How the AAMI COVID-19 Response Team Responded to Crisis

Roundtable Participants

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Gavin Stern How did this effort come together as the pandemic was unfolding?

Amanda Benedict I can provide AAMI's perspective as the facilitator for this group. As you know, since the pandemic hit, the FDA published a number of emergency use authorizations (EUAs), which included procedures for various types of equipment that were intended for restricted use during the COVID-19 pandemic. There was a desire to help manufacturers that were trying to produce this equipment and those that were assessing and improving the equipment. So, AAMI started recruiting experts from both our domestic AAMI committees for anesthesia and respiratory equipment, and also the AAMI-managed ISO committees for anesthesia and respiratory devices, to pull together a multi-stakeholder team, which we called the COVID-19 Response Team. That group is composed of manufacturers, clinicians, and regulators. I'll let the others who are in this group speak to the conversations that happened that ultimately led to standing this effort up.

Sandy Weininger In mid-March, the first EUA went out for ventilators. I distinctly remember my colleagues looking around the table saying, "Okay, now what?" And about that time I called Julian Goldman, who was the outgoing chair of the U.S. technical advisory group (TAG) for technical committee (TC) 121. I said we need to get standards folks from the U.S. that are the experts in this to come together and help us build a guidance document instantly. Julian was working with these ventilator innovation communities. AAMI standards director Colleen Elliott helped us pull together members. Together we sifted through the various standards we had in order to produce a decomposition of what we thought were the critical pieces of those standards.

At the time, many cities were out of ventilators, and these new "whiz bang" gadgets that people were putting together in their garages were about to be rolled out. Something needed to be done.

David Osborn Before that, in February, I got an email from China wanting to accelerate what at that point in time was the preliminary work item to look at high-flow therapy, because they had an indication that that was a particularly effective treatment modality for only moderately ill COVID-19 patients. This is as opposed to full-blown intensive care ventilation, which we learned here in this country, was not necessarily what you wanted to do. I pulled together my conveners and experts and we proceeded to make a draft of a new particular standard in the 80601 series, 80601-2-90, for high-flow therapy, which China then submitted as a new work item.

All of that happened between mid-February and March—a full-blown standard draft that went out for a formal new work item. Right now, it's undergoing DIS (draft international standard) ballot—ISO 80601-2-90. People were involved in China, Australia, New Zealand, Germany, and the UK—working really long hours. No matter what time we had a Zoom meeting, somebody was up in the middle of the night. So when this request for EUA guidances came in as we were just finishing the full court press on the high-flow standard, we already had people who had been thinking about some of this stuff and had it at the top of their head. As a result, we had several experts who were very recently working around the clock, thinking about the exact issues that were being put on the table; what requirements were appropriate under what conditions. We were able to hit the ground running.

Julian Goldman We had a March 20 emergency meeting of the AAMI AR Committee (anesthetic and respiratory

equipment), where I was a cochair until the end of March. We have anesthetic and respiratory experts, clinicians, hospitals, manufacturers. The idea was to bring the group together and say, "a lot of bad stuff is happening, we are a group of experts who represent a huge part of the healthcare sector, what can we do to help? Let's do whatever it takes."

And AAMI had the means—the willingness and the right venue—because in a standards environment, we are all permitted to share information, it's a protected environment in which we can collaborate in a manner that many can't do in other settings. We started our initial beat rate of weekly meetings, and the idea of the consensus report standards document was one element of our work plan.

Sandy brought up the need for standards to support FDA ventilation-related EUAs, and other FDA experts participated to provide input. Colleen, from AAMI, pointed out that, that there was a very fast vehicle for us to develop content and get it out under a consensus process—the consensus report (CR).

Ultimately, we're a group of experts who have been working together for a long time. For the public good, we saw that there was a need to pivot our focus, not on a specific standard or device, but deal with this whole respiratory equipment COVID issue. And we just did whatever it took to help answer questions and produce deliverables.

Gavin Stern **A big part of this team's effort has been this interface between the EUAs coming from the FDA and the CRs, which are a new kind of standards document. How was the CR process positioned to address this exact situation, this pandemic?**

Julian Goldman The number-one requirement was to produce guidance that was useful. It had to be completed very quickly—and needed to be updateable quickly, because it wasn't going to be perfect the first time. We weren't following a typical standards development timeline, and we knew that COVID-19 was an emerging issue. And then the final requirement was that the CRs had to be freely available and accessible to the world. The community using these standards was an atypical community. We had the maker community—people that don't know much about how to use standards. These were communities of all different kinds of very smart, but inexperienced, volunteers.

Sandy Weininger Let me add some color to that. We wanted to get these documents (CRs) out—to say that these are the kinds of requirements that should be included when making a product. For example, if they're picking a power supply, they should pick the ones with the low leakage current, not the high leakage current. We at the FDA very much wanted to see this kind of guidance out there as quickly as possible to lead people down the right path.

Julian Goldman With the maker community, we were letting the folks know that these CRs were under development while we were developing them, and that we were sharing the drafts. Their questions let us produce higher quality documents. It was night after night, meeting after meeting to crank this out. It was a massive team effort.

Amanda Benedict CRs are intended to provide a very concise and practical guidance on a really narrow topic. The emergency response CRs are useful for responding to areas where there's an immediate need for guidance. So, they're perfect for a public health emergency. One of the nice things about a CR is that it's not subject to the same formal approval and review process as a standard. It can start with an informal proposal that can come from a consensus body, or even just a group of stakeholders. The group conducts work virtually, and they set a lot of their own parameters as far as how much time they need for commenting and responding to the comments received on drafts. Work can be done very quickly to produce the document based on the appetite and the bandwidth of the group.

David Osborn We were iterating these things almost daily. We'd meet and then I frequently edited into the wee hours, so they would be in people's inboxes the next

morning. That was a period when 80 hours a week was nowhere near enough time to do everything that was going on. It was pretty intense.

Gavin Stern Standards work is a volunteer activity. How did you all do it, especially in the middle of this pandemic?

Julian Goldman We knew how important this was. I was reaching out to my own organization's experts and reaching out to other experts. All of us had many other touch points with the community. We were in touch with the Strategic National Stockpile deployment experts, and directly assessing and deploying ventilators. It's just the nature of our careers that we have a lot of other touch points, and it allowed us to share information, which just reinforced the need for what we were doing, the importance of it and our commitment to do whatever we could with the tools that we had.

Andy Doering My management at Medtronic encouraged me and others to participate.

Gavin Stern What's the response been from people in the field, from regulators and even the international community?

Sandy Weininger Regulators are thrilled because it establishes a relative consensus or safety floor for these devices.

David Osborn The users of these documents by and large were designers, not from the healthcare industry, but from other places who were trying to fulfill what they perceived to be a public need. It was for the better good, but they had no knowledge base to start with. Our goal was to try to boil down to the critical things, the critical gotchas where one would make the mistake.

No one expected these emergency devices to be as good as a real critical care ventilator or ventilatory support system that has had years of development and testing. On the other hand, if your option is a patient dying because they can't breathe adequately, or can't be oxygenated adequately, something in between is the right thing to have. As Andy said, my management didn't even blink. You get the work done.

Julian Goldman We received many interesting questions from the FDA, as Sandy's colleagues would join the calls or writing teams and ask specific questions. That was wonderful, because that produced a better-quality document by getting critical feedback immediately.

As Dave said, disseminating this to the non-medical device manufacturers that were jumping in, who didn't know what was safe, needed, or important, and what requirements could not be compromised. There was nowhere else they could get the information. We had endless phone calls with these groups of energetic engineers who never built a medical device and were trying to make something happen in few weeks.

David Osborn And it wasn't just the United States. My name shows up as a committee manager for all things respiratory at ISO, and I was approached from South America, Portugal, Scandinavia, etc. We saw similar efforts for emergency use outlines in several other countries. It wasn't just the U.S. that was seeing the pressure to do things more flexibly.

Sandy Weininger We were also talking about emergency use resuscitator systems. One was taking an Ambu bag (user-powered manual ventilator) and basically building a robot around it, to squeeze it a few times. That is conceptually different than a "classic" ventilator. Colleen was awesome in routing questions. It was a team effort—whoever could answer the questions answered. We're not so much in a pickle anymore where we need devices like tomorrow or the next day, and our safety standards are evolving. And so too must the CRs. The process is still alive.

Gavin Stern As you were helping companies from all over the world, what were some of the pitfalls that you would see? How you would help them?

Sandy Weininger One of the first ones you might think of is, it's relatively easy to build a bag squeezer, if we want to just talk about the emergency use resuscitator systems. It's another animal altogether to start adding flow or pressure monitoring and alarm systems to those devices, to put them through the complete suite of testing, and make sure they're going to last for more than a day. You have to make sure you're not going to get your fingers, hair, or clothing trapped in them or accidentally pull the electrical cord or patient connecting systems out. Those are some of the more obvious things.

David Osborn And of course the Ambu bags themselves are unlikely to be rated for even 24 hours of operation, which is another whole other kettle of fish.

Julian Goldman Overall, we helped by having information readily available to the interested manufacturers and provided an understanding upfront of what was expected. Because they didn't know these things. In fact, they hadn't necessarily thought of them yet because many of the issues were new.

Sandy Weininger There was a very high degree of uncertainty as to what the clinical requirements were, because we really didn't know how to treat COVID and didn't know the use environment. Were these going to a field hospital, to rooms erected in a convention center, an old hospital that was opened back up, a hotel room, or a gymnasium floor? All those are different use environments where different safety concerns come in.

Julian Goldman We had to warn some of these folks that there were some scenarios that were much more hazardous than they appreciated. The clinical hazards were particularly challenging. They didn't know—they looked at something that would squeeze an Ambu bag and they thought, "how hard could this be?" Well, it could be really hard, because there are a lot of things that can go wrong, such as a disconnection that prevents ventilation of the patient, or an overpressure state, among other things. There were some folks who thought that someone will be able to just stand at the bedside and stare at the device to monitor if anything goes wrong.

Facilities were overflowing with patients. We knew how tired clinicians were. Not only is it hard to be vigilant when you're sleep deprived to begin with, but now you're in an environment where you can't hear or see well because you're wearing PPE. That makes it even harder to detect the subtle malfunction of a device.

These insights are things we had to convey upfront, to ensure that unsafe devices weren't produced unintentionally.

Sandy Weininger There was shortage of clinicians. So, you didn't want to tie up a clinician to have to sit there and watch the box all day long. I mean, that really doesn't help.

Michael Jaffe This effort spawned another one, a modeling effort for considering the potential use of unsafe devices, such as the impact of using one ventilator on multiple patients. It was separate from the standards work.

Julian Goldman We reached out to a community of experts who knew how to model gas flow in breathing circuits and ventilators because we had to address the popularized scenario of ventilating multiple patients with one ventilator. That was a whole other effort that went on and produced good results to reveal just how challenging that scenario is. And those results were reported back to the Response Team.

Gavin Stern **There is concern that the pandemic will take off again in the winter. Based on the lessons learned in the year, what does this next phase of the pandemic look like for this team?**

Sandy Weininger As our needs and as the use environment evolve, and as what we learn about COVID evolves, I am hoping that the CRs can be kept up to date. For example, we were pretty responsive in coming out with the ventilatory assistance helmet CR, because word came from around the world that people were using these types of helmets, and again, we had the experts and pulled it together. That one was a bit more

challenging because that was crafting a committee report from whole cloth—there was no existing base of standards requirements for the helmets. The next one that came out was remote control, following on the FDA's immediately-in-effect guidance for remote control.

Sandy Weininger For that effort, Julian and I met with other AAMI committees to address those needs and requirements. So, as we perceived a need, we were able to pull the relevant expertise and build these CRs that were needed.

Michael Jaffe And the remote control guidance required basically looking well beyond the medical device arena for requirements, which we folded into the document.

Julian Goldman That's a great point. It's a forward-looking document, and I think it's particularly interesting because it shows the relationship of work that is being done very quickly within the AAMI COVID-19 Response Team to address COVID needs in the near term, and also lays a foundation for a more complete remote control standard for the longer term. The foundation extends beyond standards. I believe industry, the FDA, and innovators have recognized that we should be taking advantage of the opportunity that COVID has provided to accelerate innovation and advance the state of medical technology (for example, through EUAs).

Gavin Stern How will the rapid work that you've done so far inform standards over the long term? Has the world of standards changed forever?

Sandy Weininger When you think of most CRs now, they instantly respond to issues instead of taking the two to four years to develop consensus standards.

Michael Jaffe People interacting with platforms such as Zoom has become much more widespread and accepted in the standards world. But what we found is checkered. It takes more meeting hours to get to the same result, because you have to break it into pieces. It's really hard to do more than three hours in a Zoom or Teams session when doing standards work.

David Osborn In my respiratory committee, I've got 19 to 21 time zones routinely represented. So, if we're going to have meetings, somebody has to be up in the middle of the night. We try to move it around to be fair. I never thought I would end up saying that the jet lag is easier! It is very tiring to sit in front of Zoom sessions all day long. They are harder on you mentally.

One of the reasons it's been as effective as it has been is that the people who have been involved all have had 10 plus years of working with one another face to face. For a new person joining a group right now, not having met any of the people, not having social interaction to get to know them—it's going to be really hard. Although it's worked for a year, I don't see it as sustainable that way forever.

Julian Goldman We're all friends and we all respect each other, even when we disagree or are cranky. We think there's usually a reason we're disagreeing. The end result—the work product—is better when it represents our different perspectives.

Sandy Weininger It shouldn't be underestimated or undervalued, the depths of experience and institutional knowledge that our standards committees have. It's very easy to think that standards developers are plug and play, that when one retires we could let them go. That's not the case. I think a large part of the reason we were successful is because we had a diverse set of expertise from a domain perspective as well as standards craftsmanship, that we were able to very rapidly hone in on what needed to get done.

Gavin Stern There's a saying that "luck is the residue of hard work." The fact that you all had everything ready to go, someone's expertise and your relationships really made things fine-tuned for when something massive like this did present itself.

Sandy Weininger If you asked what experiences you should have to prepare yourself for a pandemic—that's essentially what happened. We all have two plus decades experience building standards. We've got people in the various different domains, from engineering to clinical, to regulatory science, and we all came together.

Julian Goldman It's worth repeating that AAMI's Colleen Elliott made sure there was a way to navigate this and to get it done. We've all been on standards committees where the process conflicts with the productivity and the timeline. That was not the case with this work.

Gavin Stern **What are some topics or issues that I haven't asked you about?**

Julian Goldman When we dealt with the first surge, we had very little information domestically. We had some information internationally; it was very scary. We had no time to prepare. Now we're clearly going into another surge.

The surges in Arizona, Texas, Montana, and other states are becoming a huge problem. They are understaffed. They don't have equipment. It's all the same things that we've heard before. The difference is that now, we as a nation have experience, and so we're able to better support and handle it. We're well positioned to leverage the group we have, the community we have, to be agile, see what new issues come up, new problems that we can help with, new technologies, and if need be, new standards to support that.

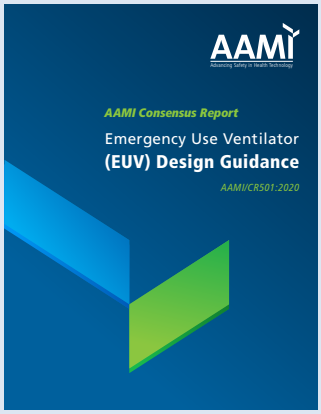
Sandy Weininger A few months ago, we started to have discussions about whether everybody should have a pulse oximeter, for example, because that's maybe a way for assessing the criticality of your disease. And so we started going down that path and saying, well, is there something to turn out? That brings up another topic—the sterilization or resterilization of PPE. That issue came in and we had a discussion, went round and round, and we decided that there is no CR that we could produce that would help in those particular situations. We've tried to pick our battles where our committee could be effective.

Amanda Benedict I would like to add my appreciation to this team for all the work that you've put in over these past eight months and continuing to be engaged. I think this has been absolutely wonderful for the larger community out there.

Gavin Stern **Thanks so much for taking part and for all the work that you're doing. We just can't thank you enough.**

COVID-19 Emergency Guidance

The AAMI COVID-19 Response Team, made up of manufacturers, clinicians, and FDA representatives, has developed the following resources to provide emergency guidance to the healthcare community in response to the coronavirus pandemic.



- AAMI CR501:2020, *Emergency Use Ventilator (EUV) Design Guidance* (8 April 2020, Revision 1.2)
- AAMI CR502:2020, *End User Disclosures for Emergency Use Ventilators (EUVs)* (17 April 2020, Revision 1.2)
- AAMI CR503:2020, *Emergency Use Resuscitator Systems Design Guidance* (22 April 2020, Revision 1.1)
- AAMI CR504:2020, *End User Disclosures for Emergency Use Resuscitator Systems* (17 April 2020, Revision 1.1)
- AAMI CR505:2020, *Emergency Use CPAP/BiPAP Design Guidance* (15 April 2020, Revision 1)
- AAMI CR506:2020, *End User Disclosure for CPAP/BiPAP* (17 April 2020, Revision 1.1)
- AAMI CR507:2020, *Basic Safety of Emergency Use Medical Devices* (6 May 2020, Revision 1)
- AAMI CR508:2020, *Emergency use Ventilatory Assistance Helmet (VAH) Design Guidance* (16 July 2020, Revision 1)
- AAMI CR509:2020, *End user Disclosures for Emergency use Ventilatory Assistance Helmet (VAH)* (16 July 2020, Revision 1)
- AAMI CR511:2020, *Emergency use Guidance for Remote Control of Medical Devices*
- Test report for Emergency Use Ventilators
- Test report for Emergency Use Resuscitator Systems
- Test report for Emergency Use CPAP/BiPAP

Visit **www.aami.org/COVID_CR** to download and for the latest information.