Patient Safety and the Anesthesia Gas Machine

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Acknowledgement:
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Outline

- APSF
- AGM-related problems
  - Closed Claims
  - Errors
    - Human factors and/or equipment failures
  - Absorbents
- Workstation Standards
- Machine Checkout
- New machine technology

APSF History and Mission

- No patient should be hurt by anesthesia
- Formal organization since 1984
  - Ellison 'Jeep' Pierce at ASA meeting
- CRNAs added to the board in the late 80's
  - Letter on APSF letterhead re: supervision late 90's
  - CRNAs withdrew- returned to board in 2001
- All CRNAs started receiving newsletters again in 2005

Patient Safety

- Institute of Medicine (IOM) report
  - Kohn LT, Corrigan JM, Donaldson MS, eds. (Committee on Quality of Health Care in America, Institute of Medicine). *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academies Press; 1999.
  - Recognizes APSF's leadership in the cause of patient safety
  - The Agency for Health Care Research and Quality (ARHQ) has enlisted APSF's assistance in developing a National Center for Patient Safety
  - Current 2006 strategies
    - Adverse events requiring communication and disclosure

Is there a safety problem related to the AGM?

- Incidence of equipment-related critical events is relatively low:
  - However morbidity associated with events can be quite high
  - Human factors or errors are the leading contributors to equipment related problems
  - Implication
    - Perhaps greater training with our equipment is needed

Near catastrophes and other reported/potential problems

- Failure to discover total obstruction of disposable breathing circuit (Quality Review in Anesthesia AANA Journal March April 2002)
- O_2 flowmeter 'misconnection' made possible by altering the oxygen-specific quick connect - N_2O (Surgery mixup causes 2 deaths. New Haven Register, January 20, 2002)
- Heliox use during laser surgery
  - O_2 flush can deliver 100%

ASA Closed Claims (1997)

- Caplan (10/1997):
  - Analysis from 1961-1994
  - 72 of 3,791 claims – 2% related to machine/delivery
  - Most Common Adverse Outcome
    - Patient Death – 47%
    - Brain Damage – 29%
  - Injury
    - Hypoxia, excessive airway pressure and agent overdose
    - In 78% of cases – it was thought that better monitoring would have prevented adverse outcomes

Occurrence & Dates 1961-1994

Equipment Group	Median	Range
Breathing circuit (n = 28)	1981	1962–1990
Vaporizer (n = 15)	1984	1978–1991
Ventilator (n = 12)	1982–1983	1980–1988
Supply tanks or lines (n = 8)	1977	1975–1983
Anesthesia machine (n = 5)	1980–1981	1977–1987
Supplemental O_2 tubing (n = 4)	1986–1987	1977–1991
All gas-delivery equipment events (n = 72)	1982	1962–1991*
Other adverse respiratory events (n = 1,058)	1983	1961–1993
Other claims (n = 2,661)	1984	1966–1994*

* $P < 0.01$ between the distribution of occurrence dates of gas-delivery equipment events and other (nonrespiratory) claims.

Equipment Misuse verses Failure

Equipment Group	Claims Characterized by: Misuse	Failure	Uncertain
Breathing circuit (n = 28)	26	2	0
Vaporizer (n = 15)	7	8	0
Ventilator (n = 12)	8	3	1
Supply tanks or lines (n = 8)	7	1	0
Anesthesia machine (n = 5)	2	3	0
Supplemental O_2 tubing (n = 4)	4	0	0
Total (n = 72)	54 (75%)	17 (24%)	1 (1%)

Misuse: 70% direct action primary anesthesia provider

30% contributory actions of ancillary personnel

Key Findings

- Gas delivery systems adverse outcomes
  - Payment – 76% of cases
  - Median award - $306,000
  - Range - $542 - $6.33 million
    - Recommendation for Improving Patient Safety– Re-evaluate "Breathing Circuit" from Human Factors Perspective

ASA Closed Claims (2004)

- James Eisenkraft (2005)
  - March 2004 personal communication
  - Events are still being processed
  - Total: 6,448 claims - 95 anesthesia gas delivery equipment
  - 1990 to 2000
    - 19 claims
    - 31% resulted in severe injury or death, down from the 80% in the 1970-1980s

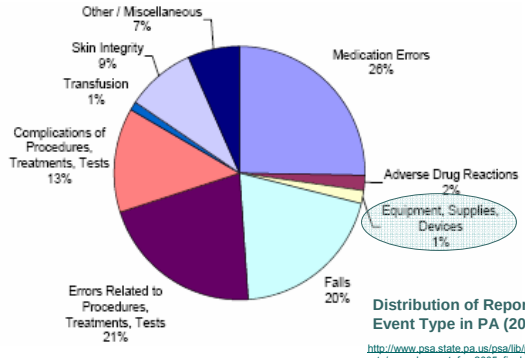
ASA Closed Claims

- 1990-2000 Claims
  - 5 deaths
  - 2 brain damage
  - 4 pneumothorax
  - 4 awareness
  - 1 cardiac arrest with full recovery
  - 3 cancellations of surgery (no actual injury)
  - 1 claim with no apparent injury
- Payments - 79% of cases (15/19)
  - Median award - $63,250
  - All were less than $500,000

ASA Closed Claims

- 1990-2000 Events
  - 4 breathing circuit problems
  - 4 supplemental O2 line
  - 7 machine problems
  - 3 vaporizer problems
  - 1 ventilator problem
- Good news:
  - Gas delivery problems over the decades are decreasing as a proportion of claims (3% in '70s, 2% in '80s and 1% from 1990-2000)

During 2005, the Patient Safety Authority collected almost 170,000 reports of adverse events and near-misses which were submitted by healthcare facilities through the Pennsylvania Patient Safety Reporting System (PA-PSRS).



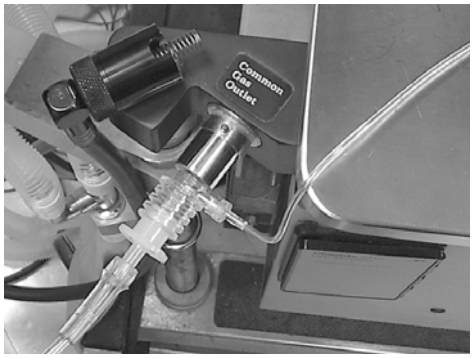
Distribution of Reports by Event Type in PA (2005)

http://www.psa.state.pa.us/psa/lib/psa/annual_reports/annual_report_for_2005_final_version.pdf

Report: Gas delivery problem prior to reaching the AGM

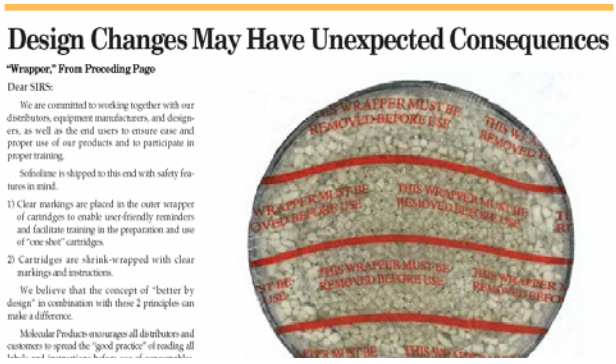
- **FDA Public Health Advisory** in March 2001 (Compliance)
- One example of an adverse event:
  - In October 1997, a hospital in Nebraska received a shipment of medical grade oxygen in large cryogenic vessels. The shipment included one cryogenic vessel of industrial grade argon properly labeled.
  - The hospital was running low on oxygen and sent a maintenance employee to connect an oxygen vessel to the oxygen supply system.
    - Without examining the label, the employee selected the argon vessel, and was unable to connect the vessel to the oxygen supply system. The solution?
    - This employee removed a fitting from an empty oxygen vessel → installed it on the argon vessel, and connected it to the oxygen system.
  - Argon was administered to a patient undergoing minor surgery. The patient died.

Figure 3. A nasal cannula mated to a common gas outlet via a 5-mm endotracheal tube connector and a gas sampling connector with a gas sampling line attached.
From: **Lampotang: Anesth Analg, Volume 101(5).November 2005.1407-1412**



Human Factors and Errors

- When possible, design of equipment should be such that human error cannot occur:
  - e.g. keyed connections for tanks, gas lines and vaporizers
- If human error cannot be prevented:
  - Design should be prevent errors from causing injury e.g. proportioning devices that prevent >75% N_2O or high pressure limit device on ventilators
- Monitors, alarms and vigilance
  - Gas Machine Check-out



Design Changes May Have Unexpected Consequences

"Wrapper," From Preceding Page

Dear SIRS:

We are committed to working together with our distributors, equipment manufacturers, and designers, as well as the end users to ensure ease and proper use of our products and to participate in proper training.

Sofnolime is shipped to this end with safety features in mind.

1) Clear markings are placed in the outer wrapper of cartridges to enable user-friendly reminders and facilitate training in the preparation and use of "one shot" cartridges.

2) Cartridges are shrink-wrapped with clear markings and instructions.

We believe that the concept of "better by design" in combination with these 2 principles can make a difference.

Molecular Products encourages all distributors and customers to spread the "good practice" of reading all

http://www.apsf.org/assets/Documents/winter2006.pdf

CO_2 Absorbents

- Two main problems:
  - Presence of strong monovalent bases
  - Desiccation or drying
  - These can lead to the following problems:
    - Compound A
    - Carbon Monoxide
    - Exothermic reactions


apsf NEWSLETTER
The Official Journal of the Anesthesia Patient Safety Foundation
Carbon Dioxide Absorbent Desiccation Safety Conference Convened by APSF

http://www.apsf.org/resource_center/newsletter/2005/summer/01co2.htm

Composition of CO_2 Absorbents (wt %)

Absorbent	$Ca(OH)_2$	KOH	NaOH	H_2O	$Ba(OH)_2$
Baralyme*	73	<5	0	11-16	+
Sodalime (old)	>80	2.6	1.3	15	-
Sodalime (new)	>80	0	2.6	16	-
Sodasorb (old)	89	3	2.7	16	-
Sodasorb (new KOH free)	92	0.0005	3.75	15.5	-
Amsorb Plus	>80	0	0	13-18	

APSF Conference on CO_2 Absorbent Desiccation: Safety Considerations
Dr. Michael Olympio / Dr. Evan Kharasch April, 2005

Desiccated absorbents

- How does it happen?
  - The retrograde flow of fresh gas through the absorber affected by:
    - Design of the anesthesia breathing system, the presence or absence of the reservoir bag, whether the APL valve is open or closed, the relative resistance through the components of the breathing circuit, the fresh gas flow rate, I:E ratio, use of heat and moisture exchangers, and scavenger suction.

Desiccated absorbents

- Degradation:
  - Desiccated absorbents can remove large amounts of potent inhaled anesthetics
    - Delay in induction
- Absorbent becomes unusually warm:
  - Temperature increases with all potent agents, greatest with sevoflurane

Compound A

- Sevoflurane
  - Degradation product is fluoromethyl-2, 2-difluror-1-(trifluoromethyl) vinyl ether (AKA Compound A)
    - By-products of sevoflurane include carbon monoxide, formaldehyde, methanol, methyl formate, dimethoxymethane, and perhaps hydrogen gas at high temperatures
- Is nephrotoxicity a real problem in humans?
  - Its effect is small and, in all but rare patients, of minimal or no clinical significance.

Eger EI, Eisenkraft JB, Wieskopf RB (2003). Pharmacology of Inhaled Anesthetics.

Compound A

- What conditions make it worse?
  - Desiccated absorbent
  - Strong bases such as barium hydroxide, sodium hydroxide, and potassium hydroxide are needed to produce significant levels compound A
    - Baralyme off the market in late 2004
  - Why not just remove NaOH and KOH?

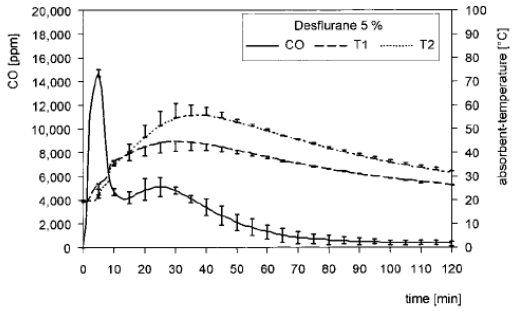
Carbon Monoxide

- All agents produced some CO
  - Use of des > iso = enf > sevo
    - Only desflurane in clinically meaningful amounts
- Elevated COHb levels have been reported, no patient injury has been*
  - Incidence of CO poisoning is unknown because the symptoms of mild poisoning are confusion, headache, nausea & failure to emerge rapidly

Wissing, H., et al., Carbon monoxide production from desflurane, enflurane, halothane, isoflurane, and sevoflurane with dry soda lime. Anesthesiology, 2001. 95(5): p. 1205-12

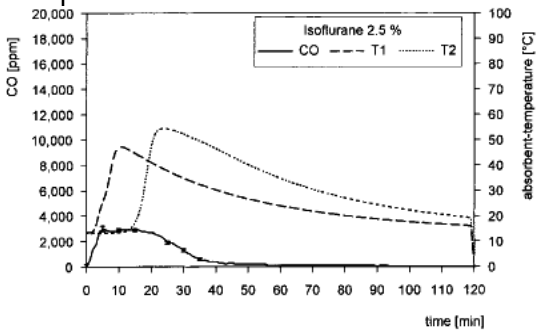
*Eisenkraft JB. Problems with Anesthesia Gas Delivery Systems. ASA, Schwartz AJ, Ed. Lippincott, Williams & Wilkins 2003: vol 33, chapter 6.

Desflurane



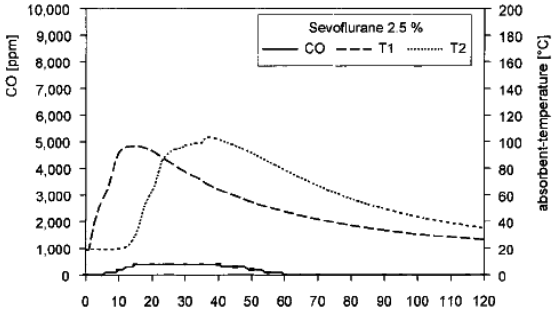
Wissing, H., et al., Carbon monoxide production from desflurane, enflurane, halothane, isoflurane, and sevoflurane with dry soda lime. Anesthesiology, 2001. 95(5): p. 1205-12

Isoflurane



Wissing, H., et al., Carbon monoxide production from desflurane, enflurane, halothane, isoflurane, and sevoflurane with dry soda lime. Anesthesiology, 2001. 95(5): p. 1205-12

Sevoflurane



Wissing, H., et al., Carbon monoxide production from desflurane, enflurane, halothane, isoflurane, and sevoflurane with dry soda lime. Anesthesiology, 2001. 95(5): p. 1205-12

Carbon Monoxide

- Increased risk:
  - Desiccated absorbent
  - 1st case / inactive OR for 24+ hours
  - 1st case, flows left on or high flow, reservoir bag left off circuit
    - Depends on the circuit
  - Remote locations

Wissing, H., et al., Carbon monoxide production from desflurane, enflurane, halothane, isoflurane, and sevoflurane with dry soda lime. Anesthesiology, 2001. 95(5): p. 1205-12

Carbon Monoxide

- Prevention:
  - Flush system with O_2 prior to use on patient
    - May not work
  - Hydration- new absorbent q Monday
    - Add a cup of water to your canister?
  - Consistent use of low flow to sustain moisture
  - Keep reservoir bag on
  - Eliminate CO_2 absorbers with strong bases

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www.apsf.org
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Canister Fires Become A Hot Safety Concern

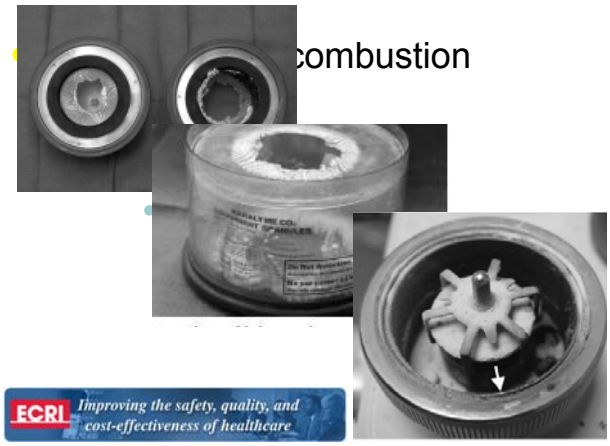
by Michael A. Olympio, MD, and Robert C. Mordl, MD

Reports of fire and/ or extreme heat occurring in the carbon dioxide absorber portion of the anesthesia circle system have come to the attention of the APSF. An October communication received from an anesthesiologist described canister overheating and a burning expiratory valve. Rapid communications and discussions revealed the existence of other.

3. Turn off the vaporizers when not in use.
4. Verify the integrity of the packaging of new CO_2 absorbents prior to use.
5. Periodically monitor the temperature of the CO_2 absorbent canisters.
6. Monitor the correlation between the sevoflurane vaporizer setting and the inspired sevoflurane concentration. An unusually delayed rise or

Ellison C. (Jeep) Pierce, Jr., MD, Retires From APSF

The APSF and ASA Meetings held this past October in San Francisco witnessed a landmark event, the retirement of Ellison C. (Jeep) Pierce, Jr., MD, from his position as Executive Director of the Anesthesia Patient Safety Foundation. Jeep is truly the father of patient safety, both in the United States and abroad. His dedication, persistence, enthusiasm, and hard work led to the formation of the Anesthesia Patient Safety Foundation, which served as the



Fires & Explosions

- Exothermic reaction
- Desiccated Baralyme & sevoflurane
  - Fires have been reported in the USA with sevoflurane only and desiccated Baralyme
  - Color indicator does not necessarily change as a result of desiccation
    - Exception - Amsorb® Armstrong Medical
- Desiccated absorbents without KOH or $Ba(OH)_2$, and with lesser amounts of NaOH, produce less heat and no fires

Fires & Explosions

- Abbott & FDA- 2003
- Audience: Anesthesia healthcare professionals
  - Abbott Laboratories issued a "Dear Healthcare Professional" letter concerning reports of fire or extreme heat in the respiratory circuit of anesthesia machines when [sevoflurane] is used in conjunction with a desiccated CO_2 absorbent
  - Sevo compromise from FDA-package label:
    - FG rates ≥ 1 L/min at 1 MAC for no more than two hours or
    - For lengthier cases FG ≥ 2 L/min
  - The letter went on to provide suggestions to reduce the risk of occurrence of these adverse events

APSF Consensus statement on prevention of desiccation

1. Turn off all gas flow when the machine is not in use.
2. Change the absorbent regularly, on Monday morning for instance.
3. Change absorbent whenever the color change indicates exhaustion.
4. Change all absorbent, not just 1 canister in a 2-canister system.
5. Change absorbent when uncertain of the state of hydration, such as if the fresh gas flow has been left on for an extensive or indeterminate time period.
6. If compact canisters are used, consider changing them more frequently.

Olympio MA (2005). Carbon Dioxide Absorbent Desiccation Safety Conference Convened by APSF. Vol 20, No. 2, 25-44.

Speaking of fires

- FDA has received 12 reports in which regulators used with oxygen cylinders have burned or exploded, in some cases injuring personnel.

APSF NEWSLETTER Summer 2006 PAGE 38

FDA and NIOSH Issue Warning About Oxygen Regulator Fires and Incorrect Use of Seals

The following report was issued on April 24, 2006, to warn providers of fires that may occur at the interface of oxygen regulators and cylinder valves resulting from the incorrect use of CGA 870 seals.

Oxygen cylinder fire

- FDA and NIOSH Recommendations
  - Plastic crush gaskets never be reused
    - They may require additional torque to obtain the necessary seal with each subsequent use.
  - This can deform the gasket, increasing the likelihood that oxygen will leak around the seal and ignite.
  - Always “crack” cylinder valves (open the valve just enough to allow gas to escape for a very short time) before attaching regulators
    - Expel foreign matter from the outlet port of the valve

ASTM F1850-00: The 2000 AGM standard

- To comply these, work stations must have monitors that measure:
  - Continuous breathing system pressure
  - Exhaled tidal volume
  - Ventilatory CO_2 concentration
  - Anesthetic vapor concentration
  - Inspired O_2 concentration
  - O_2 supply pressure
  - Arterial hemoglobin O_2 saturation
  - Arterial blood pressure
  - Continuous electrocardiogram
- Prioritized alarm system:
  - Alarms – high, medium & low priority

ASTM F1850-00

- Flowmeters:
  - Single control for each gas
  - Each flow control next to a flow indicator
  - Uniquely shaped oxygen flow control knob
  - Valve stops (or some other mechanism) are required such that excessive rotation will not damage the flowmeter.
  - Oxygen flow indicator is to the right side of a flowmeter bank
  - Oxygen enters the common manifold downstream of other gases

ASTM F1850-00

- An oxygen flush is present
  - Capable of 35-75 L/min flow which does not proceed through any vaporizers
- Vaporizers
  - Concentration-calibrated
  - An interlock must be present
  - Liquid level indicated, designed to prevent overfilling
  - "Should" use keyed-filler devices
  - No discharge of liquid anesthetic occurs from the vaporizer even at maximum fresh gas flow

ASTM F1850-00

- Pipeline gas supply
  - Pipeline pressure gauge
  - DISS protected
  - In line filter
  - Check valve
- FDA Checklist must be provided
  - May be electronic, or performed manually by the user
- A digital data interface must be provided
- An auxiliary oxygen flowmeter is strongly recommended

New

- Efforts underway to revise the preuse checkout (FDA 1993) recommendations
  - ASA Newsletter Fall 2005
  - Request for anonymous survey through University of Florida’s Virtual Anesthesia Machine Web
  - Final recommendations from task force are expected by ASA 2006 meeting
  - Automated checkout
- How are practitioners expected to keep up?

Near catastrophes and other reported problems

- FDA Center for Devices and Radiological Health MAUDE (manufacturer and user device experience)
- Deliberate omission of machine checkout is inexcusable and has had serious consequences

Summary of Safety Features of Modern Gas Machines

- More accurate and/or corrected tidal volume through compliance and fresh gas compensation (avoiding Vt augmentation)
- Potential return of sampled gas to facilitate low-flow
- Fresh gas decoupling may prevent hyperinflation of the lung
- Some forms of decoupling will even reroute the high flow of oxygen flush if it is depressed during mechanical inspiration

Olympio, MA (2003). Comparison of Breathing Circuits of Modern Anesthesia Machines: A transitional graphic presentation

Avoiding V_T augmentation to ensure set V_T = delivered V_T

- 1. Fresh Gas Decoupling
  - Dräger
    - Narkomed 6000 & Fabius GS
  - Anestar
    - Hanging bellows
- 2. Fresh Gas Compensation
  - Datex-Ohmeda
    - Aestiva & S/5 ADU

Summary of Safety Features of Modern Gas Machines

- Incorporation of electronic PEEP may prevent inaccurate, improper, or unintended PEEP
- Electronic selection of ventilation parameters might prevent improper setup of a mechanical ventilator
- Automated checkout procedures (presumably) will detect a problem that clinicians may not, particularly in these complex systems
- New disconnect alarm system for hanging bellows might reduce the incidence of inadequate ventilation

Olympio, MA (2003). Comparison of Breathing Circuits of Modern Anesthesia Machines: A transitional graphic presentation

Multiple questions regarding modern machines

- With an obstruction, will the clinician be fooled by artificial vent sounds into thinking the patient is being ventilated when he or she is not?
- During a power failure what will work?
- Will the automated checkout procedures prevent emergent and rapid initiation of the machine?

Olympia MA. Modern Anesthesia Machines Offer New Safety Features. **APSF Newsletter** 2003, accessed 9-1-06: **http://www.apsf.org/resource_center/newsletter/2003/summer/machines.htm**

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