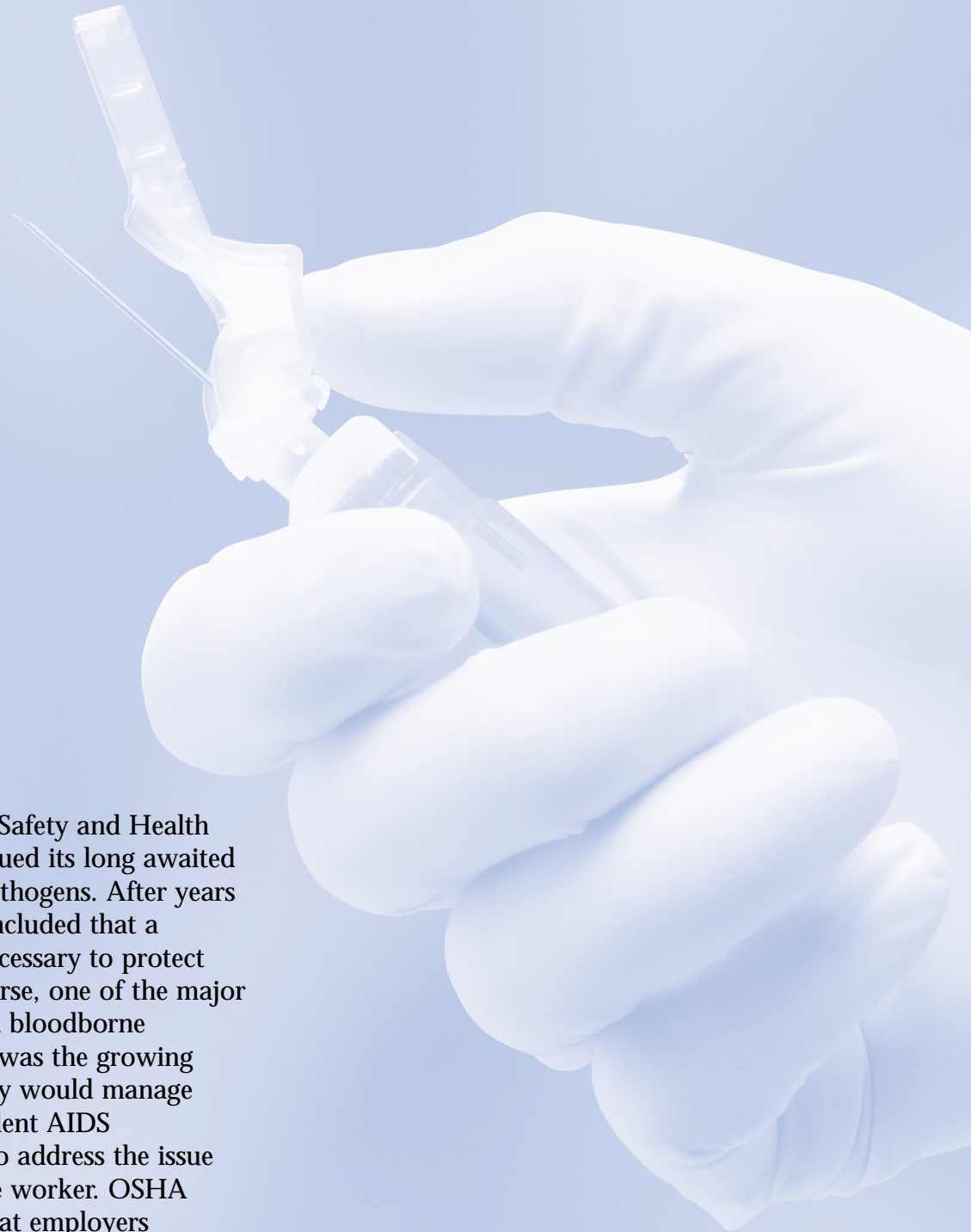


BD Eclipse™ Blood Collection Needle Clinical Publication

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In 1991, the Occupational Safety and Health Administration (OSHA) issued its long awaited standard on bloodborne pathogens. After years of investigation, OSHA concluded that a regulatory initiative was necessary to protect healthcare workers. Of course, one of the major considerations in creating a bloodborne pathogen safety regulation was the growing concern of how the industry would manage patients with AIDS. A prudent AIDS management plan needed to address the issue of protecting the healthcare worker. OSHA felt compelled to require that employers systematically design systems to ensure a high degree of safety for those staff who care for patients with AIDS.

• The Bloodborne Pathogen Standard and the Compliance Directive

As with most OSHA regulations, compliance strategy centered on three areas:

- procedures, instituted by the facility, to see that staff use precautions when caring for patients
- engineering controls which provide safety products that have demonstrated an ability to reduce accident risk
- training systems that ensure that staff know about established safety procedures and safety products

In November of 1999, OSHA officials issued what is called a compliance directive. This 178-page document serves as a set of guidelines for OSHA inspectors when conducting a safety survey. The Web site address for this bloodborne pathogen compliance directive is

www.osha.gov/bloodborne. The November 1999 compliance directive is clear in its emphasis on having healthcare facilities seriously consider purchasing safety devices that can reduce the possibility of employee needlesticks. The compliance directive is an acknowledgement of the increasing body of evidence that the use of protective medical devices has demonstrated ability to significantly reduce injuries. The compliance directive encourages the OSHA inspector to investigate how the healthcare facility has researched the effectiveness of a wide range of safety medical devices. For a facility to be in compliance with the new emphasis of a Bloodborne Pathogen Standard survey, that facility needs to show evidence of a well designed and effective safety product clinical trial evaluation process.

• Clinical Evaluation Process

An effective medical product clinical evaluation system requires a variety of components. First of all, there must be a clearly defined purpose for the system. Secondly, the steps in the process must be well designed. The third component involves having the staff completely understand both the purpose of the clinical evaluation system and each step of the process. A fourth component is providing sufficient training on the proper use of the product and adequate time for the clinical evaluation to be conducted. The final essential element of an effective clinical evaluation process is having a thorough collection of feedback information from the clinicians who used the medical product.

"We want to make sure that the staff who are going to use the product after we purchase it are the people who are conducting the clinical trials," says Linda Fink, chairperson of the University of Iowa Hospitals and Clinics' Nursing Product Evaluation Committee. "Our committee will screen some products that we know

will not be acceptable to staff. We select the supplies that we think may be of benefit to our staff and operation and then we set up clinical trials in units that can give us the best trial information. We often review product usage rates to identify which units should be involved in the evaluation." The experience at the University of Iowa Hospitals and Clinics is fairly standard by industry standards. The OSHA Bloodborne Standard is requiring a thorough process for clinical product evaluation for safety medical products. This includes documentation of those trials. "We use what we call the 'Green Sheet' for documenting the comments and evaluations from the staff," says Renee Gould, clinical trial specialist at the University of Iowa Hospitals and Clinics and member of the Nursing Product Evaluation Committee. "We take the comments noted on the 'Green Sheets' and create a clinical trial summary report that is then presented to the full committee." These kinds of reports are critical for a facility's compliance documentation for the new emphasis of the Bloodborne Pathogen Standard.

• Criteria for Evaluating Safety Products

The foundation of any clinical evaluation process is consistent, concise and well designed review criteria. Such criteria provide the safety medical device evaluation process with the basis of inquiry that can be used for various products. The emerging national criteria standard is the TDICT evaluation assessment criteria. TDICT stands for "Training for the Development of

Innovative Control Technology" project. Started in 1990, the TDICT project brings together healthcare workers, product design engineers and industrial hygienists who are dedicated to preventing exposure to bloodborne pathogens through better design and informed evaluation of medical devices. The project is directed by June Fisher, MD, associate clinical professor

of medicine at the University of California-San Francisco and lecturer in the School of Engineering at Stanford University.

By directly observing how products are used and by involving the users in systematic evaluations, TDICT has developed an effective system for evaluating and, eventually, promoting medical safety devices. Although several devices have been invented as a result of this collaboration, the major focus of the project has been on the development of evaluation forms for selecting 10 devices. They have helped both manufacturers and healthcare workers to be more critical in developing, selecting and evaluating medical devices.

Professional medical product evaluation specialists support this set of criteria primarily because the set is

very thorough. The use of this set of criteria can be defended during an OSHA Bloodborne Pathogen standard survey. The criteria provides a solid basis for safety medical products evaluation because it addresses a wide range of inquiry such as:

- the effect of the product on clinical technique
- the security of the locking mechanism
- how easy it is to lock the safety mechanism
- the reliability of the safety locking mechanism
- the level of safety provided by the safety mechanism
- the ease of teaching how the product should be used

• Clinical Evaluation Process Applied to a Safety Medical Product

The best way to see how the TDICT evaluation criteria work in practice is to actually assess a safety product.

The TDICT Safety Feature Evaluation Form for I.V. Access Devices contains the following criteria:

1. The safety feature can be activated using a one-handed technique.
2. The safety feature does not interfere with normal use of this product.
3. Use of this product requires you to use the safety feature.
4. This device does not require more time to use than a non-safety device.
5. The safety feature works well with a wide variety of hand sizes.
6. The device allows for rapid visualization of flashback in the catheter or chamber.
7. Use of this product does not increase the number of sticks to the patient.
8. The product stops the flow of blood after the needle is removed from the catheter (or after the butterfly is inserted) and just prior to line connections or hep-lock capping.
9. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated.
10. The safety feature operates reliably.
11. The exposed sharp is blunted or covered after use and prior to disposal.
12. The product does not need extensive training to be operated correctly.

Recently, the University of Iowa Hospitals and Clinics conducted clinical trials on a safety blood collection needle called the Eclipse™ manufactured by BD. The clinicians who used the product were asked 11 questions. These questions were based on the TDICT criteria. The answers constituted the following report summary:

1. **My phlebotomy technique feels the same.** This trial question relates to criterion 2 on the TDICT survey. This question ensures that the clinical technique of the users is not compromised. The product scored 4.7 out of a possible 5.0.
2. **It is easy to engage the safety shield.** This trial question relates to criterion 4 on the TDICT survey. This question assesses the product's ease of use. The product scored 4.8 out of 5.0.
3. **The safety shield locks securely.** This trial question relates to criteria 4 and 10 on the TDICT survey. This question provides inquiries about the product being able to maintain protection. The product scored 5.0 out of 5.0.
4. **The safety feature can be easily activated using a one-handed technique.** This trial question relates to criterion 1 on the TDICT survey. A one-handed technique is considered a safe method of activating a safety medical device simply because there is little chance of getting the second hand in front of the needle tip where an injury could happen. The product scored 4.8 out of 5.0.

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(Clinical Evaluation Process Applied to a Safety Medical Product cont.)

5. **The safety feature does not interfere with the ability to penetrate the skin.** This trial question relates to criteria 2 and 4 on the TDICT survey. This criteria attempts to reconfirm that the clinical technique of the user is not negatively affected. There was some initial concern about the Eclipse product in this regard. Yet the product has the needle bevel oriented in a direct line with the hinged cover so that clinicians could identify the bevel in an easier fashion than with a conventional device. The product scored 5.0 out of 5.0.
6. **The patient reports no increase in pain with this product.** This trial question relates to criterion 8 on the TDICT survey. Safety medical devices should never increase the discomfort to the patient. This product scored 5.0 out of 5.0.
7. **The safety feature does not impair the blood draw procedure.** This trial question relates to criteria 6 and 8 on the TDICT survey. This question again reconfirms that the product does not affect clinical technique. The product scored 4.8 out of 5.0.
8. **I can tell when the safety device has been activated.** This trial question relates to criteria 9, 10 and 11 on the TDICT survey. This question ensures that staff will not inadvertently receive an injury because they thought that the safety feature was activated. The product scored 4.7 out of a possible 5.0.
9. **The safety feature operates reliably.** This trial question relates to criterion 10 on the TDICT survey. Safety features should have a very low rate of failure to activate. The product rated 5.0 out of 5.0.
10. **The safety shield provides increased protection at the point of venipuncture.** This trial question relates to criteria 9, 10, 11 and 12 on the TDICT survey. These criteria ensure that the protective benefit is activated as early in the procedure as possible to maximize the safety benefit. The product rated a 5.0 out of 5.0.

The report accurately reflects the assessment of the staff who will be using the product. "We carefully assessed this product. We were most impressed with the ease of activation. If activation is difficult then the staff are less likely to use the safety feature." says Kathy Eyres MT(ASCP), the Manager of Specimen Collection at the University of Iowa Hospitals and Clinics.

• Summary

With the issuing of the Bloodborne Pathogen Compliance Directive in November of 1999, a safety medical device evaluation process and documentation is essential to a facility's ability to comply with OSHA regulation. Product evaluation processes, like the one at the University of Iowa Hospitals and Clinics, need to be clearly defined and well documented. Identifying the appropriate staff to be involved in the clinical trial is just the first step in the system. Product utilization reports can help in selecting staff. The cornerstone of any clinical trial is the list of questions or the information collection tools that the facility employs. The set of questions or criteria that is most often used is the TDICT evaluation assessment document.

That set of criteria was used in the recent clinical trial of the BD Eclipse™ blood collection needle at the University of Iowa Hospitals and Clinics. The product rated very high marks on every section of the criteria. Following the clinical trial report presentation to the Nursing Product Evaluation Committee, the Eclipse was recommended to be purchased on a facility-wide scale. The University of Iowa Hospitals and Clinics will now establish a baseline data point and use that point to determine what impact the use of the Eclipse product will have on reducing needlestick injuries.



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