Multidose vial contamination in anesthesia

The intent of this research was to address the following question: Will an alteration in the drug aspiration technique cause a significant difference in the incidence of multidose vial contamination?

The control group consisted of multidose vials collected at the end of each day from staff anesthetists. The use of these vials reflected the practice technique of a single needle and syringe for each vial. The vial, as well as needle and syringe, were used on all cases managed for the day.

The experimental group consisted of multidose vials collected at the end of each day from the four investigators. The vials and syringes were utilized in the same manner as the control group with the exception that a new needle was used each time a vial was reentered.

Upon completion of the collection period, guaiac testing, using Hemoccult® slides and developer, was performed on a 0.1 cc sample from each vial. A multidose vial was considered positive for blood contamination if traces of blue appeared on the Hemoccult slide in a 15-minute period. A chi-square statistic was applied to the cumulative data.

The control group consisted of 492 multidose vials. Of the 492 multidose vials tested, 11 were guaiac positive, 2.24% (Table I).

The experimental group consisted of 369 multidose vials. Of the 369 multidose vials, one tested guaiac positive, 0.27% (Table II). A chi-square test on the cumulative data demonstrated a significant (p < .05) difference between the two groups.

The research demonstrated that occult blood may be contained within the used multidose vials suggesting that contaminated drug may then be injected into another patient. Contamination of multidose vials with blood, even when needles are changed, suggests that the safest technique for the patient, as well as the health care provider, might be to use a new needle and syringe each time the multidose vial is entered.

Multidose vial contamination with blood carries the inherent risk of transmission of potentially lethal diseases. Anesthesia practitioners utilize multidose vials in daily anesthesia practice which may have a significant impact on patient and practitioner safety through iatrogenic disease transmission. An investigation of this potential source of contamination may result in revised practice techniques.

Introduction

A major concern in medicine is transmission of blood borne disease, namely hepatitis and human immunodeficiency virus (HIV). Hein and associ-
ates indicated that fluid within intravenous tubing may be a source of blood contamination. A routine practice among some anesthesia personnel is daily preparation of a single set of syringes and needles for each drug used. Previously, reutilization of needles and syringes for different cases has been an acceptable practice in various institutions. This practice is based on the assumption that drugs are sterile, and unless there is visible evidence of blood contamination in intravenous tubing, the patient and practitioner are free of risk of disease transmission.

The purpose of this study was to measure multidose vial contamination with blood secondary to single needle and syringe use. Therefore, this research addressed the following question: Will an alteration in drug aspiration technique cause a significant difference in the incidence of multidose vial contamination?

**Literature review**

A significant number of anesthetic drugs are contained in multidose vials. Following the use of multidose vials, anesthesia practitioners questioned their sterility and potential to carry contaminants from patient to patient. This led researchers to theorize that multidose vials may serve as a potential mechanism of cross contamination.

Initial studies of multidose vial contamination have elicited varied results. Young and associates tested 52 previously opened vials for bacterial contamination and found no growth in culture media. In addition, control vials inoculated with bacteria did not yield positive cultures following three days incubation. These results led to the conclusion that despite the potential for contamination, medications or preservatives used in multidose vials are bacteriostatic. Ravnik and Yatsco cultured 141 previously opened vials and also demonstrated no bacterial growth. Petty and associates assessed 141 previously opened vials and noted no bacterial or viral growth after culture. Furthermore, Bowden et al. assessed 857 opened multidose vials and demonstrated no growth; however, control vials that were intentionally contaminated demonstrated growth of bacteria in samples taken 24 hours later. The authors concluded that the bacteriostatic activity of most drugs used in multidose vials minimizes the risk of cross contamination. Reinforcing these results, Seth et al. and Schubert et al. produced similar findings.

In contrast, Kohan and associates cultured 490 previously opened multidose vials and measured a contamination rate of 2.7%. Then concluded that using a larger sample size permitted a more realistic measurement of contamination. Bothe was also able to produce positive bacterial growth in 7 samples collected from 26 multidose vials. Furthermore, Highsmith et al. contaminated numerous vials used in anesthesia practice. Their results indicated that few drugs possess bactericidal activity when tested over a four-day period. Because the authors used 13 commonly occurring pathogens, they could not rule out the potential for contamination of multidose vials.

Prior to 1983, multidose vials were not implicated in patient infection. However, Alter and associates reported that 10 of 11 patients receiving medication from a multidose vial contaminated with hepatitis B tested positive for this antigen. Nakashima et al. implicated multidose vials contaminated with Serratia marcescens as causing septic joints in 10 patients.

Recently, a renewed focus has arisen concerning blood and blood products and the potential for disease transmission. Hein et al. pursued the possibility of contamination of blood and blood products in intravenous fluid within the intravenous tubing and suggested that this contamination might place anesthesia personnel, who handled needles used in the delivery of intravenous anesthetics, at risk. This concern was verified by guaiac testing of fluid drawn from intravenous tubing demonstrating a 14% contamination rate.

Previous research and case studies conclude that multidose vials can be contaminated with bacteria and hepatitis B antigen. In addition, intravenous tubing may also be a source of contamination of blood borne diseases. This raises the question: Could the procedures used in present day anesthesia practice facilitate contamination of multidose vials with blood?

**Methodology**

The Hemoccult® slide and developer (SmithKline Diagnostics, Inc.) was selected as the measuring instrument. The Hemoccult slide is sensitive to blood dilutions up to 1:10,000. However, product information states that dilutions of 1:5,000 are reliably measured by the instrument (SmithKline, 1986). Morris supported the sensitivity of this instrument by demonstrating a 93-97% reliability at a dilution of 1:5,000. Hemoccult analysis also measures fewer false positive results when compared to saturated guaiac, tincture of guaiac and hematest. Ostrow reported that Hemoccult slides yielded 25% fewer false positive results than other forms of guaiac testing. In addition, Morris concluded that the use of Hemoccult slides is the most sensitive guaiac test.

Acidity has an impact on the accuracy of this instrument. Long and associates reported that
Hemoccult slide testing measured a significant number of false positive results at a pH of less than 2.0. However, anesthetic drugs tested in this study possessed pH values in excess of 2.0. Furthermore, it has been demonstrated that iodine-containing solutions may result in false positives. This variable was controlled by not utilizing iodine swabs to cleanse the vials prior to use. In order to control for false positives resulting from the anesthetic drugs themselves, all study drugs were drawn from unviolated vials and guaiac tested. Drugs shown to give false positives (succinylcholine, d-Tubocurarine and sodium heparin) were eliminated from the study.

The control group consisted of multidose vials collected at the end of each day from staff anesthetists. The use of these vials reflected the practice technique of a single needle and syringe for each vial. The vial, as well as needle and syringe, were used on all cases managed for the day.

The experimental group consisted of multidose vials collected at the end of each day from the four investigators. The vials and syringes were utilized in the same manner as the control group with the exception that a new needle was used each time a vial was reentered.

Upon completion of the collection period, guaiac testing was performed by gently agitating each vial, withdrawing 0.4 cc of fluid by individualized tuberculin syringe and placing 0.1 cc on the test window of the Hemoccult slide. The appropriate functioning of the slide was determined by placing one drop of the developer between the positive and negative performance monitors. Subsequent to a positive performance result, two drops of Hemoccult developer were placed on the slide window. The test windows were read by the same investigator for trace positive guaiac (blue) at one-minute intervals up to 15 minutes. A multidose vial was considered positive for blood contamination if at any time during the 15-minute period traces of blue appeared on the Hemoccult slide. A chi-square test was applied to the cumulative data. The chi-square statistic was used to test the difference in proportions in two or more groups.

### Results

The control group consisted of 492 multidose vials. Of the 492 multidose vials tested, 11 were guaiac positive, 2.24% (Table I). The experimental group consisted of 369 multidose vials. Of the 369 multidose vials, one tested guaiac positive, 0.27% (Table II). A chi-square test on the cumulative data demonstrated a significant (p < .05) difference between the two groups.

### Discussion

Results of this study support the potential for transmission of blood through multidose vials. Recent surveys pertaining to HIV demonstrate an increasing number of carriers among the general population. Kelen reported a 6% HIV rate of infection in a metropolitan hospital emergency room. This amounted to a 0.8% increase from the previous year. This is consistent with the Centers for Disease Control's (CDC) concern about HIV's growing prevalence.

HIV is also a growing concern for the healthcare worker. As of June 1989, 25 cases of healthcare workers seroconverting to HIV antibody positive status following occupational exposure have been reported. All 25 healthcare workers denied known risk factors. Sixteen cases are believed to have resulted from needle stick injuries, two as the result of contact with sharp HIV-contaminated objects and seven through mucous membrane exposure or bro-

### Table I

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<th>Drug</th>
<th>Positive</th>
<th>Negative</th>
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<tr>
<td>Atropine</td>
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<td>97</td>
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<tr>
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<td><strong>Total</strong></td>
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<td><strong>Percent</strong></td>
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### Table II

<table>
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</thead>
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<td>Trandate*</td>
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</tr>
<tr>
<td><strong>Total</strong></td>
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<td><strong>368</strong></td>
<td><strong>369</strong></td>
</tr>
<tr>
<td><strong>Percent</strong></td>
<td><strong>0.27%</strong></td>
<td><strong>99.73%</strong></td>
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</table>

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ken skin. In addition to these cases, at least 44 other healthcare workers with no other risk factors have been diagnosed with acquired immunodeficiency syndrome (AIDS).19

It has been determined that of all cases of healthcare workers exposed to HIV-contaminated material, 0.42% will convert to an HIV seropositive test.20 This incidence may seem small but, with the probable 100% mortality of AIDS, it cannot be overlooked. Because the greatest incidence of exposure to the healthcare worker occurs from needle sticks, healthcare providers may appreciably decrease the incidence of such occurrences by a simple change in technique.

While HIV continues to be a main focus in current literature, hepatitis continues to be the greater risk to the patient and healthcare provider who comes in contact with blood and blood products. Although the mortality rate of hepatitis B is considerably lower than with HIV, hepatitis B still incurs a 1% mortality rate of those infected.21 It is important to note that approximately one-tenth of those infected with hepatitis B virus will become chronic carriers capable of transmitting this infection to sexual partners, as well as to household contacts.22

Viral hepatitis also continues to be an ever-present risk to the patient and healthcare provider although the mortality rate is undefined. Viral hepatitis may cause chronic liver disease in 10-40% of those infected.23 One study over a four-year period showed that 10% of high risk patients were diagnosed with hepatitis. Of these patients, 42% were diagnosed with hepatitis B, while 25% were considered viral in origin.24

These statistics indicate that patients are certainly at risk when exposed to blood and blood products. This study demonstrated that anesthesia care providers may be placing themselves and their unsuspecting patients at great risk. In February 1989, the AANA Board of Directors adopted Infection Control Guidelines for Anesthesia.25 These guidelines, along with the CDC's recommendations, were designed to prevent and control the spread of infection within the operating room environment. These recommendations were formulated to protect the healthcare worker, in particular, by preventing needle stick injuries. The use of needles and syringes with multidose vials is directly addressed by the AANA guidelines: "Used needles and syringes should not be reinserted into multidose vials."

The research results of this study support the stated AANA guidelines but an emphasis must also be placed on patient safety as well as that of the healthcare provider. The research demonstrated that occult blood may be contained within the used multidose vials suggesting that the contaminated drug may then be injected into another patient. Contamination of multidose vials with blood, even when needles are changed, suggests that the safest technique for the patient as well as the healthcare provider would be to use a new needle and syringe each time the multidose vial is entered.

The research demonstrates that using the practice technique of one needle and syringe per multidose vial may certainly place the patient at undue risk. The research supports the AANA and CDC guidelines as the only technique to eliminate the risk of transmission of blood borne diseases.

Incorporating these guidelines, however, may create some challenges. Present day healthcare costs have risen at an insurmountable rate. The increased cost of syringes and needles, as well as the increased amount of time required to prepare extra supplies, will undoubtedly be incurred by the patient.

The logistics of this solution must also be considered. In a busy anesthesia department, inventories may increase dramatically. This will ultimately result in increased capital expenditures, the cost of which would be ultimately absorbed by the patient.

Probably the most difficult problem to overcome in incorporating a new technique is reeducation of the anesthesia care provider. Care providers must learn to recognize that certain techniques may have detrimental effects on themselves and patients. The care provider must be given the time to learn and assimilate the new technique.

Another potential solution may be the use of unit dose medication, possibly prepackaged in a syringe. This drug delivery configuration, although costly, would eliminate the risk of contamination. The extra cost incurred by a unit dose system may be justified when considering the potential risk of incurring a long-term or fatal disease.

This study found contamination of multidose vials occurs following the use of a single needle and syringe. Consequently, guidelines established by the AANA and CDC must be seriously considered by all anesthesia providers. The risk/benefit ratio of a change in current technique must also be seriously considered with adoption of revised approaches to drug administration if warranted.

REFERENCES

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