: in group A, they did 10 cases and identified 94 compliance alerts, and in group B, 10 cases and 87 compliance alerts. The compliance alerts included things such as mean arterial pressure, temperature flow, cardiac index, blood gases, saturation, Hct, PO2, and CO2. And you can see that the average reaction time decreased from 30 seconds to 4 seconds with implementation of the compliance system. That's pretty astounding really. This is what the graph looks like, and you can see that the compliance alerts along black diamond line are where the perfusionist was able to see, and the others without compliance alerts (Figure 2).

Also, they looked at critical value reaction time across different alert types. And in each case, it was statistically significantly different in the average reaction times that were seen in five different types of alerts. And these are some critical measures, just arterial mean blood pressure and cardiac index, and you see with the alert, they maintained less, much less variation, except for this one little guy that I'll talk about in a second. Important measures, as I said, arterial mean, blood temperature, and CO2, again, are much better with the alert group than without the alert (Figure 3).

Then they took four practitioners, and they put them in both groups. And although the average reaction times between the practitioners were slightly different, all practitioners demonstrated a decrease in reaction time with implementation of the alerts, compliance alert system. So I think that's really important. The interesting finding, where the critical measure of black diamond shown at the 60 second mark, is that they had a critical measure outlier of mean arterial pressure, less than 50 mm Hg, and they went back and they reviewed the proctor notes. And as similar to what I described at the beginning of the presentation where the anesthesiologist had something hidden, the compliance alert was on the screen behind a blood gas screen they were entering a blood gas on (Figure 4).

And the use of this information was to pressure the laboratory then to be able to send these blood gas feeds

![Figure 2](image-url)

**Figure 2.** Critical value reaction time: control vs. compliance alert (CA) system. CA system usage decreases the critical value reaction time vs. control (Con). The average reaction time decreased from 30 seconds (SEM 5 seconds) to 4 seconds (SEM 1 second) with implementation of the compliance alert system. ***p < .0001.

![Figure 3](image-url)

**Figure 3.** Critical value reaction time: different types of alerts. Compliance alert (CA) system usage decreases the critical value reaction time vs. control (Con) across different alert types. Statistically significant differences in average reaction time were seen in five different types of alerts: MAP < 50 mm Hg (MAP), CI < 1.5 L/min/m² (CI), pCO2 > 55 mm Hg (CO2), CVP > 25 mm Hg (CVP), and pO2 > 400 mm Hg (pO2). **p < .005, ***p < .0005, ****p < .0001.

![Figure 4](image-url)

**Figure 4.** Critical value reaction time: different types of alerts. Compliance alert (CA) system usage decreases the critical value reaction time vs. control (Con) across different alert types. Statistically significant differences in average reaction time were seen in five different types of alerts: MAP < 50 mm Hg (MAP), CI < 1.5 L/min/m² (CI), pCO2 > 55 mm Hg (CO2), CVP > 25 mm Hg (CVP), and pO2 > 400 mm Hg (pO2). **p < .005, ***p < .0005, ****p < .0001.

automatically to the Viper. And distractions can certainly affect performance during critical duties. The compliance report is something that I think is an invaluable tool, what could be more important than actual knowledge of the compliance of your case right after you’ve done it. And immediately after you submit the case, you can have a compliance report. Real-time management of compliance reports allows immediate consultation with employees if you’re a manager.

So in summary, I do think that the game changer is the response to the result of monitoring. And I have shown that a patient that has a perfusionist using real-time alerts and alarms is getting a different level of care. More immediate response, to me, means better. And I have shown there’s a benefit to having information from multiple monitors presented to the perfusionist. It just makes our jobs a lot easier. Real-time alerts and alarms on the screen incorporated into the perfusion medical record can support the argument that response time is shortened.

And I believe I have shown an argument for improved safety with real-time monitoring. I think perfusionists need to participate and advocate for safer systems, and I’m hoping that maybe one of the next standards that the AmSECT accepts will be a perfusion electronic record that has all the capabilities that I have proposed. Thank you.

REFERENCES