A review: occupational safety in blood banking—concepts and conundrums

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The field of blood banking is grappling with a new facet of regulation and risk. Long accustomed to regulations governing the safety and efficacy of blood products, blood bankers are now anticipating federal regulations on occupational safety. Yet despite all attempts to reduce occupational safety risks—through appropriate procedures introduced by management, diligent efforts by employees, and oversight activities by regulatory agencies—safety remains an elusive quality. Just as a truly risk-free society is not obtainable, workplace safety can never be absolute. What then are the goals of occupational safety programs? How should risks be managed in blood banking environments?

This review will attempt to define reasonable goals for worker safety in blood banking. There are different perspectives that must be considered in defining the requirements for safety. The risk of an environment must be understood and accepted by those working in it. In reviewing these concepts, readers will be able to assess what "safety" means to them in their environment and subsequently take appropriate measures to satisfy their own safety requirements and those of regulatory agencies.

The definition of safety

A theoretical discussion in personal terms

The concept of safety involves intangible assurances and tangible outcomes. How "safe" an activity must be is established by one's own needs in the context of a particular situation. A person enrolling in jump school must recognize that the parachute will open on a certain proportion of jumps. If the student is unwilling to accept the risk that the parachute will fail to deploy occasionally, the student will never leave the airplane door.

Putting aside inaccurate perceptions of the risks involved, the benefits to be gained from an activity must ultimately outweigh the risks before a person will engage in the activity. When a person seeks out an activity, such as skydiving, the participant clearly derives some benefit, even if only psychological, from participation. A person deriving high benefit from an activity may be able to accept higher risks and still make his own risk/benefit equation tally to the positive side. If an individual perceives little benefit from participation in an activity, less risk will be assumed before the activity will be abandoned. Personal motivation must also be recognized: one may tend to minimize risks of an activity that one wishes to perform but maximize the risks of activities one really wishes to avoid.

Practical considerations

Clearly, "safety" means different things to different people. In today's society, a common approach to safety is couched in absolute terms: If an untoward event *can* happen, the activity is unsafe. Given recent increases in concern over avoiding infection with the human immunodeficiency virus (HIV), laboratory workers today seek absolute guarantees that HIV will have no chance of infecting them.

This concept of absolute safety prevalent in society today[1] has become mirrored in statutes, regulations, and societal consciousness. While recreational or nonessential activities are not closely regulated (eg, one does not need a license to fly a hang-glider), occupational and other activities in which one has limited choices are much more closely regulated in an attempt to create an environment that has minimal risk.[2] Although we are free to choose a profession, society attempts to codify risk reduction toward the end of eliminating, or at least defining and controlling, risks

that may be encountered in the workplace.

The concept of absolute safety and the fear of transmission of an incurable disease, AIDS, are redefining safety in the clinical laboratory. Although clinical laboratory workers had higher rates of tuberculosis, diarrhea, and possibly hepatitis and shigellosis *prior* to implementation of now-common safety precautions,[3-6] clinical laboratories are not generally regarded as "unsafe" places to work today. The proportion of persons with AIDS who were health care workers is the same as the proportion of the workforce that is employed in health care.[7] However, the laboratory is an environment where one may come into contact with blood that may contain an infectious agent,[8] and transmission of HIV from a concentrated culture has occurred despite apparent observance of applicable safety precautions.[9] It is also known that 15–20 percent of some laboratory workers have serologic evidence of past hepatitis B infection,[10,11] far above the prevalence in the U. S. population of approximately 2–3 percent.[12] What are the risks of transmission of HIV in the clinical laboratory, and how can they be eliminated or controlled?

HIV is transmitted either through sexual contact or parenteral exposure to blood or other tissues or fluids containing the virus. These modes of HIV spread, long appreciated for the hepatitis B virus (HBV), do not seem to pose strong threats to the safety of health care workers. HBV transmission occurs with much higher efficiency than transmission of HIV. For example, 6–30 percent of individuals inadvertently stuck with a needle contaminated with HBV become infected.[13,14] In contrast, studies of health care workers parenterally exposed to HIV have reported seroconversion rates of 1 percent or less.[9,15-17] The oft-cited case of a needlestick injury of a nurse with a needle contaminated with the blood of a patient who had AIDS and was an HBV carrier is illustrative: the nurse developed hepatitis but did not become seropositive for HIV antibodies.[18] Prior to June 1987, six cases had been reported in which cutaneous contact with blood from individuals with AIDS had resulted in seroconversion of a care giver. The exposures in these cases had generally been prolonged and had offered the infected blood access to the host's body through skin that was not intact.

The report of three health care workers who seroconverted for HIV after short exposure to infected blood through skin with only (apparently) minor abnormalities[19] increased the level of concern that HIV transmission was a potential worthy of note in laboratories. Two additional factors led government, industry, and workers' representatives to reassess safety measures for laboratory workers. Two of the individuals whose blood caused these infections were not known at the time of the exposure to be HIV positive. Furthermore, increased concern was being expressed by some public officials that HIV was spreading quickly to individuals who would not be able to recognize that they had been placed at risk of HIV transmission.

Initial recognition in the 1960s and 1970s of HBV transmission as a laboratory hazard[20,21] led to infection-control measures directed at isolation and special handling of high-risk samples.[22] Until even recently, this approach had been endorsed by governmental agencies.[23] Numerous warning tags, labels, and alert systems have been devised in an attempt to warn lab workers and other health care providers that specimens from a particular patient represented a risk of infection. Given the low prevalence in the western world of HBV, and the introduction of standard lab safety practices such as a prohibition on eating and mouth pipeting in the laboratory and recommendations that hands be washed before eating, these precautions seemed reasonable in that they focused attention on those samples with significant potential for infection.[24] However, this approach has not been entirely successful: 12,000 cases of occupationally acquired HBV infection occur annually in this country among health care workers.[25] There are several reasons for this continued transmission of HBV to laboratory workers. First, basic safety precautions were not always followed. Second, specimens and patients were not always appropriately labeled. (750,000 Americans are HBV carriers and 1 percent of admissions may be HBV carriers.[23]) Thus, there remained a great potential for a health care worker to be exposed unknowingly to an infective specimen.[16,26,27]

The lab precautions used over the last decade were developed in response to HBV as the primary infectious agent of concern to blood bankers. Recognition of the potential transmissibility of HIV in laboratory situations has changed some of the variables in the equation of safety. Although present in blood at a far lower concentration than HBV and having an infection efficiency far below that of HBV,[13,14] HIV infection appears much more likely to cause clinical

disease.[28] Although the prevalence of hepatitis B surface antigen is ten times the seropositivity rate of HIV in the population of the United States, the crisis of HIV infection, and the real although extremely low possibility of HIV transmission to health care workers[9,17] has spurred the introduction of a new approach to protecting laboratory and other health care workers.

Safety Precautions

Lab safety standards today are intended to prevent transmission of all infectious agents from samples *known* to be infectious and those *not* suspected of harboring a transmissible agent. Termed "universal precautions," these standards regard every patient and specimen as potentially infectious.[7,29] As HBV and HIV hold the greatest potential for morbidity after infection among agents likely to be encountered in laboratories (other than microbiology labs) in this country, safety procedures have been designed to interrupt their transmission.[30,31] When other agents are of concern, application of the same principle would require use of precautions designed to safeguard against the spread of these agents with all specimens.[32] The alternative, testing all samples or patients for HIV, for example, would be impractical, pose substantial ethical problems, and still permit an unknown exposure to many health care workers.[7,29]

Knowledge of the potential routes of transmission of agents, especially HBV and HIV, thus becomes critical. Although all body fluids and tissues are now regarded as potentially infective, and HIV has been isolated from blood, semen, vaginal secretions, saliva, tears, breast milk, cerebrospinal fluid, amniotic fluid, and urine, the concentrations of virus found in some of these fluids may be below that required for infectivity.[7] The Joint Advisory Notice from the Departments of Labor and Health and Human Services recommends taking into account these and other variables when assessing exposure risk.[25] In the case of HIV, direct introduction inside the body appears to be necessary for infection, and only blood, semen, vaginal secretions, and breast milk have been implicated in HIV transmission.[8] Cutaneous contact with unbroken, undamaged skin does not appear to be a likely transmission route. Similarly, aerosols do not appear to represent a risk of transmission of HIV, based on the reported inability to transmit aerosolized HBV to gibbons.[33] This requirement for parenteral exposure for HIV transmission may be reflected in the lack of HIV seroconversions among health care workers with nonpercutaneous exposures, whereas 0.9 percent of workers with percutaneous or mucosal exposures have seroconverted.[13] Nevertheless, the approach taken by federal regulatory agencies and the guidelines proposed by the National Committee for Clinical Laboratory Standards (NCCLS)[34] would indicate that all routes of exposure *should* be avoided—even if these routes do not appear very effective in causing infection—because of the *possibility* of transmission and the dire consequences of infection.

What does this mean in practical terms? In simple and summary form: Avoid coming in physical contact with a fluid or tissue that may contain an infectious agent. The application of this recommendation becomes universal under current concepts, as all human fluids and tissues, except intact skin, are assumed to be infectious. Given the nature of the infectious agents at risk for transmission, all human blood would be considered as requiring biosafety level 2 precautions to avoid exposure.[35]

The means by which this contact is to be avoided will vary by the function being performed. In most tasks, however, barrier protection of hands is critical in interrupting transmission.[36] For personnel working with donors, gloves or equivalent protection should be worn during functions that may be anticipated to result in contact with blood, such as collection and handling of the predonation blood sample, venipuncture, and needle withdrawal. While the need and advisability of glove usage during normal donor phlebotomy continues to be debated, there is consensus that gloves are necessary if the phlebotomist's skin is not unbroken. In the laboratory, the production of components may result in leakage of segments; therefore, gloves should be worn. Some procedures, such as the segmenting of tubing, do not routinely cause direct exposure but, with some regularity, do result in an unavoidable spillage or splattering. For processes such as this, additional appropriate protective gear, such as safety glasses or eye or face shields, should be worn. Alternatively, a shield may be installed on the device, or some other barrier may be erected to obviate the necessity of additional protective gear.

Some type of protective garment should also be worn when working in a laboratory or collection site. This may be a buttoned, long-sleeve lab coat, overalls, or a uniform. A garment worn by a worker should pre-

vent direct contact with blood if a spill or splatter occurs. The garment could be removed to avoid contact through soaking. For other activities *not* commonly performed in blood banking, the garment may need to be waterproof, such as a plastic apron being worn over a gown.

Although transmission through breaks in skin and mucous membranes is important, one of the greatest risks of transmission of an infectious agent to health care workers is through skin puncture with a contaminated sharp object. Needlestick injuries are the most common of occupational injuries in health care and among the most effective in allowing a virus parenteral access. Needlesticks account for 80 percent of exposure among health care workers being tested for HIV exposure.[13,37] Data from the experience of the American Red Cross suggest that approximately 3,000 incidences of needle-related injuries occur during the processing and phlebotomy of 12 million U.S. volunteer whole blood donors annually. Regardless of all other safety precautions utilized, it is *essential* that *extreme diligence* is observed when handling needles and other sharp objects. Plastic or latex gloves, even in multiple layers, will not protect a worker from this form of injury. Needle capping and destruction have been abandoned, but in blood banking, there continues to be a need to handle needles after their removal from a donor's vein. The recent development of guards for needles that will allow the collection of pilot tubes after phlebotomy and that provide a safe and secure protective housing for their disposal will greatly reduce risks of needlestick injury in donor phlebotomy.

The clean-up of spills always presents a risk of direct exposure. Gloves should always be worn during the clean-up of spills, and special care should be exercised to avoid unexpected exposure. In addition, broken glass or other sharp objects may increase the potential for transmission of an infectious agent in this situation. Disinfection routines should take into account the amount of infectious material that could not be physically removed and the porosity of the surface. Contact for 20 minutes with household bleach diluted 1:10-1:100 is sufficient to inactivate HIV and HBV.[34,38]

Blood bankers working in laboratories have asked numerous questions about aerosols. How are they created and are they dangerous? True aerosols—microscopic droplets (≤ 5 microns) suspended in air —are not likely to be produced in blood bank laboratories. As mentioned earlier, aerosols do not appear to be viable vectors of HBV transmission. However, splattering and small, undetected splashes may be the mode of transmission in many cases of laboratory-acquired infections.[39] The splattering that may occur when removing the tops of evacuated pilot tubes may be reduced by covering the tops with a gauze or opening the tubes only after centrifugation. Blood bank centrifuges that contain open tubes do not obtain rotational velocities likely to produce aerosols. Although small droplets may be produced when a plastic bag or glass tube breaks in a centrifuge, these are confined within most centrifuge housings and can be allowed to settle before cleaning. Blending, sonicating, and vigorous mixing of samples, however, should be performed in a biological safety cabinet.[7] Thus, at present, current recommendations would not seem to suggest that special precautions need to be taken when centrifuging blood bags or specimens.

The lack of immediately available handwashing facilities on mobile blood drives presents a problem. It is recommended that hands be washed with soap and water whenever gloves are removed and/or hands or gloves are soiled. Use of common towelettes has not been recommended because of inadequate cleansing action. [34] Other alternatives might include a spray bottle filled with soap and another filled with rinse water or a towelette saturated with a topical disinfectant.

Care should also be taken in an environment in which both gloves and ungloved hands are present. Items that might be handled both ways, such as telephones, keyboards, records, writing implements, doorknobs or faucets, could become contaminated and present a theoretical exposure risk through an ungloved hand.[36,40,41] Although environmental contamination has never resulted in HIV transmission, it may be of more concern in the case of HBV.[7,31] One approach to this problem is mechanical, such as installing foot pedal or elbow-activated sinks and foot pedal phones. A simpler approach is to standardize technique and classify items as "clean" or "dirty."

Because of communications with representatives of the blood banking industry, federal agencies proposing workplace regulations understand that the risk of blood from a volunteer donor containing HIV or HBV is much less than when the blood originates from a patient.[14] This decreased risk is attributable to the testing of previous donations, health history assessments, and similar procedures. However, approx-

imately 1–2 of every 10,000 individuals completing the donation process have been exposed to HIV, and 10–50 times that proportion are positive for hepatitis B surface antigen. Thus, although handling only blood from volunteer donors may entail a much smaller likelihood of encountering infectious blood than handling patient specimens, this risk of exposure is not zero. Appropriate safety precautions must be taken, but the exact stipulations of federally required or recommended safety procedures are still under development.

Handwashing and glove use appear to present the greatest difficulties for blood bankers. Precisely following the recommendations for patient care of the Centers for Disease Control (CDC)[7] would require a phlebotomist to change gloves between contact with each donor. As most mobile blood drives have phlebotomists working with three or four donors at one time, innumerable glove changes would be required—with handwashing accompanying each. On the other hand, the Joint Advisory Notice has stated that barrier protection, such as glove use, is necessary, but does not require the changing of gloves other than to maintain worker protection.[25] This apparent discrepancy can be resolved by recognizing that the donation process is already safe. Transmission of an infection from one donor to another apparently does not need to be addressed, except perhaps in the perceptions of donors. Consequently, appropriate use of barrier precautions for donor phlebotomists would not require changing gloves unless soiled.

These comments, and any listing of safety procedures, can never encompass appropriate safety techniques for all tasks. When evaluating the potential for exposure in a task, what level of risk should cause a modification of the procedure or the institution of an additional safety precaution? This question cannot be answered precisely, but may be addressed from two vantage points. One is a cost/benefit approach. Although this concept may make sense on an overall perspective, it is not always acceptable to those taking the risk, regulatory agencies, and juries. The other approach is one of common sense. What is reasonable to one person may not be regarded as such by another. However, if an activity may be foreseen to present a substantial safety risk to those involved, appropriate precautions should be taken. Factors that should be taken into account when evaluating risks include:

- The type and volume of specimen to be encountered
- The likelihood of the specimen containing infectious agents (given the assumption that the person from which it came was infectious) and their concentration
- The probability and predictability of direct contact occurring
- The probable route of exposure and the transmission efficiency of the agent(s) in question via this route.

While absolute guidelines are not possible in such an evaluation, thoughtful consideration of the risks—and documentation of these evaluations—should result in procedures that most would regard as "reasonable." Recognition that nothing is absolute—and that even stringent decontamination procedures must be viewed in terms of probabilities[38,44]—may provide assistance in guiding the process.

Administrative Requirements

The administrative requirements regarding worker safety must also be mentioned. The above discussion used terms such as "recommendations" and "should." Is this truly advice or are these preventive actions mandatory? Although the scientific basis for some of the recommendations made here or in other documents may be less than conclusive, it would appear that governmental recommendations will be followed with regulations and that "should" is to be interpreted as "must." There are several reasons for this. The prestige of the Centers for Disease Control in matters relating to infection control and the credibility of NCCLS indicates that their suggestions must be taken very seriously. Moreover, the special relationships blood collecting agencies attempt to cultivate with volunteer donors and the community at large require that they maintain the highest standards of safety in all aspects of their operation. Thus, it would be prudent to regard these recommendations carefully in order to maintain the public's trust and confidence in this aspect of the operation, as a reflection of the agency's total commitment to quality and safety.

The involvement of the Occupational Safety and Health Administration (OSHA) in laboratory safety is another important consideration. OSHA has begun the administrative rule-making process to codify the recommendations of the CDC and the Joint Advisory Notice[5] into federal regulations.[45] In the interim, OSHA intends to enforce the intent of these recom-

mendations for safe practices through what is known as the "general duty" clause of the OSHA statute.[45] This section of the law requires employers to "provide a work environment that is free from recognized hazards that (may). . . cause death or serious physical harm. . . ."[46] In addition, OSHA issued similar guidelines in 1983 pertaining to glove protection for exposure to samples possibly containing HBV.[23] These may be used in a regulatory fashion to enforce the provisions of the CDC recommendations.[47]

These recommendations and advisory notices go beyond detailing concepts of safe practices. They also include procedures for education, record keeping, incident recording, and employee counseling. Establishment of procedures in concordance with the recommendations is not sufficient to satisfy OSHA regulations. Not only must employees receive training regarding proper procedures, they must be required to follow them under supervision and must be disciplined when found to be deviating from the procedures in an unsafe manner. Management personnel are advised to review appropriate OSHA and CDC documents to ensure that the laboratory's entire safety system, not just the recommended procedures, conform to these expectations.

Steps to Safety

Some thoughts on implementation

Reviewing current safety protocols—or revamping them entirely—can be a major undertaking, possibly too overwhelming to know where to begin. A few pointers are offered to initiate the process.

To begin, the tasks that must be performed should be analyzed to determine the source of potential risks. This implies a step-by-step review of all procedures performed, preferably by supervisory and line personnel working together to identify where and how exposure might take place. Once functions that represent potential risk have been identified, each should either be modified or a protective measure initiated and entered into the standard operating procedure. Removal of the potentially dangerous function or changing the equipment or procedure to remove or reduce the risk of exposure are obviously preferred approaches. Although inactivation of viruses before analysis is sometimes feasible,[15] the instability of certain analytes important in blood banking, especially IgM antibodies, would preclude thermal inactivation steps.[48] If the necessary degree of safety cannot be achieved in a reasonable manner by procedural or equipment alterations, protective measures such as barrier precautions must be initiated.

The Joint Advisory Notice[25] recommends classifying all tasks into one of three categories:

Category I: Tasks that involve potential exposure and that require protective equipment.

Category II: Tasks that do not involve exposure but exposure may occur because of performance of unanticipated Category I tasks.

Category III: Tasks that do not involve potential exposure. In this category, it is presumed that persons performing these tasks are not required as a part of their employment to perform Category I tasks.

This codification can take place using the guidelines mentioned above for evaluating exposure risks.

Through this approach, management can help employees follow safety protocols. The standard operating procedure for each task will include appropriate safety precautions. Staff will be educated and trained in these safety precautions. The situations in which precautions must be taken will be delineated, and staff will know when certain safety precautions must be utilized. This should limit the need for administrative oversight.

Prevention is a key in safety, but despite diligent efforts by all involved, occasional mishaps may occur. Planning ahead to thwart the effects of an exposure in an individual is an important second line of defense. Where vaccination is available, such as for hepatitis B, this should be seriously considered by all employees at potential risk for exposure. Management should support vaccination and other prophylaxis programs through visibility, accessibility, and financial support.[25] Although postexposure prophylaxis is often effective for hepatitis B, unknown exposure and inadequate postexposure prophylaxis may result in a serious disease that could have been avoided. Procedures for offering testing and counseling to workers should also be developed.

Some Final Thoughts

Is safety too expensive? Will safety procedures that are currently being "recommended" cost too much time, money, or donor support? What have we accomplished with these safety programs? The attempted introduction of a new laboratory safety code in Great Britain a decade ago[49] brought an avalanche

of opposition because of high costs and "impractical" requirements.[50] What role should blood bankers play in providing information, support, and direction to the regulatory agencies now developing safety regulations in this country?

It may be asserted that safety, like quality, is free.[51] The real costs occur when safety is not achieved. When safe procedures are followed, an intangible good is derived by all affected. When an accident occurs, real expenses may mount quickly in terms of lost products, decreased worker morale, and productivity and injury awards.[52]

A work environment free of unnecessary risk is a right of employees. By carefully defining the meaning of safety, thoroughly considering the risks involved, and applying societal and personal concepts of safety, blood bankers can make important contributions to the provision of safe workplaces.

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Readers are directed to references 8, 23, 25, 34, 35, and 45 for full details on safety practices and policies recommended or required by the federal government.

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