The Incidence of Blood Contamination of Lead Unit Dose Containers With and Without Single-Use Protective Inserts Used with Commercially Prepared Radiopharmaceutical Unit Doses

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Objective: This investigation evaluated the effectiveness of disposable plastic inserts in radiopharmaceutical unit dose lead containers (pigs) in preventing the distribution of doses in blood-contaminated containers. Technologists commonly dispose of the syringes by placing them into the lead pigs, leaving the needles uncapped. This process raises the question of unsuspected blood contamination of these pigs. Consequently, the distribution of commercially prepared radiopharmaceutical doses in reusable lead pigs may result in radiopharmaceutical doses being distributed in containers that are contaminated with blood.

Methods: Using a simple chemical wipe test designed to determine the presence or absence of blood contamination, 618 pigs from commercial radiopharmacies throughout the U.S. were tested for contamination. The inside of the pigs and inserts, if present, were wiped before and after dose administration. Of the pigs tested, 292 came from radiopharmacies that used a protective, disposable plastic insert inside the pig, and 326 came from radiopharmacies that did not use an insert.

Results: Of those pigs without the protective disposable inserts, 39.3% arrived in the nuclear medicine department in pigs contaminated with blood. Of those pigs with inserts, 1% arrived with blood-contaminated inserts. After dose administration, 46.3% of the pigs without inserts were contaminated with blood and 3% of the protective inserts were contaminated.

Conclusion: The proper use of disposable plastic inserts reduces the possibility of distributing radiopharmaceutical unit doses in containers contaminated with blood.

Key Words: blood contamination; bloodborne pathogens; lead pigs; unit dose lead containers; disposable liners

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Commercial radiopharmaceutical suppliers usually supply their unit dose products in syringes contained in reusable lead containers, commonly called pigs. Technologists often dispose of the syringes used to administer radiopharmaceuticals by placing them into the lead pigs, leaving the needles uncapped. This process has raised the question of unsuspected blood contamination of these containers. Consequently, the distribution of commercially prepared radiopharmaceutical unit doses in reusable lead pigs may result in radiopharmaceutical doses being distributed throughout the nuclear medicine community in containers that are contaminated with blood. Transporting radiopharmaceutical doses in contaminated pigs exposes both technologists and patients to a potential route of environmental transmission of bloodborne pathogens (*1,2*).

One such bloodborne pathogen is the human immunodeficiency virus (HIV). As of June 1997, the Centers for Disease Control and Prevention (CDC) reported that 52 health care workers with known occupational transmission and 114 workers with suspected occupational transmission had documented HIV seroconversion after exposure to the virus (*3*). Though blood is the single most important source of HIV infection, environmental transmission of this virus from contaminated pigs is not likely due to the fragility of the virus. However, infection cannot be totally eliminated (*2,4*). Contaminated equipment can be disinfected with chemical germicides such as a 1:1000 dilution of household bleach or 0.3% hydrogen peroxide to which HIV is relatively sensitive (*2*). Cleaning protocols mandated by OSHA in its Bloodborne Pathogen Standards should help decrease any likelihood of environmental transmission or contraction of this virus (*5*).

Hepatitis B virus (HBV) is another bloodborne pathogen that could be transferred environmentally from a blood-contaminated object to another object or person. This virus has been characterized as the greatest occupational risk from bloodborne pathogens by the Occupational Safety and Health Administration (OSHA) (*6*). Each year approximately 8,700 health care workers contract hepatitis B, and 200 health care workers per year will die of the disease (*7*). Unlike the human immunodeficiency virus, the hepatitis B virus remains viable in conditions that would otherwise destroy other pathogens (*8*). HBV is relatively stable on environmental surfaces and retains

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its infectivity in dried blood for at least 1 week at room temperature (*1*). Its high concentration (10^8–10^9 HBV particles) per milliliter of blood also contributes to the virus' infectibility (*1*). Blood diluted until no longer visible or chemically detectable may still contain 10^2–10^3 HBV particles per milliliter of blood (*2*). Equipment that comes in contact with blood should undergo the same cleaning procedures as for the human immunodeficiency virus. These procedures should be followed by disinfection measures such as with 2% glutaraldehyde or 70% isopropyl alcohol (*2*).

In response to OSHA's recommended procedures to minimize needle sticks (*9*), one commercial radiopharmaceutical manufacturer has implemented the use of a protective, disposable, plastic insert in unit dose lead pigs. These inserts were originally developed to reduce the risk of needle sticks to nuclear pharmacy personnel by providing customers with a point-of-use sharps container to dispose of uncapped used needles attached to syringes. It was hypothesized that these inserts also might prevent the distribution of blood-contaminated containers. This study evaluated that hypothesis.

MATERIALS AND METHODS

Over an 8-mo period, 618 unit dose lead pigs and, if present, their inserts were tested for blood contamination. The pigs came from large and small commercial radiopharmacies throughout the U.S. A complete test for contamination was performed on each pig and insert before and after dose administration. The pigs from the 27 nuclear medicine departments were evaluated; 292 unit doses came from radiopharmacies that used protective, disposable plastic inserts inside their pigs and 326 unit doses came from radiopharmacies that did not use inserts. Testing was accomplished by a sensitive and specific forensic blood detection kit based on methodologies described by Lee (*10*) and packaged by a forensic science service.

The blood detection test kit was specifically designed to detect the presence of blood contamination in a three-stage process. Stage 1 required the application of ethanol, an extraction agent, to a cotton swab tip. The ethanol-soaked swab was used to wipe the inner surface of the pig or insert completely. Stage 2 entailed adding phenolphthalin, containing zinc dust to maintain its reduced state, to the same swab tip. Finally, Stage 3 called for the addition of an oxidizing agent, such as hydrogen peroxide or sodium perborate as the developing solution, to the cotton tip. A reddish-pink color change on the swab tip after the final stage indicated a positive test for blood contamination (Table 1) (*10*).

TABLE 1
Bloodstain Detection Kit Procedure*

Solution A: Ethanol mixture
Solution B: Phenolphthalin working solution
Solution C: Developing solution

1. Saturate one long cotton swab with 2–3 drops of Solution A.
2. Swab the bottom surface of each lead pig or insert as completely as possible. As the swab is being withdrawn, use a circular motion to wipe the sides of the pig or insert up to its rim. The 2–3 drops should have made the swab wet enough to have contacted the entire inner surface of the pig or insert.
3. Place 1–2 drops of Solution B on the cotton tip.
4. Within 10–15 sec, place 1–2 drops of Solution C on the cotton tip. The appearance of a reddish-pink color on the swab tip indicates a positive test for the presence of blood. If no color change occurs or the change takes longer than 30 sec to appear after the addition of Solution C, then the test is considered negative for the presence of blood.

*Developed by David Sugiyama (*personal communication*, 1997).

In the presence of the heme group of hemoglobin found in blood, the developing solution oxidized the phenolphthalin to phenolphthalein. Blood, if present, exhibited peroxidase-like activity directly proportional to its hemoglobin content which catalyzed the peroxide oxidation of phenolphthalin to phenolphthalein in alkaline solution. The colorless phenolphthalin, once converted to phenolphthalein in alkaline solution, exhibited a reddish-pink color indicating a positive test (Fig. 1). Other chemical oxidants give a color reaction before addition of the developing solution. A false-positive reaction would therefore be detected after addition of the phenolphthalin solution alone (*10*).

RESULTS

The incidence of blood contamination was calculated as a percentage of the total inserts and pigs that were tested. Of those pigs without the protective, disposable inserts, 39.3% arrived in the participating nuclear medicine departments with blood contamination. Of those pigs with inserts, 1% had blood contamination on arrival. After dose administration, 46.3% of the noninsert pigs were contaminated with blood and 3% of the inserts from the insert pigs were contaminated. Only 5.8% of the insert pigs with inserts removed were found to be contaminated with blood before dose administration. This percentage increased to 6.5% after dose administration. Figures 2-4 present these frequencies graphically.

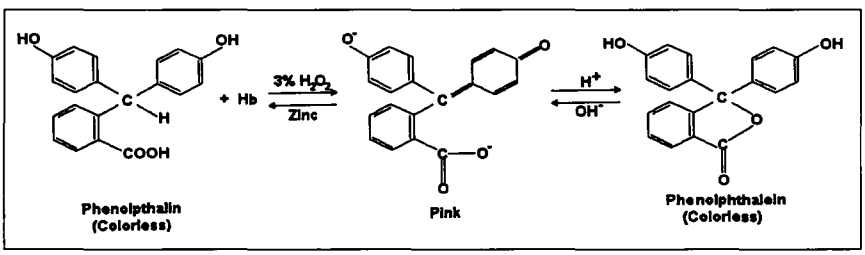

FIGURE 1. Primary chemical reaction involved in the catalytic blood detection test used in this study. In the presence of hemoglobin and a peroxide-like oxidant, colorless phenolphthalin in alkaline solution is oxidized to reddish-pink phenolphthalein indicating a positive test for the presence of blood (*10*).

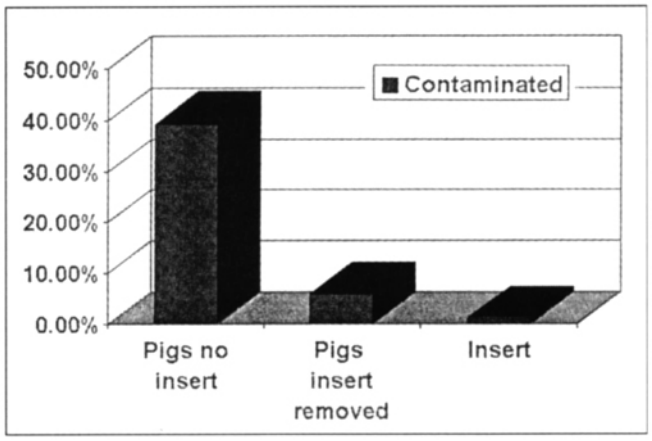

FIGURE 2. Histogram of blood contamination rates on arrival in the nuclear medicine department.

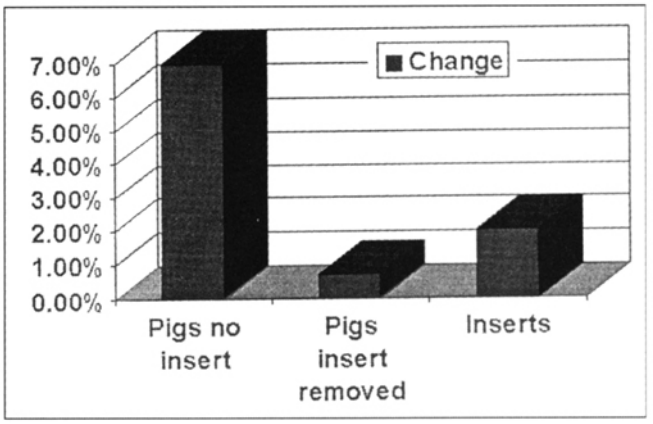

FIGURE 4. Histogram of change in blood contamination rates before and after dose injection.

DISCUSSION

We observed several factors that might have affected study results. Not all departments returned used syringes to the commercial radiopharmacy, regardless of the type of lead pig. The used syringes were either immediately discarded or temporarily placed in the pig or insert until they could be disposed of later in the department's radioactive trash. Also, both types of pigs frequently were used to store used cotton balls, alcohol prep pads and intravenous administration supplies. On occasion technologists would remove an insert in order to use the lead pig for other purposes. Sometimes the insert then was replaced before returning the pig to the radiopharmacy. In addition, despite recommendations to the contrary, technologists frequently recapped syringes before placing them back in the pigs.

An unexpected result was the discovery that some inserts were contaminated with blood on arrival in the nuclear medicine department (Fig. 2). It was later determined that these inserts had been unknowingly recycled at one radiopharmacy, thereby causing the insert contamination on arrival. After this discovery the radiopharmaceutical manufacturer in question reported that an in-house audit system had been initiated to prevent reuse of the disposable inserts.

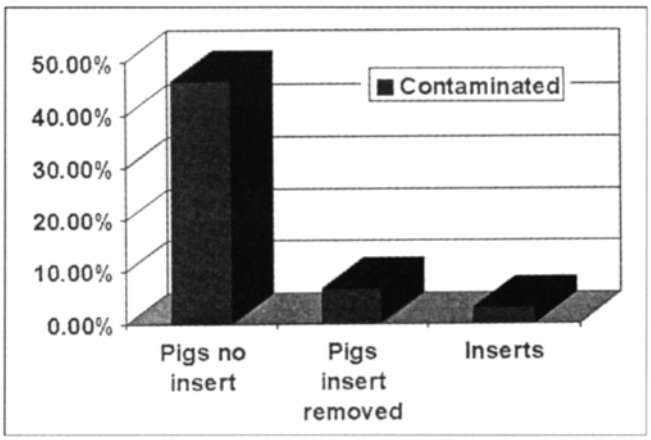

FIGURE 3. Histogram of blood contamination rates after injection of the radiopharmaceutical.

A high percentage (39.3%) of noninsert pigs was contaminated with blood on arrival in the nuclear medicine department (Fig. 2). If the radiopharmacies were cleaning their lead pigs on a regular basis, it appears that the process was not effective.

The results of contamination of pigs with inserts removed may have been caused by technologists removing the inserts and using the pigs to carry blood-containing objects. This was demonstrated by the incidence of contamination of the inside of the pigs (with the inserts removed) both before and after the dose had been administered. (Figs. 2 and 3).

Although technologists handled the doses and lead pigs in a variety of ways, (i.e., not placing used syringes in lead pigs, recapping syringes before disposal, using pigs in unexpected ways), there is no indication that these variations gave false-positive contamination results.

CONCLUSION

Lead pigs without the use of protective, disposable, plastic inserts exhibited a greater incidence of blood contamination than pigs with inserts. The proper use of disposable, plastic inserts in lead pigs significantly reduced the possibility of distributing radiopharmaceutical unit doses to nuclear medicine departments in blood-contaminated containers.

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