EVALUATING SAFER NEEDLES

A UNISON GUIDE

"NEEDLE SAFETY AT WORK"

Number 2

Safer Needles – the campaign

UNISON has begun a needlestick campaign to reduce the number of injuries caused by sharps and needles. Details of the campaign, the risks from needlestick injuries and UNISON's objectives can be found in other publications listed at the end of this booklet.

This guide gives further details on safer needles and includes guidelines for the use of Safety Feature Evaluation Sheets.

What is a Safer Needle Device

Safer needle devices have safety features (engineering controls) built into the product which prevent needlestick injuries. The term "safer needle device" is broad and includes many different types of devices, from those that have a protective shield over the needle to those that do not use needles at all. The common feature of effective safer needle devices is that they reduce the risk of needlestick injuries for healthcare workers over the conventional, inherently dangerous older needles. There are also other devices which prevent injury from other sharps, such as safety lancets and safety surgical blades.

Think of an unguarded piece of machinery in an industrial workplace. Use of conventional needles without integrated safety features in the healthcare environment is no different. They are dangerous by design and should be eliminated wherever possible.

Asking healthcare workers to "work safely" around such deadly, poorly designed, obsolete products is a recipe for disaster, a situation that would not be allowed to exist in any other industry sector. The fight was won by industrial workers for adequate machine guarding in the 1960s; today, healthcare workers must win the fight for safer needles. In the USA this fight is now being won and it our duty to win it in the UK.

Do Safer Needles really work?

In the United States research has shown that most needlestick injuries can be prevented by switching to needleless I.V. connectors and using devices with incorporated safety features. The US Center for Disease Control (CDC) sponsored a multi-hospital study and proved that safer devices can dramatically reduce needlestick injury rates. The results appeared in the January 17, 1997 issue of CDC's *Morbidity and Mortality Weekly Report.* The study found that when drawing blood, one of the highest-risk procedures, needlestick injuries could be cut by between 27 and 76 percent with the use of safer needles. The investigation also found that the use of safer needles did not lessen the quality of patient care. Further, the safer needles were generally accepted by healthcare workers.

Are some Safer Needles safer than others?

The types of safety features used in safer needle devices can be categorised according to certain aspects of the safety feature i.e. whether the feature is “passive” or “active”.

Passive safety features remain in effect before, during and after use; healthcare workers do not have to activate them. Passive features enhance the safety design and are more likely to have a greater impact on prevention. An example of such a product would be a spring-loaded retractable syringe or self-blunting blood collection device.

Active devices require the healthcare worker to manually activate the safety feature. An example of such a product would be a needle with a sheath that the healthcare worker must manually pull over the used needle. Failure to do so would leave the worker unprotected. In the USA some employers have used the excuse of not buying safer needles because they claim that healthcare workers do not activate the protective sheath before disposing of the products in a needle disposal box. However, it may be entirely logical to dispose of such unsheathed needles if the disposal box is close by, especially since some cases of activation have resulted in needlestick injuries.

In the United States in 1992, as a direct result of a petition by the Service Employees International Union, the Federal Drugs Agency (FDA -who register medical devices) published a “Needleless Systems” safety alert warning about the risk of needlestick injuries from the use of hypodermic needles as a connection between two pieces of I.V. equipment. This alert was based on research that demonstrated that secondary I.V. tubing with connector needles was associated with the highest risk of needlestick injury. The use of needless I.V. systems or systems with recessed needles to connect adjoining equipment was strongly encouraged in this alert. Today, it is estimated by the FDA that more than 50 percent of all hospitals in the USA use needleless I.V. connection systems.

What are the characteristics of a Safer Needle?

The US FDA has suggested that needles with safety features designed to protect healthcare workers should:

- Provide a barrier between the hands and needle after use;
- Allow or require the worker’s hands to remain behind the needle at all times;
- Be an integral part of the device and not an accessory;
- Be in effect before disassembly and remain in effect after disposal to protect downstream workers;
- Be simple and self-evident to operate and require little or no training to use effectively.

These are the same criteria the FDA has used to approve more than 250 safer needle products, and to reject a similar number that did not meet these standards. *Ironically, the FDA has refused to evaluate the safety of any conventional needles with these or any other safety criteria.*

Additional information

In the USA many hospitals have conducted extensive evaluation studies of safer needle devices on their own. The University of Virginia's International Health Care Worker Safety Centre and its EPINet needlestick injury data collection system has been distributed to more than 1,500 hospitals in the United States. Currently needlestick injury data is available online from a 77-hospital database and can be accessed free of charge at www.med.virginia.edu/medcntr/centers/epinet/. UNISON has called on the Department of Health to research and produce similar information in the UK.

Product evaluations

While data already exists in the US on which safer needles are best for which uses, many of these products are not yet available in the UK. UNISON's campaign has already begun to have an effect on the demand for safer needle products in the UK and we expect many more devices to become available over this and the following years.

At this time we recommend that all healthcare employers should conduct their own evaluations on the safer products available. Often manufacturers of the devices will provide help with this. *Directly involving the frontline healthcare workers who will be using these safer products is critical in this evaluation process.* To help employers conduct such evaluations in the workplace, we have been granted permission to reprint and have included in the next section a set of "Safety Feature Evaluation Sheets" developed by Dr. June Fisher and her staff at the Training for Development of Innovative Control Technology Project (TDICTP), San Francisco, USA. Four separate sheets – for evaluating safety syringes, I.V. connectors, vacuum-tube blood collection systems, and I.V. access devices – are reproduced here, beginning with general guidelines.

Legal requirements to evaluate safer needles

Regulation 7 of The Control of Substance Hazardous to Health Regulations 1999 (COSHH) makes it clear that employers must as far as is reasonably practicable avoid exposures to hazards, such as blood borne viruses. Where this is not possible they must use a range of measures, including the use of "engineering controls" to minimise the risk.

In the case of needlestick injuries the introduction of safer needles means that previous risk assessments which have not taken them into account are no longer "suitable and sufficient". Consequently, evaluation of safer needle devices is, in UNISON's opinion, legally required. We are in discussions with the Department of Health and Health and Safety Executive to clarify this.

GUIDELINES FOR THE USE OF SAFETY FEATURE EVALUATION SHEETS

Co-ordinators

Determine which products are to be evaluated and provide at least four or more test samples for each individual evaluating the product. (Each evaluator should have enough samples to disassemble and test the design thoroughly).

Set up a testing station for each type of device that allows testers to evaluate products in a simulated patient procedure. Provide training dummies (injection pads, oranges, etc.) as necessary.

Provide visual instructions and a rating system to each evaluator.

Encourage each evaluator to comment on the sheets and prioritise the questions at the end of the evaluation. This will provide a useful decision-making tool and will help alert you to specific areas of concern that may not have been covered by the questionnaire.

Evaluators

Re-enact all steps of intended or possible procedures to be performed with the device being tested.

Attempt to misuse the device and circumvent or disable the safety feature.

Answer each question, including the short answer section at the end. If you do not understand a question, please write comments directly on the sheets.

Notes: Certain assumptions have been made in the development of these forms based on information about currently available products. We recognise the likelihood that the ideal product may not exist. UNISON welcomes your comments on the use of these tools.

Safety Syringes - Safety Feature Evaluation Form

Date_____Department_____Occupation_____

Product_____Number of times used_____

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

		Agree /Disagree					
During Use							
1.	Safety feature can be activated using a one handed technique	1	2	3	4	5	N/A
2.	Safety feature does not obstruct vision of the tip of the sharp	1	2	3	4	5	N/A
3.	Use of this product requires you to use the safety feature	1	2	3	4	5	N/A
4.	Product does not require more time to use than a non-safety device	1	2	3	4	5	N/A
5.	Safety feature works well with a wide variety of hand sizes	1	2	3	4	5	N/A
6.	Device is easy to handle while wearing gloves	1	2	3	4	5	N/A
7.	Device does not interfere with uses that do not require a needle	1	2	3	4	5	N/A
8.	Device offers a good view of any aspirated fluid.	1	2	3	4	5	N/A
9.	Device will work with all required syringe & needle sizes	1	2	3	4	5	N/A
After Use							
10.	There is a clear and unmistakable change (audible or visible) that occurs when the safety feature is activated.	1	2	3	4	5	N/A
11.	The safety feature operates reliably	1	2	3	4	5	N/A
12.	The exposed sharp is permanently blunted or covered after use and prior to disposal	1	2	3	4	5	N/A
13.	This device is no more difficult to process after use than non-safety devices	1	2	3	4	5	N/A
Training							
14.	User does not need extensive training for correct operation	1	2	3	4	5	N/A
15.	The design of the device suggests proper use	1	2	3	4	5	N/A
16.	It is not easy to skip a crucial step in the proper use of device	1	2	3	4	5	N/A

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions that you feel should be asked regarding the safety/utility of this product?

*** UNISON note: This evaluation sheet (slightly amended) is reprinted by permission of the Training for Development of Innovative Control Technology Project, San Francisco. For more information try their website on: www.tdict.org**

Vacuum – Tube Blood Collection Systems
Safety Feature Evaluation Form

Date_____Department_____Occupation_____
_____

Product_____Number of times used _____

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

	Agree	**Disagree**	
1. The safety features can be activated using a one-handed technique	1	2 3 4 5	N/A
2. The safety feature does not interfere with normal use of this product	1	2 3 4 5	N/A
3. Use of this product requires you to use the safety feature	1	2 3 4 5	N/A
4. This product does not require more time to use than a non-safety device	1	2 3 4 5	N/A
5. The safety feature works well with a wide variety of hand sizes	1	2 3 4 5	N/A
6. The safety feature works with a butterfly	1	2 3 4 5	N/A
7. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated	1	2 3 4 5	N/A
8. The safety feature operates reliably	1	2 3 4 5	N/A
9 The exposed sharp is blunted or covered after use and prior to disposal	1	2 3 4 5	N/A
10. The inner vacuum tube (rubber sleeved needle) does not present a danger of exposure	1	2 3 4 5	N/A
11. The product does not need extensive training to be operated correctly	1	2 3 4 5	N/A

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

UNISON note: This evaluation sheet is reprinted by permission of the Training for Development of Innovative Control Technology Project, San Francisco. For more information try their website on: www.tdict.org

I.V. Access Devices - Safety Feature Evaluation Form

Date_____Department_____Occupation_____

Product_____Number of times used_____

Please circle the most appropriate answer for each question. Not applicable (N/A may be used if the question does not apply to this particular product.

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

Of the above questions, which three are the most important to your safety when using this product.

Are there other questions which you feel should be asked regarding the safety/utility of this product?

UNISON note: This evaluation sheet is reprinted by permission of the Training for Development of Innovative Control Technology Project, San Francisco. For more information try their website on: www.tdict.org

I.V. Connectors - Safety Feature Evaluation Form

Date_____Department_____Occupation_____

Product_____Number of times used_____

Please circle the most appropriate answer for each question. Not applicable (N/A may be used if the question does not apply to this particular product.

		Agree Disagree	
1.	Use of this connector eliminates the need for exposed needles in connections	1 2 3 4 5	N/A
2.	The safety feature does not interfere with normal use of this product.	1 2 3 4 5	N/A
3.	Use of this product requires you to use the safety feature.	1 2 3 4 5	N/A
4.	This product does not require more time to use than a non-safety device.	1 2 3 4 5	N/A
5.	The safety feature works well with a wide variety of hand sizes.	1 2 3 4 5	N/A
6.	The safety feature allows you to collect blood directly into a vacuum tube, eliminating the need for needles.	1 2 3 4 5	N/A
7.	The connector can be secured (locked) to Y-sites, hep-locks, and central lines.	1 2 3 4 5	N/A
8.	A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated.	1 2 3 4 5	N/A
9.	The safety feature operates reliably.	1 2 3 4 5	N/A
10.	The exposed sharp is blunted or covered after use and prior to disposal.	1 2 3 4 5	N/A
11.	The product does not need extensive training to be operated correctly.	1 2 3 4 5	N/A

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product.

This guide has been adapted from material produced by the Service Employees International Union (SEIU) a sister union of UNISON in the United States. For more information try their website on: www.seiu.org

The evaluation sheets are reprinted by permission of the Training for Development of Innovative Control Technology Project, San Francisco. For more information try their website on: www.tdict.org

Other UNISON Publications:

This is one of a series of UNISON guides and leaflets which will look at the issue of needlestick and sharps injuries. Other materials so far produced are:

"Needle Safety at Work, Safer Needles - Questions and Answers" a UNISON guide was issued to branches as HC/116/99. This can be obtained from**:**
UNISON Health Group, 1 Mabledon Place, London, WC1H 9AJ.

An article based on this guide appears in Health and Safety Organiser, Issue 6, December 1999 – available from **UNISON Health and Safety Unit, 1 Mabledon Place, London WC1H 9AJ.** For an e-mail version contact**:** healthandsafety@unison.co.uk **.**

An accompanying poster (stock no. 1671) is also available from UNISON's **Communications Department** (address as above).