

An Evaluation of Anesthesiologists' Present Checkout Methods and the Validity of the FDA Checklist

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The United States Food and Drug Administration (FDA) published the Anesthesia Apparatus Checkout Recommendations (checklist) in order to improve the methods anesthesiologists use to check out anesthesia equipment. Whereas no published study of current checkout methods had been performed since the introduction of the FDA checklist, we compared anesthesiologists' current anesthesia equipment pre-use checkout methods with anesthesiologists' use of the FDA checklist. One hundred and eighty-eight anesthesiologists were tested to compare the number of prearranged anesthesia machine faults that could be detected with 1) their own checkout methods and 2) the FDA checklist. The average number of machine faults detected with the individual anesthesiologists' checkout methods was 1.03/4 (25.8%) and with the FDA checklist was 1.20/4 (29.9%). For only one fault, malfunction of the oxygen/nitrous oxide ratio protection system, was there a statistically significant improvement ($P < 0.01$) with the use of the FDA checklist. Anesthesiologists in residency training detected more faults (average 2.46/8, 30.8%) than did anesthesiologists who primarily practiced direct patient care (1.98/8, 23.9%) ($P < 0.01$). Our data indicate that the mere introduction of the FDA checklist did not improve the ability of anesthesiologists to detect anesthesia machine faults. (Key words: Equipment, anesthesia; anesthesia machines; FDA Anesthesia Apparatus Checkout Recommendations (Checklist); malfunctions; preuse checkout methods.)

In 1978, Cooper *et al.*¹ demonstrated that 14% of mishaps in anesthesia were directly attributable to anesthesia system failures. A later study by his group² attributes only 4% of incidents with negative outcomes to equipment failure; however, in 22% of all incidents studied, some form of failure to check or inspect was cited as an associated factor. Craig and Wilson³ determined that in 33% of 81 incidents studied, a "failure to perform a preanesthetic check [was] the commonest associated factor." Bufington *et al.*⁴ studied clinicians' machine checkout rou-

tines and found that participants detected an average of only 44% (2.2/5) of intentionally created machine faults.

In the past decade, increasing evidence¹⁻⁵ has suggested that a routine preuse inspection of the anesthesia equipment would improve patient safety. The American Society of Anesthesiologists (ASA), the Anesthesia Patient Safety Foundation, and others support preuse checklists to enable the anesthesia practitioner to ensure that the anesthesia delivery system is correctly connected and adjusted and is functioning as intended. In addition, the United States Food and Drug Administration (FDA), in cooperation with the ASA, anesthesia equipment experts, and anesthesia machine manufacturers, developed a generic apparatus checklist to enable the practitioner to thoroughly check out anesthesia equipment before use and between cases‡ (fig. 1). The checklist was published in the Federal Register in February, 1987, was distributed at the ASA "Patient Safety and Risk Management" exhibit booth during the 1986 annual meeting, and was printed in the October 1986 issue of the ASA Newsletter§ and the September 1986 issue of the Anesthesia Patient Safety Foundation Newsletter.¶

Although the FDA checklist has been widely published and disseminated, we questioned whether it has improved the ability of anesthesiologists to check out anesthesia equipment. An FDA state contract awarded in 1987 to four states** produced information indicating that the level of preuse checkout was inconsistent and that use of the FDA (or similar) checklist was minimal.

This study was designed to investigate three hypotheses: 1) the current checkout methods used by anesthesiologists are adequate for the detection of anesthesia machine faults; 2) introduction of the FDA checklist would not improve the anesthesiologist's ability to detect anesthesia machine faults; and 3) the level of understanding of the

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‡ United States Food and Drug Administration: Anesthesia Apparatus Checkout Recommendations. Rockville, MD, Federal Register, February, 1987.

§ American Society of Anesthesiologists Newsletter. October, 1986, pp 5, 6

¶ Anesthesia Patient Safety Foundation Newsletter. 1(3 [September 1986]):13-17

** United States Food and Drug Administration: Investigation of anesthesia equipment checkout procedures. Contract 223-87-4224.

physics and mechanics of an anesthesia machine (as determined by a multiple-choice written test) would have no effect on the participant's ability to detect anesthesia machine faults.

Materials and Methods

The study population consisted of anesthesiologists who were either in residency training or in clinical practice. All participants were volunteers who reported familiarity with one or both of the two models of anesthesia machines used for the study. Two anesthesia machines were loaned to us by the manufacturers for use in the study: these were a North American Dräger Narkomed 2A and an Ohmeda Modulus II.

The study was conducted in two different locations: in Metropolitan District of Columbia hospitals ($n = 35$), and in Continuing Medical Education (CME) meetings for anesthesiologists ($n = 153$).

A Mobile Anesthesia Study Center was designed and built by the FDA to house the modified anesthesia machines and the necessary support equipment. The inside of the Mobile Anesthesia Study Center was designed to simulate an operating room, including oxygen and nitrous oxide wall outlets, a scavenging system, and fully configured anesthesia machines. Exceptions included the deletion of vaporizing agents and those monitors not integral to the anesthesia machines. The necessity for construction of the Mobile Anesthesia Study Center was identified when it became necessary to move the machines and support equipment to remote testing sites. At the CME meetings, booths resembling the configuration of the Mobile Anesthesia Study Center were constructed to house the study machines.

The study design incorporated several steps and included two possible formats (fig. 2). The participants were initially asked to complete a questionnaire relating to training and type of practice. After completion of the questionnaire, the participants were given approximately 15 min to check out the study machine of their choice using their traditional checkout methods and to record any faults detected (four possible faults could be found). The participants were informed that the machines contained faults but no specific number of faults was mentioned. The participants then received a copy of the FDA checklist to study while the investigator changed the set of faults. The participants were then asked to recheck the machine while referring to the FDA checklist and to list any faults detected (four possible faults could be found), again in an approximately 15-min period. The final step was the completion of a written test. For each of the eight possible faults, three multiple-choice questions were devised that related directly to each fault, for a total of 24 questions.

For each fault, a 2×2 contingency table was constructed; a comparison of the fault detection before and after introduction of the FDA checklist was performed using chi-squared analysis. Simple regression analysis was used to compare written test scores to fault detection.

Eight different machine faults were created in the study machines. These were divided into two sets, A and B, of four faults each. Whether the participant had fault set A or fault set B first was determined by the condition of the machine from the previous participant who had used that machine. Within each set, the four faults were independent and did not interfere with one another. During the study each participant was exposed to both sets of faults, one with their own methods and one with the FDA checklist. No attempt was made to instruct the participant in the use of the checklist. The two sets of faults were selected based on their potential to injure anesthetized patients, on reports of their actual occurrence in practice, and on the ability of the investigators to alter the machines to install the faults. The faults were designed in such a way that machine checkout procedures were necessary for their detection. If properly performed, the FDA checklist would result in detection of all of the faults. This was confirmed in practice by the investigators, who were able to perform the checklist step by step and discover each fault.

Set A contained the following faults:

A1. Oxygen/nitrous oxide ratio protection system: In the North American Dräger machine, the oxygen ratio monitor controller was bypassed and the alarm overridden. In the Ohmeda machine, the Link-25 proportioning mechanism was, through a system of electronic brakes and clutches, designed to simulate a broken chain. These bypasses allowed any mixture of oxygen and nitrous oxide to be delivered, including hypoxic mixtures.

A2. Fail-safe valve: The mechanism controlling the North American Dräger oxygen failure protection device and the Ohmeda pressure-sensor shut-off valve was bypassed. This allowed nitrous oxide to flow in the absence of oxygen supply pressure.

A3. Oxygen analyzer: The oxygen analyzers were modified such that they would read 21% in room air but would not read over 65–85% oxygen at an inspired oxygen fraction of 1.0, simulating a faulty sensor.

A4. Low-pressure leak: A leak in the low-pressure system was created between the flowmeters and the common gas outlet; it quantitated at approximately 1 l/min at 20 cmH₂O. In the Ohmeda machine, the fault was created distal to the outlet check valve. This was done to allow the checkout procedures for the low-pressure systems in the two different machines to be similar.

Set B contained the following faults:

B1. Ventilator leak: a 1.5–2.0 l/min (at 20 cmH₂O) leak was simulated when the ventilator was in use. In the

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This checkout, or a reasonable equivalent, should be conducted before administering anesthesia. This is a guideline which users are encouraged to modify to accommodate differences in equipment design and variations in local clinical practice. Such local modifications should have appropriate peer review. Users should refer to the operators manual for special procedures or precautions.

- *1. **Inspect anesthesia machine for:**
machine identification number
valid inspection sticker
undamaged flowmeters, vaporizers, gauges, supply hoses complete, undamaged breathing system with adequate CO₂ absorbent
correct mounting of cylinders in yokes
presence of cylinder wrench
- *2. **Inspect and turn on:**
electrical equipment requiring warm-up. (ECG/pressure monitor, oxygen monitor, etc.)
- *3. **Connect waste gas scavenging system:**
adjust vacuum as required
- *4. **Check that:**
flow-control valves are off
vaporizers are off
vaporizers are filled (not overfilled)
filler caps are sealed tightly
CO₂ absorber by-pass (if any) is off
- *5. **Check oxygen (O₂) cylinder supplies:**
 - a. Disconnect pipeline supply (if connected) and return cylinder and pipeline pressure gauges to zero with O₂ flush valve.
 - b. Open O₂ cylinder; check pressure; close cylinder and observe gauge for evidence of high pressure leak.
 - c. With the O₂ flush valve, flush to empty piping.
 - d. Repeat as in b. and c. above for second O₂ cylinder, if present.
 - e. Replace any cylinder less than about 600 psig. At least one should be nearly full.
 - f. Open less full cylinder.
- *6. **Turn on master switch (if present)**
- *7. **Check nitrous oxide (N₂O) and other gas cylinder supplies:**
Use same procedure as described in 5a. & b. above, but open and *CLOSE* flow-control valve to empty piping.
Note: N₂O pressure below 745 psig. indicates that the cylinder is less than ¼ full.
- *8. **Test flowmeters:**
 - a. Check that float is at bottom of tube with flow-control valves closed (or at min. O₂ flow if so equipped).
 - b. Adjust flow of all gases through their full range and check for erratic movements of floats.
- *9. **Test ratio protection/warning system (if present):**
Attempt to create hypoxic O₂/N₂O mixture, and verify correct change in gas flows and/or alarm.
- *10. **Test O₂ pressure failure system:**
 - a. Set O₂ and other gas flows to mid-range.
 - b. Close O₂ cylinder and flush to release O₂ pressure.
 - c. Verify that all flows fall to zero. Open O₂ cylinder.
 - d. Close all other cylinders and bleed piping pressures.
 - e. Close O₂ cylinder and bleed piping pressure.
 - f. **CLOSE FLOW-CONTROL VALVES.**
- *11. **Test central pipeline gas supplies:**
 - a. Inspect supply hoses (should not be cracked or worn).
 - b. Connect supply hoses, verifying correct color coding.
 - c. Adjust all flows to at least mid-range.
 - d. Verify that supply pressures hold (45-55 psig.).
 - e. Shut off flow-control valves.
- *12. **Add any accessory equipment to the breathing system:**
Add PEEP valve, humidifier, etc., if they might be used (if necessary remove after step 18 until needed).
- 13. **Calibrate O₂ monitor:**
 - *a. Calibrate O₂ monitor to read 21% in room air.
 - *b. Test low alarm.
 - c. Occlude breathing system at patient end; fill and empty system several times with 100% O₂.
 - d. Check that monitor reading is nearly 100%.
- 14. **Sniff inspiratory gas:**
There should be no odor.
- *15. **Check unidirectional valves:**
 - a. Inhale and exhale through a surgical mask into the breathing system (each limb individually, if possible).
 - b. Verify unidirectional flow in each limb.
 - c. Reconnect tubing firmly.
- ††16. **Test for leaks in machine and breathing system:**
 - a. Close APL (pop-off) valve and occlude system at patient end.
 - b. Fill system via O₂ flush until bag just full, but negligible pressure in system. Set O₂ flow to 5 L/min.
 - c. Slowly decrease O₂ flow until pressure *no longer rises* above about 20 cm H₂O. This approximates total leak rate, which should be no greater than a few hundred ml/min. (less for closed circuit techniques).
CAUTION: Check valves in some machines make it imperative to measure flow in step c. above when pressure *just stops rising*.
 - d. Squeeze bag to pressure of about 50 cm H₂O and verify that system is tight.
- 17. **Exhaust valve and scavenger system:**
 - a. Open APL valve and observe release of pressure.
 - b. Occlude breathing system at patient end and verify that negligible positive or negative pressure appears with either zero or 5 L/min. flow and exhaust relief valve (if present) opens with flush flow.
- 18. **Test ventilator:**
 - a. If switching valve is present, test function in both bag and ventilator mode.
 - b. Close APL valve if necessary and occlude system at patient end.
 - c. Test for leaks and pressure relief by appropriate cycling (exact procedure will vary with type of ventilator).
 - d. Attach reservoir bag at mask fitting, fill system and cycle ventilator. Assure filling/emptying of bag.
- 19. **Check for appropriate level of patient suction.**
- 20. **Check, connect, and calibrate other electronic monitors.**
- 21. **Check final position of all controls.**
- 22. **Turn on and set other appropriate alarms** for equipment to be used.
(Perform next two steps as soon as is practical)
- 23. **Set O₂ monitor alarm limits.**
- 24. **Set airway pressure and/or volume monitor alarm limits** (if adjustable).

If an anesthetist uses the same machine in successive cases, the steps marked with an asterisk (*) need not be repeated or may be abbreviated after the initial checkout.

†† A vaporizer leak can only be detected if the vaporizer is turned on during this test. Even then, a relatively small but clinically significant leak may still be obscured.

FIG. 1. The FDA Anesthesia Apparatus Checkout Recommendations. (Reproduced from the ASA Newsletter, October 1986, p 42.)

Dräger machine, a leak was created in the low-pressure system between the flowmeters and the common gas outlet. In the Ohmeda machine, the leak was created downstream of the common gas outlet.

B2. Vaporizer leak: With one of the three vaporizers in the "ON" position, a 1.5–2.0 l/min (at 20 cmH₂O) leak was simulated in the low-pressure circuit between the flowmeters and the common gas outlet. (Pilot studies indicated that participants had trouble locating this fault; therefore, for ease of detection in the Ohmeda machine, the leak was created downstream of the common gas outlet.)

B3. Incompetent circle-system unidirectional valve: A simulated incompetent inhalation valve created reverse flow through the inspiratory limb during exhalation.

B4. High-pressure leak: A substantial high-/intermediate-pressure oxygen leak was simulated between the source of gas (either wall outlet or cylinder) and the flow control valves. The leak was created by siphoning oxygen pressure from the high- or intermediate-pressure oxygen line, between the backup oxygen E-cylinder and the pipeline check valve. The leak was sized such that, when conducting the FDA checklist step 5, the gauge would decrease from full (2,000 psi) to zero in approximately 30 s. The leak was not audibly discernible over normal background noise levels.

After participation in the study, the participants were assigned a number. At the completion of all data collection, the results of the checkout tests were mailed to the participants, filed by the assigned number.

During the performance of the experiment, we received informal feedback from the participants concerning their expected performance; however, no data were collected.

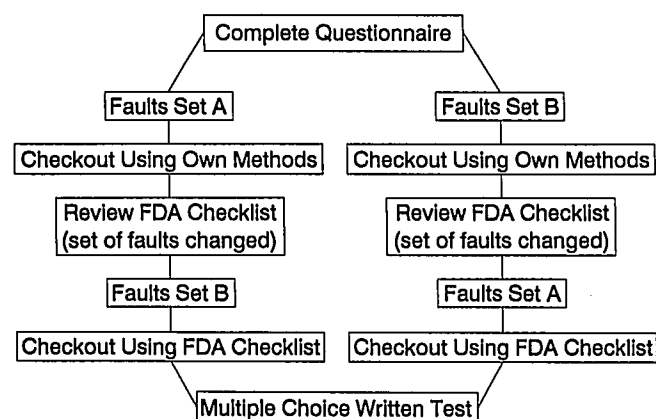


FIG. 2. Study formats.

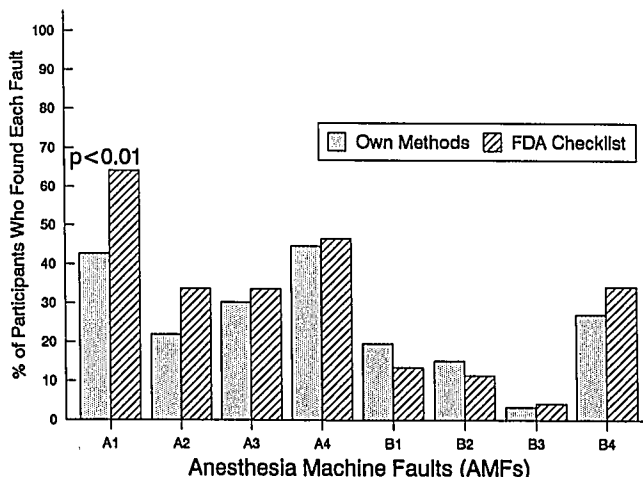


FIG. 3. Fault detection: participants' own methods versus the FDA checklist. ($P < 0.01$ for fault A1; $P > 0.05$ for all other faults.)

Results

A total of 188 anesthesiologists participated in the study. Of these, 5 subjects did not submit a questionnaire, and 14 did not submit a completed multiple-choice test. For demographic comparison, $n = 183$, and for calculations correlating fault detection and test scores, $n = 174$. Of the 183 participants who submitted a questionnaire, 54 (29.5%) were in residency training. Of the remaining subjects, 47 (25.7%) were primarily involved in direct patient care; 56 (30.6%) were primarily supervised residents and/or certified registered nurse anesthetists; and 26 (14.2%) were engaged in a combined practice.

Ninety-six of the 188 participants (51%) began with fault set A, and 92 (49%) began with fault set B. The data were analyzed using detection of each individual fault before and after the use of the FDA checklist.

When we compared the detection of each fault with and without the use of the FDA checklist, there was a statistically significant difference ($P < 0.01$) between the participant's own methods and the use of the FDA checklist for only one fault, the oxygen/nitrous oxide ratio. For the remaining seven faults, there was no significant change ($P > 0.05$) in detection after introduction of the checklist (fig. 3). In addition, no participant found all of the faults.

When comparing the total number of faults found by all participants, there was no significant difference between participants who used the Ohmeda machines and those who used the North American Dräger machines ($P > 0.05$). In addition, when comparing detection of individual faults, there was no significant difference between the two types of machines ($P > 0.05$).

In the comparison of fault detection and written test scores for all participants, the regression line had a statistically positive slope ($P < 0.01$; $y = -1.307 + 0.026x$).

The coefficient of determination, however, was very low ($R^2 = 0.141$; correlation coefficient $r = 0.376$).

The number of faults found *versus* the number of faults missed as a function of the number of test questions pertaining to each fault answered correctly is summarized in table 1. (Three test questions were associated with each of the eight faults.) When all three of the test questions relating to a fault were answered correctly, there was a statistically significant ($P < 0.01$) higher percentage of faults detected (45.9%, 181/394) than missed (33.97%, 339/998). Conversely, there was a statistically significant ($P < 0.01$) lower percentage of faults detected (10.4%, 41/394) than missed (18.84%, 181/998) when only one of the three test questions relating to a fault was answered correctly.

Participants tested in local area hospitals ($n = 35$) detected significantly more total faults ($P < 0.01$) than participants tested in CME meetings (fig. 4). The average number of faults found by the hospital group was 2.91/8 (36.3%) *versus* 2.07/8 (25.9%) for the CME group. This disparity can be traced directly to the detection of one fault. For the group that attempted to find the high-pressure leak with the FDA checklist, 88% of the hospital group detected this fault, whereas only 23% of the CME group detected it.

There was no statistically significant difference ($P > 0.05$) in fault detection between all participants and those who primarily supervise residents and/or certified registered nurse anesthetists, who primarily practice direct patient care, who have a combined practice, or who are in residency.

Residents (average 2.46/8, 31%) detected significantly ($P < 0.05$) more faults than participants who primarily practice direct patient care (average 1.91/8, 23.9%) but not in comparison with anesthesiologists who primarily practice supervision (average 2.41/8, 30%) or participants engaged in a combined practice (average 1.93/8, 24%). Supervisors detected more faults than those who primarily practice direct patient care ($0.1 > P > 0.05$).

Discussion

Anesthesiologists are often compared to airline pilots.†† Both operate technologically advanced equipment and use monitoring instruments to ensure that the equipment is operating properly. As with airline passengers, anesthetized patients may be severely injured or die as a result of equipment failure, but this type of injury is considered preventable. For many years, the aviation industry has used checklists as integral parts of essential operational

TABLE 1. Faults Found *versus* Faults Missed

	Number of Test Questions Pertaining to Each Fault Answered Correctly			
	0/3*	1/3†	2/3*	3/3†
Faults found (total = 394)	1.01% (4)	10.41% (41)	42.64% (168)	45.94% (181)
Faults missed (total = 998)	2.30% (23)	18.84% (181)	44.89% (448)	33.97% (339)

* $P > 0.05$.

† $P < 0.01$.

procedures. The introduction by the FDA of a generic checkout procedure for anesthesia machines was an attempt to design a uniform procedure that could be followed by all anesthesia practitioners on any anesthesia machine. Because Buffington *et al.*'s⁴ work was performed prior to the introduction of the FDA checklist, we repeated his experiment to determine if a variable introduced into the machine checkout procedure (the FDA checklist) would improve the ability of the anesthesiologist to detect machine faults.

Our initial plan was to obtain a random sample of anesthesiologists from hospitals in our geographic region. It became apparent, however, that it would not be possible to test a sufficient number of subjects in this setting because of scheduling difficulties. We therefore elected to perform the bulk of our study at a site where anesthesia personnel congregate, *e.g.*, at CME meetings. The population studied cannot be considered random and does not represent the general population of anesthesiologists in this country; however, we do not believe that this necessarily obviates the validity of our data. Furthermore, one might assume that practitioners who volunteer for this type of study would generally be comfortable and facile with the use of anesthesia machines and might be expected to perform at a higher level than a population that was randomly selected. The impression received by the investigators when soliciting participants for the study indicated that generally only those practitioners who were relatively comfortable with anesthesia equipment would volunteer to participate.

We did not attempt to solicit formally the impressions of the participants as to their performance on the test, nor did we disclose the "correct answers" prior to the completion of data collection, in an effort to avoid bias of our results. However, it was the impression of the data collectors that, after the test, participants were generally unsure of their ability to check out anesthesia machines *thoroughly*, and many of the participants left the study somewhat puzzled and concerned over their performance.

It was somewhat disconcerting to find that for only one of eight possible machine faults was there an improvement in detection with the FDA checklist over the practitioners'

†† Spierdijk J, Department of Anesthesiology, University of Leiden, the Netherlands; de Bruijne H, Chief Pilot Boeing 747, KLM Royal Dutch Airlines; and Checklist Procedures: Aviation shows the way to safer anesthesia, KLM Newsletter.

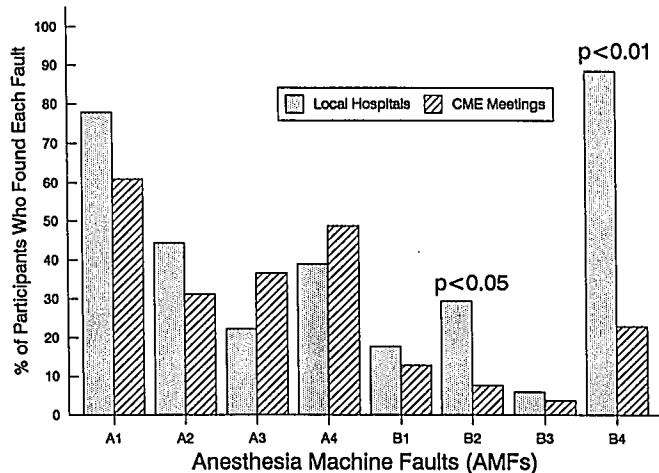


FIG. 4. Fault detection in local hospitals versus detection in Continuing Medical Education meetings using the FDA checklist. ($P < 0.01$ for fault B4; $P < 0.05$ for Fault B2; $P > 0.05$ for all other faults.)

own checkout methods, and that fault detection was low regardless of the method used (20–30% detection rate). If the practitioner had followed the FDA checklist step by step, presumably all of the faults would have been detected. The overall fault detection was surprisingly low considering that the participants knew that they were checking machines that had faults.

Although there was a statistically positive correlation ($P < 0.01$) between the number of correct answers on the written test (average 17.36/24, ± 2.65) and the number of faults detected (average 2.26/8, ± 1.45), we had expected the correlation to be much stronger ($R^2 = 0.141$). Our assumption was that practitioners who had scored well on the written test would detect significantly more faults. Our results suggest that the practitioners may understand the function of the machines but may be unable to apply that understanding to practical clinical skills.

Participants in local area hospitals detected more faults, particularly the high-pressure leak fault, than did participants at the CME meetings. This may be explained by the fact that the institutions in our region have residency programs that presumably are actively engaged in teaching anesthesia machine checkout procedures.

It is surprising that participants who use anesthesia machines on a daily basis—the direct patient care group—did not detect more faults than the supervisory group, whose interaction with anesthesia machines would be less direct (average 1.9/8 vs. 2.4/8, $0.1 > P > 0.05$).

It was encouraging and was anticipated that residents performed at a higher level than many participants who engage in direct patient care. One would expect that residents would be exposed to more rigid evaluation tech-

niques while receiving their formal training in anesthesiology, and their superior performance may be indicative of the increasing emphasis placed during anesthesia training on machine checkout procedures.

A significant deficiency in our data collection may have been the lack of information regarding the participants' length of time away from residency training. The findings related to the residents' performance would suggest that practitioners closer to their training years might have outperformed those who had been in practice longer. However, this information was not collected in our study.

The data from our study, however, indicate that the FDA checklist did not improve the ability of anesthesiologists to detect machine faults. A number of factors could account for these findings. It is possible that the lack of formal training in machine checkout and the use of a checklist for this purpose make adaptation to this method difficult for the practitioner. It is also conceivable that, if no ongoing reinforcement of checkout procedures occurs, this facility is lost over time. In addition, the complexity of modern anesthesia machines could detract from the ability of the anesthesiologist to perform a thorough checkout. The responsibility of the manufacturers to supply training aids that correlate with the ability to detect faults and/or to market a machine that is more ergonomically designed are other factors that must be noted.

An ongoing study to determine if formal training in the use of the FDA checklist improves the ability to detect machine faults should be conducted to determine the validity of the checklist itself. Rewriting of the FDA checklist may be required to improve its utility as a clinical tool.

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