Standards for Ventilation Monitoring—Program 3

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History of Ventilation Monitoring

- Classic teaching of the stethoscope on the chest or trachea
- "Malpractice crisis" of late 1970's focused attention on anesthesia accidents
- Harvard Risk Management Committee analyzed 1976-84 events:
  - Vast majority of preventable accidents due to failure of ventilation: ***spontaneous or controlled***

The classic teaching has revolved in years gone by including during my training about the stethoscope on the chest and trachea, and that was great, and I think an effective ventilation monitor as far as it went. However, in the late 1970's, the attention legitimately focused on some very catastrophic events that occurred that attracted a lot of attention and were a major contributor to the so-called malpractice crisis. In Boston, at Harvard, the risk management committee was formed to look at the events that occurred between 1976 and 1984 and discovered, as I hope you know through some of the things that I've written and talked about a lot, that the vast majority of preventable anesthesia accidents were due to failure of ventilation -- either spontaneous or controlled ventilation, in all settings, but we were looking into intraoperative accidents at the time.

History of Ventilation Monitoring - 2

- Original 1985 "Harvard monitoring standards" mandated continuous monitoring of ventilation during "any administration of anesthesia:"
  - *"Palpation or observation of the reservoir breathing bag, auscultation of breath sounds, monitoring of respiratory gases such as end-tidal carbon dioxide, or monitoring of respiratory gas flow. Monitoring end-tidal carbon dioxide is an emerging standard and is strongly preferred."*

The original 1985 Harvard monitoring standards first introduced the concept of continuous as opposed to intermittent, and I think that's a critical distinction and I think it is a distinction that is relevant to today's discussion about monitoring, capnography monitoring during sedation, and of course, with any administration of anesthesia, which we'll talk about the distinction in a minute. The original standards talked about the observation of the breathing bags so on and so forth, monitoring respiratory gas flow, monitoring end-tidal carbon dioxide, this is 1985 now, is an emerging standard and is strongly preferred. That was the initial idea of capnographic monitoring as a standard of care.

History of Ventilation Monitoring -3

- ASA original Standards for Basic Intraoperative Monitoring – 1986
  - "Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. While qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds may be adequate, quantitative monitoring of the CO_2 content and/or volume of expired gas is encouraged."

The ASA the following year first published its basic intraoperative monitoring standards. Every patient receiving general anesthesia, adequacy of ventilation, and it goes on to talk about the clinical monitoring, but then quantitative monitoring of the CO2 content and/or volume of expired gas is encouraged. The original idea that capnography would be a significant component of ventilation monitoring enshrined in the original ASA monitoring standards.

History of Ventilation Monitoring – 4

- **ASA original Standards for Basic Intraoperative Monitoring – 1986:**
  - **"When an endotracheal tube is inserted, its correct positioning in the trachea must be verified by clinical assessment and by identification of carbon dioxide in the expired gas. End-tidal CO_2 analysis, in use from the time of endotracheal tube placement, is encouraged."**
  - **"During regional anesthesia and monitored anesthesia care, the adequacy of ventilation shall be evaluated, at least, by continual observation of qualitative clinical signs."**

The same standards went further with intubated patients because of the traditional and appropriate understanding that incorrectly placed endotracheal tubes, not recognized until the patient arrested or became profoundly cyanotic first, then arrested, was one of the greatest causes of the catastrophic anesthesia accidents of the seventies. So then the verification of the correct placement of endotracheal tubes in the trachea, by end-tidal CO2 analysis, in use from the time of endotracheal tube placement is encouraged after that but the identification of carbon dioxide in the expired gas was the original standard. Then, interestingly, in the original 1986 standards, during regional anesthesia and moderate anesthesia care, the adequacy of ventilation shall be evaluated at least by continual observation of the qualitative clinical signs. So that in the original ASA standards, the concept of using technology such as capnography to monitor ventilation during sedation or MAC, had not yet been accepted and I think that the fact that the technology at the time was certainly not what it is today had a lot to do with that.

History of Ventilation Monitoring - 5

- "Early warning" of ventilatory compromise from capnography emphasized; desaturation on pulse oximeter actually a very late finding
- ASA standards – 1992 further modification: capnography "…is strongly encouraged."
- ASA standards – 1995 major change: capnography mandatory on intubated patients

Why do we emphasize ventilation monitoring? Because ventilatory compromise, the early warning as I was alluding to earlier, is critical because the saturation on the pulse oximeter is actually a very late finding.

In 1992, capnography became strongly encouraged for patients getting general anesthesia. Then finally, in 1995, the first year where I was chair of the committee, we made capnography mandatory for intubated patients and that was perceived as a significant step forward because there still at that time were some practitioners who were worried that capnography could be misleading. I think the preponderance of the evidence in the ten years between 1985 and 1995 led enough people to correctly believe that the benefits far outweighed any risks, making the standard, and this is very important that this is a standard, because that has huge medical legal implications of course as everyone knows, and that became mandatory for intubated patients.

History of Ventilation Monitoring – 6

- Later addition of reference to capnography with use of laryngeal mask as well as OET
- ASA standards – 1998 amendment: capnography mandate expanded to include face mask general anesthesia:
  - "Qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds are useful. Continual monitoring for the presence or expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure or equipment…."

Then, shortly after that the change was made to add the new device, laryngeal mask, to be the equivalent of an intubated patient in the sense that capnography was mandatory. Then the last and very important change in 1998, making capnography mandatory, to include face mask anesthesia for general anesthesia because that was again there was concern by some practitioners that the lack of a clear digital number was in some way inhibitory or even dangerous and eventually we prevailed convincing people that while qualitative clinical signs were valuable, continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient procedure or equipment, meaning that continual monitoring, capnographic monitoring, for all patients receiving anesthesia care, will be mandatory- a standard of practice.

ASA Guidelines for Office-Based Anesthesia

- Adherence to "Standards for Basic Anesthetic Monitoring" expected
- "…appropriate anesthesia apparatus and equipment which allow monitoring consistent with ASA Standards for Basic Anesthetic Monitoring…" required
- No specific attention to distinction of sedation vs. anesthesia

There is a key provision in the ASA guidelines for office-based anesthesia basically saying that the applicable ASA standards must be observed. Of course the standards for basic anesthesia monitoring are expected because they apply to all anesthetizing locations and all anesthetics, wherever. The potential spillover of course to dental anesthesia administered by non-anesthesiologists is an interesting political and potentially legal question. The other components of the guidelines for office-based anesthesia are of course appropriate anesthesia apparatus and equipment, which allow monitoring consistent with the ASA standards which of course implies capnograph.

Sedation vs. Anesthesia

- **Published formal standards for monitoring during sedation do not exist**
- **Widely varying institutional policies and procedures, especially regarding supposed differing levels of sedation**
- **JCAHO, AAAASF, and AAAHC all interested and concerned**

There is no specific distinction in the ASA guidelines for office-based anesthesia between sedation versus anesthesia. The line, if you like, between sedation and moderate anesthesia care, is very blurry and seems a lot to depend on who interprets it, and then of course who's administering the actual sedation. So, at the moment, published formal standards for monitoring during sedation do not really exist. There are widely varying institutional policies and procedures, especially regarding the different levels of sedation -- the terminology, taxonomy for which keeps changing as we just heard. Everyone knows the JCAHO is interested in sedation and sedation safety. There are two organizations having to do with ambulatory anesthesia and ambulatory care centers. They're all interested and concerned but neither of these three organizations, actually, have published anything official about sedation monitoring standards so it's still something that is open although there will be, as you see, de facto standards of care because they're not published formally by recognized so-called authoritative organizations.

DeFacto Standard of Care for Sedation

- **Ventilation monitoring concept widely recognized**
- **Some type of ventilation monitoring for sedated patient clearly is a *de facto* standard of care**
- **Method of meeting this standard is up to practitioner, so far**

So the standards evolve and come out of practice and of course ventilation monitoring as a concept is, I hope you now understand, widely recognized. Therefore I believe and will state, and if absolutely necessary would testify that some type of ventilation monitoring for the sedated patient is clearly the de facto standard of care. Now the method, as I hope now has been illustrated through the evolution of the monitoring standards, is up to the practitioner, because it is not a prescribed standard for sedation, especially in an office.

DeFacto Standard of Care for Sedation -2

- **Using continuous electronic monitoring such as capnography (as an extension of the human senses) for sedated patients makes sense just as it did for intubated patients in 1985**
- **Cost of capnography trivial compared to even merely responding to one mal-practice lawsuit from an adverse event**

Then comes the interesting question: Continuous electronic monitoring such as capnography, including this new technology, as I alluded to before, as an extension of the human senses for sedation patients, to me today, makes just as much sense as it did for intubated patients in 1985. So that, is it, will it, I believe it is, or can be, considered the de facto standard of care now, but obviously it's not widely accepted yet, partly because of the sophisticated technologies just now being introduced, but again the people doing sedation, not involving anesthesiologists, or even necessarily CRNA's, for procedures in offices or suites may not be familiar with these ideas. I do add, however, that the cost of capnography, of course, is trivial compared to even merely responding for having a settlement or judgment in a single malpractice lawsuit from an adverse event.

DeFacto Standard of Care for Sedation -3

- With the advances in capnography for sedation patients and the resulting ability to apply electronic monitoring in addition to simple observation of breathing for everyone, it makes sense, both clinically and for standard of care, to use capnography to monitor sedation patients.

So, in conclusion, with the advances in capnography that we've talked about and resulting ability to apply this electronic monitoring, in addition to obvious clinical monitoring for every patient getting sedation, to me it makes sense both clinically and for a standard of care to use capnography monitoring in sedating patients. Will there be an ASA standard that says that? Possibly but probably not in the foreseeable future, because of the spillover to pediatrics, oral surgery, GI in particular which we're going to hear about. Quality tools such as this will, I believe, reduce liability risks by reducing adverse events.