In 1978, the Food and Drug Administration (FDA), developed a generic anesthesia equipment preuse checklist. The checklist was first released by the FDA in August 1986 and endorsed by the American Association of Nurse Anesthetists on October 18, 1986. The FDA checklist was revised in 1992 to improve the abilities of anesthesia providers to detect machine faults. In the present study, the investigators attempted to determine the effectiveness of the revised FDA checklist in detection of anesthesia machine faults as compared to providers' usual methods. Whereas no published study of preanesthesia safety inspection had been performed since the revision of the FDA checklist, the authors compared the detection abilities of anesthesia providers before and after inclusion of the revised FDA checklist. Twenty-two anesthesia providers were tested to compare the number of prearranged anesthesia machine faults that could be detected with (1) their usual checkout methods, and (2) with the revised FDA checklist. Data describing the subjects' fault detection abilities were analyzed using the t test for paired observation (P value < 0.05 considered significant).

Statistical analysis revealed no significant difference (P = 0.479) when subjects used the FDA checklist and when they used their usual method. Use of the FDA machine checklist was no more effective than the provider's usual method in discovering machine faults. When using their normal method, 54.5% of providers did not discover more than 50% of programmed faults. Approximately 40.9% of providers who used the revised FDA checklist did not discover over 50% of programmed faults.

Key words: Anesthesia equipment, anesthesia machines, Food and Drug Administration anesthesia apparatus checkout recommendations, malfunctions, preuse checkout methods.

Introduction
Patients who undergo surgery place total reliance on the anesthesia-surgery team for their immediate and future physiological well-being. The conducted anesthesia permits surgical procedures to be performed with minimal pain, awareness, or hemodynamic changes. Patient safety is a major concern for both patient and anesthesia provider. Studies of anesthesia safety have emphasized the important role that human error contributes to clinical anesthesia practice. Human error was found to be a major contributing factor in 82% of preventable anesthesia incidents in the study by Cooper.1

Traditional studies of anesthesia safety focused on anesthesia morbidity and mortality. Anesthesia
safety studies have found the incidence of anesthesia mortality to vary between 1 in 185,000 to 1 in 200,000.\(^2\) However, a more promising approach to improving anesthesia safety began with the studies of Jeffery Cooper in 1978.\(^1\) He described the events surrounding critical incidents in an attempt to define their origin.

Cooper's work in analyzing anesthesia "critical incidents" found a significant association between failure to perform a normal preuse check and occurrences of critical incidents.\(^3\) Further research in anesthesia machine fault detection by Buffington and associates concluded that abilities of anesthesia providers to recognize anesthesia machine safety faults were inadequate.\(^4\)

The Food and Drug Administration (FDA) in 1978 developed and promoted a generic anesthesia equipment preuse checklist, which was endorsed by the American Association of Nurse Anesthetists (AANA), the American Society of Anesthesiologists (ASA), and others. These professional anesthesia organizations worked with the FDA to develop a generic anesthesia equipment preuse checklist, applicable for all anesthesia machines currently in use.\(^5\) Several studies on the use of this anesthesia preuse checklist discovered that few anesthesia providers either utilized the FDA checklist or were able to effectively utilize it when conducting a preuse inspection.\(^6\,\(^8\)

In an effort to directly assess the effectiveness of the FDA checklist in anesthesia fault detection, March and Crowley conducted a study to determine fault detection abilities of academic anesthesiologists using the FDA checklist.\(^6\) The authors found that the average number of faults detected with the FDA checklist was only 29.9%, and they concluded that the FDA checklist was not instrumental in improving anesthesiologists' abilities to recognize machine faults. One limitation of this study is that the subjects were academic anesthesiologists and not practitioners in an average hospital setting.

Representatives from anesthesia professional organizations (ASA and AANA), anesthesia equipment manufacturers, and the FDA revised the content and format of the FDA checklist in 1992;\(^9\) the final version of the anesthesia apparatus checkout recommendations was published in 1993 (Table 1). The purpose of our study was to evaluate the effectiveness of the revised FDA checklist in detection of anesthesia machine faults. The study also assessed the usefulness of present checkout methods used by anesthesia providers.

This study was designed to investigate two questions:

1. Are the current checkout methods used by anesthesia providers adequate for the detection of anesthesia machine faults? For the purpose of this study, adequacy of fault detection was defined as the ability to detect more than 50% of anesthesia machine faults.

2. Will the introduction of the revised FDA checklist improve providers' abilities to detect anesthesia machine faults over their usual methods?

While the ability to detect only 50% of machine faults is considered far short of ideal expectations, the authors felt that the study results would yield a significant conclusion if the quality standard was found to be lower than one normally acceptable for satisfactory care of the anesthetized patient. In addition, previous FDA studies had described low-fault detection rates as a reference for comparison, not as a goal for anesthesia safety.\(^8\) The low detection rate is in no way implied to be a goal for safety standards in anesthesia.

Materials and methods

In this study, the investigators used a research design similar to the one devised by March and Crowley and substituted the revised FDA checklist for the original one.\(^5\)\(^9\) The goal of this research was to determine whether or not the revised FDA checklist is an effective tool for fault detection.

A total of 22 subjects voluntarily participated in the research study. The study included 12 staff nurse anesthetists, eight anesthesiologists, and two senior student nurse anesthetists from two private hospitals. Students who participated were senior-year graduate students in anesthesia training. Of the anesthesiologists, one had less than 1 year of experience since completing residency, one had between 2 and 8 years of experience, and six had more than 8 years of clinical experience. The CRNA participants included one with less than 2 years of experience since graduation, one between 2 and 8 years of experience, and 10 with more than 8 years of clinical experience.

The authors obtained institutional approval for conducting the study from the Investigation Review Board of Bryan Memorial Hospital prior to initiating the research. The study did not impose personal risks to study participants or patients, as it was conducted in an area outside the operating rooms. In addition, comprehensive safety measures were taken after completion of the study to ensure operational readiness of the anesthesia machines.

The independent variable consisted of the revised FDA anesthesia checklist, a generic preuse evaluation tool adaptable for all anesthesia machines. Dependent variables consisted of (1) the
Table I
Anesthesia apparatus checkout recommendations, 1993

This checkout, or a reasonable equivalent, should be conducted before administration of anesthesia. These recommendations are only valid for an anesthesia system that conforms to current and relevant standards and includes an ascending bellows ventilator and at least the following monitors: capnograph, pulse oximeter, oxygen analyzer, respiratory volume monitor (spirometer) and breathing system pressure monitor with high and low pressure alarms.

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 operator’s manual for the manufacturer’s specific procedures and precautions, especially the manufacturer’s low pressure leak test (step #5).

Emergency Ventilation Equipment

*1. Verify Backup Ventilation Equipment Is Available & Functioning

High Pressure System

*2. Check Oxygen Cylinder Supply
   a. Open O2 cylinder and verify at least half full (about 1000 psig).
   b. Close cylinder.

*3. Check Central Pipeline Supplies
   a. Check that hoses are connected and pipeline gauges read about 50 psi.

Low Pressure System

*4. Check Initial Status of Low Pressure System
   a. Close flow control valves and turn vaporizers off.
   b. Check fill level and tighten vaporizers’ filler caps.

*5. Perform Leak Check of Machine Low Pressure System
   a. Verify that the machine master switch and flow control valves are OFF.
   b. Attach “Suction Bulb” to common (fresh) gas outlet.
   c. Squeeze bulb repeatedly until fully collapsed.
   d. Verify bulb stays fully collapsed for at least 10 seconds.
   e. Open one vaporizer at a time and repeat: ’c’ and ’d’ as above.
   f. Remove suction bulb, and reconnect fresh gas hose.

*6. Turn On Machine Master Switch and All Other Necessary Electrical Equipment

*7. Test Flowmeters
   a. Adjust flow of all gases through their full range, checking for smooth operation of floats and undamaged flowtubes.
   b. Attempt to create a hypoxic O2/N2O mixture and verify correct changes in flow and/or alarm.

Scavenging System

*8. Adjust and Check Scavenging System
   a. Ensure proper connections between the scavenging system and both APL (pop-off) valve and ventilator relief valve.
   b. Adjust waste gas vacuum (if possible).
   c. Fully open APL valve and occlude Y-piece.
   d. With minimum O2 flow, allow scavenger reservoir bag to collapse completely and verify that absorber pressure gauge reads about zero.
   c. With the O2 flush activated, allow the scavenger reservoir bag to distend fully, and then verify that absorber pressure gauge reads < 10 cm H2O.

Breathing System

*9. Calibrate O2 Monitor
   a. Ensure monitor reads 21% in room air.
   b. Verify low O2 alarm is enabled and functioning.
   c. Reinstall sensor in circuit and flush breathing system with O2.
   d. Verify that monitor now reads greater than 90%.

10. Check Initial Status of Breathing System
    a. Set selector switch to “Bag” mode.
    b. Check that breathing circuit is complete, undamaged and unobstructed.
    c. Verify that CO2 absorbent is adequate.
    d. Install breathing circuit accessory equipment (e.g. humidifier, PEEP valve) to be used during the case.

11. Perform Leak Check of the Breathing System
    a. Set all gas flows to zero (or minimum).
    b. Close APL (pop-off) valve and occlude Y-piece.
    c. Pressurize breathing system to about 30 cm H2O with O2 flush.
    d. Ensure that pressure remains fixed for at least 10 seconds.
    e. Open APL (pop-off) valve and ensure that pressure decreases.

Manual and Automatic Ventilation Systems

12. Test Ventilation Systems and Unidirectional Valves
    a. Place a second breathing bag on Y-piece.
    b. Set appropriate ventilator parameters for next patient.
    c. Switch to automatic ventilation (ventilator) mode.
    d. Fill bellows and breathing bag with O2 flush and then turn ventilator ON.
    e. Set O2 flow to minimum, other gas flows to zero.
    f. Verify that during inspiration bellows delivers appropriate tidal volume and that during expiration bellows fills completely.
    g. Set fresh gas flow to about 5 L/min.
    h. Verify that the ventilator bellows and simulated lungs fill, and empty appropriately without sustained pressure at end expiration.
    i. Check for proper action of unidirectional valves.
    j. Exercise breathing circuit accessories to ensure proper function.
    k. Turn ventilator OFF and switch to manual ventilation (Bag/APL) mode.
    l. Ventilate manually and assure inflation and deflation of artificial lungs and appropriate feel of system resistance and compliance.
    m. Remove second breathing bag from Y-piece.

Monitors

13. Check, Calibrate and/or Set Alarm Limits of All Monitors
   • Capnometer
   • Oxygen Analyzer
   • Pulse Oximeter
   • Respiratory Volume Monitor (Spirometer)
   • Pressure Monitor with High and Low Airway Alarms

Final Position

14. Check Final Status of Machine
   a. Vaporizers off
   b. APL valve open
   c. Selector switch to “Bag”
   d. All flowmeters to zero
   e. Patient suction level adequate
   f. Breathing system ready to use

*If an anesthesia provider uses the same machine in successive cases, these steps need not be repeated or may be abbreviated after the initial checkout.
number of machine faults correctly detected when
the anesthetist used his or her usual preanesthesia
checkout method, and (2) the number of machine
faults detected using the revised FDA checklist.

Control variables consisted of following the
same procedure and using the same sets of pro-
grammed machine faults for each study partici-
pant. Each fault chosen for the study was identi-
fied as a potential source of machine error that
could endanger patient safety. Each fault was iden-
tified on the revised FDA checklist as an integral
part of the preuse checking procedure to ensure
proper functioning of the anesthesia machine. The
eight machine faults simulated for the research
study were:

1. CO₂ absorber leak: A leak between the ab-
sorber cannister surfaces was created with a one-
fourth inch paper pad barrier to simulate a leak
within the absorber system.

2. Vaporizer leak: A vaporizer leak was simu-
lated by partially closing a vaporizer filling cap.

3. Unidirectional valve failure: The unidirec-
tional valve on the inspiratory limb was removed
to simulate a reverse flow error during the exhal-
tation phase of ventilation.

4. Oxygen analyzer failure: The oxygen ana-
lyzer was modified to read less than 90% at an in-
spired oxygen fraction of 1.0.

5. Suction bulb leak: A leak was created within
the rubber suction tester bulb to simulate a low
pressure system leak.

6. Inadequate oxygen cylinder supply: The
reserve oxygen E cylinder was replaced with a cy-
linder containing less than 200 pounds per square
inch gauge.

7. Faulty resuscitation bag unit: The inhala-
tion valve of the bag-valve unit (ambu bag) was
forced into a fixed closed position.

8. Unintended setting of positive end-expira-
tory pressure (PEEP): The PEEP setting knob was
positioned so that maximal PEEP would be deliv-
ered via the breathing circuit.

Limitations of the study were:

1. Heightened sensitivity of study participants
to search for anesthesia machine faults.

2. Participants voluntarily engaged in the
study, which limits applying the study results to
the true population of anesthesia providers.

3. The original plan for this research was a

crossover design in order to eliminate the possibil-
ity of confounding the test results. However, it was
necessary to alter this plan in order to accommo-
date scheduling conflicts of study participants and
move the subjects efficiently through the testing
stations. Because a crossover design was not used,
the influence of testing order cannot be excluded.

The setting for the study was a temporary test-
ing area equipped to simulate an operating room
including two Ohmeda Modulus II anesthesia ma-
chines and an independent oxygen supply. The
machine faults chosen for the study were selected
because they represent major safety hazards to pa-
tients, were included on the FDA revised checklist,
and were practical to install on the testing anesthe-
sia machines.

The authors simulated four artificial machine
faults in each of two Ohmeda Modulus II anesthe-
sia machines. Listed below are the eight pro-
grammed machine faults:

**Machine 1**
A. Carbon dioxide absorber leak.
B. Inadequate oxygen cylinder supply.
C. Failure of oxygen analyzer.
D. Faulty resuscitation bag unit.

**Machine 2**
A. Unintentional PEEP.
B. Vaporizer leak.
C. Unidirectional valve failure.
D. Low pressure suction bulb leak.

The format of the study included four steps:

1. The participants of the study first com-
pleted a demographic questionnaire which de-
scribed prior anesthesia training, time period since
graduation, and current practice setting.

2. The participants were instructed to take ap-
proximately 15 minutes to evaluate anesthesia ma-
chine I, use their traditional checkout method, and
record any faults noted. A precise time limit was
not imposed.

3. The participants were then given a copy of
the revised FDA checklist to review for approxi-
mately 5 minutes.

4. The study participants were then asked to
check anesthesia machine II using the revised FDA
checklist and record any faults that were detected.

Instrumentation for the study consisted of two
Ohmeda Modulus II anesthesia machines, the sub-
ject questionnaire, anesthesia machine component
faults, and the data collection form.

The data collected in this research study con-
sisted of the number of correct faults identified by
study participants for each set of faults. Scores per
fault set for all subjects were converted into a mean
score for the entire group. The investigators se-
lected the t test for paired observations as the sta-
tistical procedure because the study compared fault
detection before and after introduction of the re-
vised FDA checklist. The study subjects served as
their own control. A P value less than 0.05 was
considered significant.
Results

For the purpose of this study, inadequate fault detection was defined as detection of 50% or less of anesthesia machine faults. The authors concluded from analysis of the data that the current checkout methods used by anesthesia providers were inadequate for the detection of more than half of anesthesia machine faults. For fault set A, 12 of 22 subjects (54.5%) found 50% or less of the machine faults. In fault set B, a total of 9 of 22 subjects (40.9%) found 50% or less of the programmed faults.

The authors of this research study concluded from data analysis that introduction of the revised FDA checklist did not significantly improve providers' abilities to detect anesthesia machine faults. There was no statistically significant difference ($P = 0.479$) between the fault detection scores using the anesthetists' own method and the revised FDA checklist.

An individual analysis was performed for each programmed fault in the study. The authors noted the faults most frequently recognized by subjects were:

1. Inadequate oxygen cylinder supply.
2. Failure of oxygen analyzer.
3. Carbon dioxide absorber leak.
4. Ventilator leak.
5. Low pressure vaporizer leak.

Those faults which were not detected by 50% or more of the subjects were:

1. Faulty resuscitation bag unit.
2. Unidirectional valve failure.
3. Unintentional PEEP.

Discussion

After reviewing results of the fault detection data, the authors observed that study participants detected similar numbers of faults whether using their own method or using the revised FDA checklist. Analysis of the $t$ test supports the conclusion that there was no significant difference between the two methods of fault detection in this study.

Even though the subjects worked diligently to discover as many faults as possible, the results indicated that a large percentage of experienced anesthesia providers displayed inadequate fault detection skills, even with the benefit of the newly revised FDA checklist. The results of this research study suggest several opportunities for improvement in clinical anesthesia practice. Given the great responsibility inherent in the provision of anesthesia, the need for improved fault detection is imperative.

The authors suggest that more improvement is needed than current methods ensure through anesthesia training programs, inservice refresher, or self-study. In the design for this study, the participants were given approximately 5 minutes to examine the revised FDA checklist. However, no formal training or inservice teaching was provided for the subjects. Because it is likely that the subjects felt a heightened awareness for potential machine errors in the testing situation, educators may conclude that this is an area worthy of greater study.

Other variables pertaining to the study design may have affected the results of the data. The location for the study was adjacent but outside the operating room; thisrequired subjects to participate in the study between surgical cases or outside of normal work hours. Some subjects were interrupted to return to the operating room, while others participated in the study between scheduled cases.

Study participants were eager to find all possible faults and were sensitive about their performance. Study participants tested each machine without other subjects looking on, and the privacy of each subject was assured. Because of the subjects' sensitivities, anonymity of each score was promised. In a small anesthesia department, individual privacy would be violated if years of experience were correlated with test scores. Therefore, no analysis for relationship of score with years of experience was performed with the data.

In addition, there was no analysis performed to determine any potential difference between types of anesthesia providers. The stated purpose of the study was only to determine effectiveness of the fault detection method. In order to enlist maximum participation from the entire anesthesia staff, participants were assured of confidentiality in testing.

In order to eliminate the possibility of obscuring the test results, it is suggested that this study be replicated using a crossover design. It is also suggested that this study be replicated with the addition of inservice training on the use of the revised FDA checklist. It may also be beneficial to incorporate into the study design a mechanism to give immediate feedback to subjects about their performance.

The data of this research study demonstrated that introduction of the revised FDA checklist did not significantly improve providers' abilities to detect anesthesia machine faults. Given the enormous responsibility of anesthetists for patient safety, the authors concluded that current checkout methods used by the study subjects were inadequate for the detection of anesthesia machine faults.

Perhaps the principle of inservice training would provide the link between theory and out-
come to promote the use of the FDA checklist. Research by Henry concluded that participants who were exposed to an educational course on the original FDA checklist experienced an increase in fault detection ability. Additional research is needed about the use of inservice training when introducing a new anesthesia practice element.

Another suggestion arising from this study incorporates the idea of continuing education. Professional anesthesia educators could potentially reach many clinical practitioners if this study was duplicated at state and national meetings. The hands-on experience of testing with immediate feedback could encourage behavioral changes to promote inclusion of a checklist into daily practice.

In conclusion, prior research has demonstrated the clear need to improve anesthesia safety and preuse checkout procedures. The revised FDA checklist represents an effort by anesthesia groups to raise awareness about safety problems and provide a step-by-step method to ensure preuse anesthesia machine safety. Data from this study demonstrated that introduction of the revised FDA checklist did not improve providers' abilities to detect anesthesia machine faults.

Perhaps what is needed is an integrated approach to improving safety through education, training, and evaluation. Just as manufacturers of a new product "sell" their merchandise via repeated exposure through the media, anesthesia safety advocates may need to marshall a great campaign to call attention to the problem. Using existing communication avenues, the importance of the preuse anesthesia checklist could be broadcast through anesthesia professional meetings, publications, and inservice training. It is essential that anesthesia practitioners recognize the need to improve the preuse anesthesia machine inspection.

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ACKNOWLEDGMENT
The authors wish to thank the following: Ruth Hassinein, PhD, for statistical analysis and valuable advice; Margaret Gibson for manuscript revision and technical assistance; Sharon Hadenfeldt, CRNA, MSN, and Carol Elliott, CRNA, MPA, for manuscript analysis; and Jay Crowley, BSME, for his cooperation and background assistance.

The views expressed in this article are those of the authors and do not reflect the official policy of the U.S. Public Health Service, the Department of Health and Human Resources, or the U.S. Government.
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