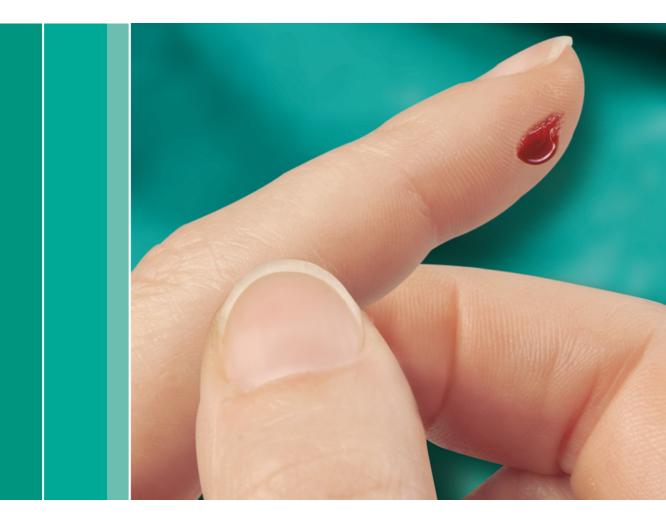
Risk Prevention in Infusion Therapy



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Definition

Sharp Injuries are skin penetrating stab wounds caused by sharp instruments and accidents in a medical setting. These instruments include needles, lancets, scalpels and broken glass.^{1,2}

Needlestick Injuries (NSIs) are defined as an accidental skin penetrating stab wound caused by hollow-bore needles such as hypodermic needles, blood-collection needles, IV catheter stylets, and needles used to connect parts of IV delivery system. ^{1,3,4}

Definition Risks

Risks

Healthcare workers (HCWs) face a high risk of an occupational exposure to blood and body fluids (BBF). This exposure can lead to the transmission of pathogens causing an infection and hazardous consequences for their health. 5,6

The common high risk situations of such an occupational exposure involving the exchange of BBF are: 5,6,7

- 1. Percutaneous injury
- 2. Mucous membrane contact
- 3. Non-intact skin contact

Percutaneous injuries represent the most dangerous situation for HCWs where safety products and measures haven't already been established. Percutaneous injuries may be caused by objects like needles, surgical instruments or glass.^{5,7}

Nearly 80% of all percutaneous sharps injuries are caused by a needlestick, with 56% attributed to hollow-bore needles (See Figure 1). 1

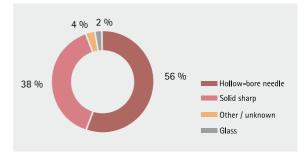
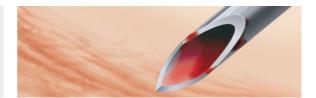


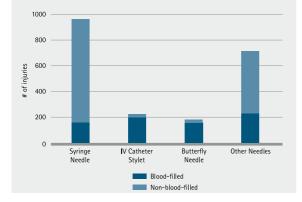
Figure 1: Types of devices causing percutaneous injuries

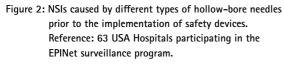


Syringe needles, IV catheter stylets, and Butterfly needles represent nearly 65 % of all injuries from hollow-bore needles and are considered high-risk because they involve blood-filled needles. Nearly every 2nd hollow-bore needlestick also endangers the HCW to the risk of a blood exposure (See Figure 2).⁸ Regarding the group of HCWs most frequently affected by NSIs, nurses showed the highest percentage with up to 50% of all injuries sustained. ^{1,8,9,10}

Additionally physicians and laboratory staff had an explicit risk of NSIs with contaminated hollow-bore needles. $^{\rm 1,9}$

In addition to HCWs directly working with medical devices, house-keeping and laundry personnel are also susceptible to the hazardous consequences of NSIs (See Figure 3). 1,9





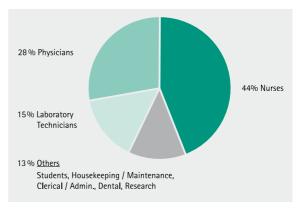


Figure 3: Occupational groups of HCWs exposed to BBF after percutaneous injuries





Risks Causes

Causes

In general, needlestick injuries (NSIs) are caused by simple and preventable mistakes in handling sharp medical devices.^{1,4} According to EPINet surveillance data, 60% of reported NSIs occurred after the clinical procedure was performed. These incidents happened before or during the disposal process (See Figure 4).¹¹

Studies show an increased risk of injuries with rushing, anger, distraction, and multiple attempts to complete a procedure. Additional factors with a negative impact on safe handling were healthcare worker (HCW) fatigue, uncooperative patients, or teams affected by staff shortage.¹²





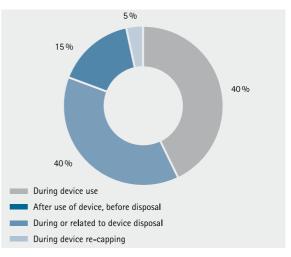
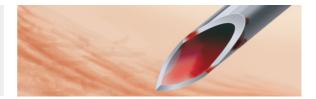


Figure 4: When NSIs occur



Most exposures occur within the patient room, followed by operating room and the emergency department (See Figure 5). ¹³

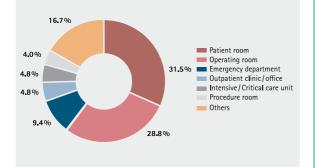


Figure 5: Areas within the healthcare facility where needlestick and sharp-object injuries most frequently occurred

Causes of Sharps Injuries

The Centers for Disease Control and Prevention (CDC) summary of the most common causes: ^{1,4}

- Lack of personal protective equipment, safety devices, and sharps disposal containers
- Lack of procedures for sharps injury reporting
- Lack of awareness with occupational hazards
- Insufficiently trained staff
- Limited access to sharps disposal containers
- Shortage of staff
- Recapping needles after use
- Passing sharp instruments from hand-to-hand in the operating suite
- Failure to use sharps disposal containers immediately after use
- Unpredictable medical incidents
- Unexpected patient reactions

Consequences

Transmissible diseases

The main concern regarding a needlestick injury (NSI) is not characterized by the trauma itself, but by the percutaneous exposure to a patient's blood and body fluids (BBF) which may carry infectious diseases.¹⁴

A NSI can lead to the transmission of pathogens. At least 20 different pathogens involving viruses, bacteria and fungi have been transmitted to healthcare workers (HCWs) through NSIs (See Table 1).^{1,4}

The likelihood of developing a disease after a NSI depends on various independent factors: pathogen concentration in the BBF, depth of the wound, blood volume, amount of pathogens transmitted and the infection phase of the pathogen carrier. The seroconversion rate and availability of vaccinations or post exposure prophylaxis (PEP) treatments also play a critical role,

as infected HCWs face the consequences of developing acute and chronic diseases and even the probability of death.¹⁵

Due to clinical severity and health complications, the most debilitating diseases associated with NSIs are the blood-borne pathogens HBV, HCV and HIV (See Table 2). $^{\circ}$

Table 1: Diseases transmitted to HCWs after NSIs. 14, 16

Hepatitis B	 Malaria 	 Toxoplasmosis
 Hepatitis C 	 Syphilis 	 Brucellosis
= HIV / AIDS	 Tuberculosis 	 Herpes
		 Diphtheria
		 Blastomycosis
		Dengue Virus
		 Rocky Mountain spotted fever

Disease

Epidemiology

Incubation period

Infectivity

Consequence to infected individual

Vaccination

Post exposure prophylaxis (PEP)

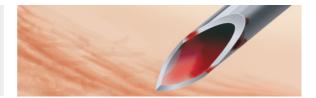


Table 2: Viruses with the highest risks associated with their transmission after sharp and needlestick injuries.

Hepatitis B Virus (HBV)	Hepatitis C Virus (HCV)	Human Immunodeficiency Virus (HIV)
Viral liver infection 17	Viral liver infection	Immune system infection
Incidence: = 2 billion people infected ¹⁷ = 10 to 30 million people infected annually ¹⁸ Prevalence: = 350 million people live with chronic infection ¹⁷	 Incidence: 170 million people infected ^{20,25} 3 to 4 million people infected annually and increasing 	Incidence: = 33.4 million people living with HIV ²⁸ = 2.7 million people newly infected annually ²⁸
= 30-180 days (average 90 days) ^{17, 19}	= 42-70 days ²⁶	= 14-28 days
 30% risk of seroconversion after percutaneous exposure to positive source ²⁰ 5.9% of all infections are due to NSIs ⁶ 	 3% risk of seroconversion after percutaneous exposure to positive source ²⁰ risk of infection after NSI with HCV-infected blood is 1.8% ²⁴ 	 0.3% risk of seroconversion after percutaneous exposure to positive source²⁰ 57 documented and 140 possible cases of HIV transmission to U.S. HCWs in 2001¹ 78% of the 57 cases of occupational HIV transmission were due to a NSI¹
 estimated 600,000 people die each year due to acute or chronic consequences ¹⁷ 5-10% of people develop chronic infec- tion ²¹ chronic infection carries an estimated 20% lifetime risk of death from cirrhosis and 6% from liver cancer ²¹ In regions of high HBV endemic, associated risks may be as high as 40% ²² 	 75-80% of patients develop chronic infection ²⁷ 60-70% of chronically infected persons develop active liver desease ²⁷ of the chronically infected patients with active liver disease, 10-20% develop cirrhosis, while 1-5% develop liver cancer²⁷ 	 severe and persistent impairment of cellular immunology associated with immunodeficiency described as AIDS 2.0 million people died of AIDS in 2008 ²⁸
= available 17	no vaccine exists ⁴	no vaccine exists ²⁴
 immediate clinical treatment of HBV infection is possible and proved to be mostly effective ²³ PEP should begin within 24 hours after exposure ²⁴ 	 no effective PEP is currently available ²⁴ 	 PEP with antiviral drugs as soon as possible within 72 hours with uncertain effectiveness and many adverse effects

Consequences

Incidence rate

The availability of actual figures regarding the incidence rates of needlestick injuries (NSIs) are insufficient and limited in general, especially for national and global figures. Two major factors are responsible for this situation.

First, data is non-comprehensive due to a lack of surveillance and reporting systems in the concerned healthcare facilities.⁹ The second factor is related to a prevalent and persisting underreporting of incidences, which has been demonstrated by numerous studies.²⁹ As an example, Wicker published results demonstrating that only 28.7% of injured healthcare workers (HCWs) reported the NSI, 50.4% did not report the NSI and 20.9% only reported occasionally or gave no response in the surveillance questionnaire.³⁰ In the U.S. an extensive survey documented an underreporting of 58%.³¹ Other studies exposed the severity of underreporting of needlesticks with estimates higher than 90%.³²

Some principal reasons for not reporting were time constraints, perception that the percutaneous injury did not represent a significant exposure, lack of knowledge about the reporting mechanism and concern about confidentiality and professional discrimination.³³

Estimates from the U.S. show results of 385,000 percutaneous injuries sustained annually by hospital staff.³⁴

Perry and Jagger estimate the annual U.S. rate to be 500,000 while other authors have estimated up to 756,000 injuries annually.^{29,35}

Available figures for European countries demonstrated incidences of 100,000 for the UK and 500,000 cases per year in Germany.^{23, 23, 36}

Data collection by EPINet suggests that in an average hospital, workers suffer approximately 30 NSIs per 100 beds per year.⁴

Risk related cost

NSIs cause various direct and indirect costs due to their severe nature (See Table 3).

Direct costs, such as follow-up diagnosis and medical treatments, are often a consequence of recommended procedures, showing therefore a more prominent impact to the healthcare facility. Indirect costs after a NSI must also be considered as important, because of staff retention, compensations for lost employment and damages, insurance premiums and future litigations (See Figure 6). Furthermore, even a non transmitted disease can produce emotional trauma and distress, resulting in personal counseling and lost productivity.¹¹

Table 3: Costs associated directly and indirectly with NSIs.

Direct costs	Indirect costs
Short-term Blood sampling Urgent testing (lab.) Vaccinations Health care visits Post-exposure prophylaxis	 Time loss due to anxiety & distress Administrative effort
Long-term HCW counseling Follow-up blood test Long-term treatment	 Loss of HCW work days Higher insurance premiums Associated litigations Compensation claims

Various studies have estimated the financial impact of NSIs. As an example of short-term direct costs, Hatcher described that a single NSI would cost the healthcare facility 2,234 (€ 1,409) to 3,832 (€ 2,417).³⁷

Financial Impact

Each NSI without infection costs employers between \$ 2,234 (€ 1,409) and \$ 3,832 (€ 2,417). 37,39

In the case of a transferred blood-borne disease after a NSI, the overall long-term financial cost has been calculated to be as high as \notin 922,000. 33



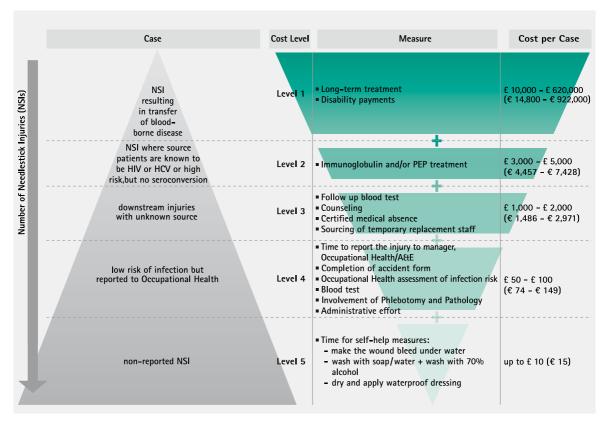


Figure 6: Costs associated with NSIs. The costs are segregated into 5 levels and number of NSIs increases from level 1 to level 5. Compensation claims are not explicitly included and have to be added individually 38

Impact of Needlestick Injuries		
 Emotional trauma 	 Staff retention 	
 Distress 	 Infection risk to patients 	
Impairement on family & social relationships	 Illness 	



Preventive strategies

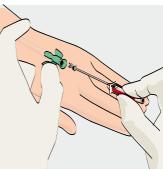


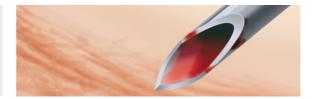
Figure 7: Use of punctureresistant sharps disposal containers.

Figure 8: Use of a safety device. Protection by proper handling of a safety hypodermic needle.

Figure 9: Example of safety device effectiveness.







Preventive strategies

The effective prevention of needlestick injuries (NSIs) to avoid the exposure to blood or body fluids (BBF) requires a comprehensive approach combining various strategies and actions. ^{4, 14, 32, 40}

A general training and educational program on universal precautions and proper use of sharp devices must be established. This has to include not only the safe application of hollow-bore needles, but also their disposal, the adaptation of safe work practices and the reporting of NSIs. ^{14,32}

As an example of an effective reduction of injuries, the implementation of point-of-use sharps containers lowered recapping-associated needlesticks from 23% of all needlesticks to only 5% (See Figure 7).⁴¹

Experience shows that continuous reinforcement of educational strategies alone may be insufficient to sustain a reduction of NSIs.^{40, 42} Therefore the prevention of NSIs has to be enforced by the use of needle protective devices.³² The introduction of safety devices instead of non protected conventional devices can achieve a significant reduction of the risk of NSIs (See Figure 8).³

The effectiveness of safety devices varies between the device type and departments within the healthcare setting. A recent study evaluated the incidence of NSIs among different safety devices and concluded that Passive (fully automatic) Safety devices are more effective than Active devices which requires users to activate the safety mechanism. Consequently, in some areas the transmission of pathogens from percutaneous injuries could be nearly eliminated (See Figure 9).⁴³⁻⁴⁵

Safety devices have been shown to reduce NSIs by 22% to 100%. However, NSIs associated with safety devices still occur for the following reasons:

- Inherently risky activation procedure
- Inadequate training
- Incomplete activation
- User noncompliance

Prevention 1,4

- Continuous education in safe use and disposal of sharp devices
- Mandatory reporting of all sharps and NSIs
- Use of needle-free systems where possible
- Use of safety devices
- Suitable access to and correct use of sharps containers
- Immediate disposal of sharps into appropriate containers
- Frequent collection and proper disposal of sharps containers
- Ban recapping of needles
- Elimination of unnecessary injections

Introduction of safety devices is an important component in the prevention of NSIs, and its influence cannot be understated. Additional elements such as education and training that focus on proper use is essential for the protection of Healthcare Workers from NSIs.⁴³⁻⁴⁵

Riskprevention



Introcan Safety® 3

Closed IV Catheter.

- Multiple use blood control septum aids in prevention of blood exposure.
- Passive Safety Technology protects against needlestick injuries and related infections.
- Fully automatic protection cannot be bypassed.
- Innovative, integrated Catheter Stabilization Platform to reduce catheter related complications.



Introcan Safety®

Shielded IV Catheter.

- Passive Safety Technology protects against needlestick injuries and related infections.
- Fully automatic protection cannot be bypassed.



Vasofix® Safety

Shielded IV Catheter.

- Passive Safety Technology protects against needlestick injuries and related infections.
- Fully automatic protection cannot be bypassed.
- Port for needle-free injection.



Venofix[®] Safety

Winged IV needle for short-term infusions, blood collections, injection and transfusion.

- In-vein activation of safety mechanism possible with one hand.
- Audible click confirming activation.
- Needle fully covered





B. Braun Safety Hypodermic Needle

- Hinged protective sheath that permanently encapsulates needle.
- Luer-lock / Luer-slip.
- Easy and intuitive handling.



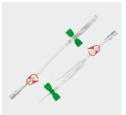
Solofix® Safety

- Sterile single-use safety lancet for capillary blood collection.
- Irreversible needle retraction mechanism.
- Needle-free access eliminates risk of needlestick injury.



Diacan® S

- Safe dialysis fistula needle.
- Integrated protective mechanism, which can be activated in one smooth movement.



Surecan® Safety II

- Access port needle with special bevel and safety mechanism
- Visual confirmation of safety mechanism activation



Riskprevention



Sterican® Mix

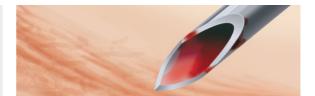
Safety drug admixture needle. Its special bevel design helps reducing needle stick injuries and related consequences.



Aesculap® Safety Scalpel

- Disposable scalpel with integrated safety mechanism to prevent from sharps injuries during surgical procedures.
- Safety mechanism can be easily activated with one hand.





Medibox®

- A reliable, easy and safe container for disposal of medical sharps.
- Impact-resistant, puncture-resistant, and leak proof.
- Touch-free, twist-off and insertion inlets for safe disposal of contaminated needles and medical sharps.
- Permanent locking mechanism to prevent tampering.
- Overfill warning by maximum fill and visible content level.
- Freestanding, ergonomic design and easy to operate.



Personal Protective Equipment (PPE)

 The use of mask, gloves and goggles is recommended by the CDC to prevent from blood exposure during peripheral venipuncture.



Vasco[®] Nitril

Single use medical glove for effective protection against micro organisms and chemical agents according to EN 374, EN 420.



Literature

Literature

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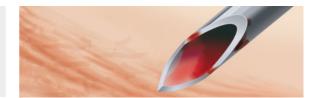
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Notes





The summarized scientific information in this document has been prepared for healthcare professionals. It is based on an analysis of public literature and guidelines. The intention is to give an introduction to the risks commonly associated with infusion therapy and to increase the awareness of healthcare workers to these kinds of problems. Due to its summary nature, this text is limited to an overview and does not take into account all types of local conditions. B. Braun does not assume responsibility for any consequences that may result from therapeutical interventions based on this overview.