

***Appendix K
ABC's of Viral Hepatitis
&
Safety Feature Evaluation Sheets***

Know the ABC's of Viral Hepatitis

	<u>Transmission</u>	<u>Vaccine Availability</u>	<u>Complications</u>
A	+Person to person (fecal-oral) +Contaminated food/water.	Available	+Fulminant Hepatitis +Relapse
B	+Sexually +Via infected blood and body fluids +Contact with contaminated surfaces +From mother to child during birth or after	Available	+Fulminant Hepatitis +Chronic liver disease +Cirrhosis +Liver cancer
C	+Injecting-drug use +Via blood	Not Available	+Chronic liver disease +Cirrhosis +Liver cancer
D	+Via blood +Only in presence of Hepatitis B	Not Available	
E	+Fecal-oral in developing countries.	Not Available	+High mortality in pregnant women

Know the risk of Hepatitis B

■ HOW CAN YOU GET IT

Hepatitis B virus (HBV) is **hardy** and easier to "catch" than you might realize. HBV is found mainly in blood and body fluids. In certain situations, it is up to 100 times more contagious than HIV, the virus that causes AIDS. Hepatitis B virus can survive on surfaces for up to 1 month in some instances increasing your chances of infection. There are an estimated 1 to 1.25 million persons with chronic HBV infection in the United States that are infectious to others.

■ IT CAN MAKE YOU VERY SICK

Hepatitis B attacks your liver and can make you extremely ill. Some patients even require hospitalization. The disease can lead to cirrhosis of the liver or liver cancer. Each year there are up to 150,000 new infections with Hepatitis B and about 4,000 people die due to Hepatitis B-related chronic liver disease in the United States.

■ IT CAN BE PREVENTED

Protect yourself and your children with Hepatitis B vaccination...preventing chronic Hepatitis B infection can reduce the risk of primary liver cancer. Many don't have the Hepatitis B protection they need.

■ THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) RECOMMENDS:

Universal vaccination for all infants

Vaccination of all infants, children and adolescents from birth to age 18

Vaccination for at-risk adults

■ Just 3 shots of vaccine provide protection

Soreness, swelling and redness at the site of injection are the most common side effects.

To find out if Hepatitis B vaccination is right for you, contact your doctor

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GUIDELINES FOR THE USE OF SAFETY FEATURE EVALUATION SHEETS

Coordinators:

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 examine the design thoroughly.)

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

Provide visual instructions and rating system with each evaluator.

Encourage each evaluator to comment on the sheets and prioritize 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 which may not have been covered by the questionnaire.

Evaluators:

Re-enact all steps of the intended or possible procedures 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.

NOTE: The utility of these criteria is for initial screening of devices and NOT for clinical assessment/pilot testing. Certain assumptions have been made in the development of these forms based on information about currently available products. We recognize the likelihood that the ideal product may not exist. TDICT welcomes your comments on the use of these tools.

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SAFETY FEATURE EVALUATION FORM

SAFETY SYRINGES

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. The safety feature can be activated using a one-handed technique 1 2 3 4 5 N/A
2. The 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. 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 is easy to handle while wearing gloves 1 2 3 4 5 N/A
7. This device does not interfere with uses that do not require a needle
..... 1 2 3 4 5 N/A
8. This device offers a good view of any aspirated fluid 1 2 3 4 5 N/A
9. This device will work with all required syringe and needle sizes 1 2 3 4 5 N/A
10. This device provides a better alternative to traditional recapping 1 2 3 4 5 N/A

After Use:

11. 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
12. The safety feature operates rapidly 1 2 3 4 5 N/A
13. The exposed sharp is permanently blunted or covered after use and prior to disposal
..... 1 2 3 4 5 N/A
14. This device is no more difficult to process after use than non-safety devices 1 2 3 4 5 N/A

Training:

15. The user does not need extensive training for correct operation 1 2 3 4 5 N/A
16. The design of the device suggests proper use 1 2 3 4 5 N/A
17. It is not easy to skip a crucial step in proper use of the 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 which you feel should be asked regarding the safety/utility of this product?