1. Introduction

The W.I.S.E. meeting (Workshop on Injection Safety in Endocrinology) took place from 13-16 October in Brussels, Belgium. This high-level forum discussed the application of the new EU Directive on sharps safety to diabetes care. It was co-sponsored by the European Medical Association, under the direction of its President, Dr. Vincenzo Costigliola, and BD Diabetes Care. WISE brought together 57 leaders from 14 countries; the attendees included Nurses, Diabetes Educators, Doctors, Occupational Medicine Specialists, Pharmacists, Engineers, Hygienists, Payers and insurers, Administrators (e.g. hospital management), Business people and Politicians.

The purpose of WISE was to confirm that sharps injury and blood exposure risks exist in diabetes treatment in the hospital setting, to clarify obligations of hospitals/health care settings as per the EU Directive on sharps safety and to provide specific guidelines/recommendations for safe injections in diabetes in the hospital/institutional setting.

The new WISE Recommendations to Ensure the Safety of Injections in Diabetes will serve as the roadmap for applying the new EU Directive to diabetes care. They are published elsewhere in this supplement. The present article will summarize the individual presentations and discussion groups at WISE. Biographical information related to the speakers is presented in the Appendix.

2. Speakers

2.1. Background

- Needlestick risks during injection: an overview from the U.S. 2001-2009

Dr. Janine Jagger (USA)

Figure 1 shows the U.S. estimated percent market share of safety devices* as they have evolved from 1998 to 2009. All safety device categories rose dramatically after federal legislation was passed in late 2000, but needles and syringes tend to lag behind phlebotomy and intravenous devices [1]. About 58% of the 4,149 injuries reported from 50 US hospitals in the EPINet Research Network from 2001-2009 were from injecting devices, and of these 18% were from insulin injections. Figure 2 shows the percentages of injuries from safety and non-safety insulin devices in the USA. Safety devices are implicated in a worrisome number of “through-and-through” skin injuries, probably from the use of a lifted skin fold to give the injection. This raises the disturbing dilemma of possible simultaneous contamination of the health care worker from the patient (when the needle is advanced), and of the patient from the health care worker (when the needle is withdrawn). The use of shorter needles which may be inserted straight in (i.e., at 90°), and do not usually require a lifted skin fold may be one way to address this issue.

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* various abbreviations are used to designate safety devices: ESIP (Engineered Sharps Injury Protection Devices), SEND (Safety Engineered Needle Devices); SND (Safety Needle Devices) and SEPM (Safety-Engineered Protection Mechanisms).
Injections in diabetes, current hospital practice and risks

Dr. Anders Frid (Sweden)

A report on Needlestick Injuries (NSI) by the Dutch Hepatitis Center [2] was published in March 2009 in which a clear distinction was drawn between high risk and low risk accidents. Accidents with devices for capillary sampling (e.g., lancets) are cited as a high risk while ones with insulin injecting devices are considered low risk. For low risk accidents the Dutch authorities consider a vaccination for Hepatitis B to be sufficient protection. Since all staff in the hospital is vaccinated, they see no real risk. However, according to one study [3], Hepatitis B (HBV) DNA was discovered in 11% of patients with type 2 diabetes, compared to 3% in the control sample, a statistically significant difference. It is not sufficient risk control to rely on the fact that a high proportion of healthcare workers treating people with diabetes will have had the HBV vaccination. The vaccination coverage is far from 100% [4]. Moreover, there are other dangerous viruses (such as HIV and Hepatitis C [HCV]) for which there is no vaccination. Looking at infection risk across the board, there are more than 30 viral diseases that a NSI can transmit, of which the most dangerous are HBV, HCV and HIV. Regarding the latter the prevalence of seropositivity among people with diabetes is higher than (HCV) [5] or equal to (HIV) [6] in the general population. More NSI than the norm occur in treating people with diabetes. Those injuries are a high risk source of possible infection despite the small size of diabetes needles, and the introduction of readily available safety-engineered needle devices have been clearly shown to reduce the risk of injury and infection.

Determinants of risk of needlestick injury-associated infections

Dr. Janine Jason (USA)

The key determinants of the risk of infection from a percutaneous injury are the likelihood that a source is infected, the immune status of the injured health care worker (HCW), the viability of contaminating organisms, the volume of the inoculum and its infectivity, the invasiveness of the injury and the receipt or non-receipt of appropriate Post-Exposure Prophylaxis (PEP). Key questions to consider regarding the likelihood of infection are: Was the sharp used on a patient? If so, is the source patient known? If the source is infected, what are his clinical status and viral titer(s)? If the source is unknown, what is the likelihood he was infected? In the latter question, local epidemiologic data is often the most reliable guide. The rates of transmission from percutaneous injuries involving a known positive source are, for HBV to a nonimmunized host: ~23% - 62% (reduced with PEP) and to an immune host: 0%; for HCV: ~1.8% (range: 0%-10%); and for HIV: ~0.2-0.5% (varies with exposure parameters and reduced with PEP). PEP in a non-vaccinated health care worker (HCW) exposed to HBV should include HBIG plus HBV vaccine or HBV vaccine alone. Effectiveness of PEP decreases with increasing time post exposure with the maximum interval likely < 7 days after NSI. Antiviral PEP is not available for HCV. Management choices in a non-immune HCW exposed to HCV+ blood are problematic. Ig and antivirals are not effective post exposure to HCV+ blood. No HCV vaccine exists. The goal, unfortunately, is early disease identification with management performed by a specialist.

2.2. New EU directive

The new EU directive 2010/32/EU on sharps safety - and its relevance in diabetes care

Prof. Dr. Andi Wittmann (Germany)

A new EU Directive on sharps injury prevention was passed in 2010 [7], with the impending mandatory implementation deadline of May 2013 in all EU countries. One of the provisions of the directive is that all at-risk injections must be given with a safety-engineered device [8]. This obligation covers
all procedures in the hospital as well as those performed in distributed institutional settings (e.g. nursing homes, home health settings, ambulatory clinics) [9]. The new directive “applies to all workers in the hospital and healthcare sector, and all who are under the managerial authority and supervision of the employers”. It includes “students undertaking clinical training” and applies to objects or instruments “able to cut, prick, cause injury and/or infection”. Its guiding principle is “never assuming that there is no risk”. Risk assessment should “cover all situations where there is injury, blood or other potentially infectious material” [10]. The directive specifies that “Workers exposure must be eliminated by taking the following measures, without prejudice to their order: 1. specifying and implementing safe procedures; 2. providing medical devices incorporating safety-engineered protection mechanisms; 3. recapping shall be banned with immediate effect”. There are many additional procedures and elements that are critical to building the “wall of safety” that this directive envisions (Fig. 3). Without any one of the “bricks” this wall is weakened and is likely to fall down.

What is a “safety device”? ISO standards (essential components and capabilities)

Mr. Ralph Hilberath (Germany)

The ISO standard document EN ISO 23908: 2011 is entitled, “Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling”. It requires that once in safe mode, the safety feature(s) protect against accidental sharps injury until safe disposal; that the Safe mode be apparent to the user; that activation allows the user’s hand to remain behind the exposed contaminated sharp; that the safety feature result in no negative effect on performance or proper disposal of the device; that the device resist inadvertent activation; and that the performance of the safety feature be clinically tested. Therefore, for diabetes this standard requires that the user’s finger not be able to reach the back-end of a pen needle (i.e. the non-patient end needle end) and that shorter length needles be used so as to avoid having to raise a skin fold for injection.

2.3. Epidemiology of NSI risk

NSI in diabetic injections in US hospitals

Dr. Chris L. Pashos (USA)

The goal of our study was to quantify the incidence and assess the risk of NSI in nurses caring for patients with diabetes mellitus as well as to evaluate the outcomes associated with those NSI. A total of 400 nurses caring for patients with diabetes in 381 different hospitals throughout the United States over a period of at least 1 year voluntarily completed an Internet-based data collection instrument. The nurses self-reported comprehensive data on their experience with NSI, focusing on those occurring within the past year. If respondents experienced multiple NSI during this period, detailed data were collected on...
the most recent event. Of the 400 nurses, 313 (78.3%) reported experiencing at least one NSI, 110 (27.5%) reported at least one NSI within the last 12 months, and 44 (40% of 110) reported multiple NSI. Nearly two-thirds of these injuries (n = 73/110; 66.4%) were punctures that drew blood, resulting in one case of contracted HCV. The cumulative annual incidence of NSI events was 448 NSI per 1000 nurses. Nurses reported the injury in adherence with existing regulations and policies in only 21.8% of the cases. Disposable syringes were involved in 88 (80%) of the NSI events. In half of the injuries (n = 55), the needle device was equipped with a safety feature that was ineffective, primarily because it was not fully activated (n = 47/55; 85.5%) or it malfunctioned (n = 2-5; 3.6-9.1%). NSI most commonly occurred while nurses were injecting insulin (n = 33; 30%). In the 2 weeks following their NSI, 60.1% of nurses noted that they were more afraid of needed devices than before the injury and 41.8% felt anxious, depressed, or stressed. As a direct result of the NSI, nurses missed a total of 77 days of work. This study is the first to show the relatively high risk both of NSI and of NSI that draws blood among nurses injecting insulin with a disposable syringe and confirms previous incidence estimates of NSI among nurses. Additionally, this study reveals significant post-NSI emotional distress, suggests significant under-reporting of NSI to hospital officials, and demonstrates the need for a more effective needle safety device.

■ NSI in diabetic injections in European hospitals

Dr. Ken Strauss (Belgium)

With the June 2010 publication of EU Council Directive 2010/32/EU, scrutiny has now been focused on the safety and protection of diabetes nurses. We studied the frequency and risks of Needlestick Injuries (NSI) associated with diabetic injections in European hospitals. A total of 634 nurses participated from 13 western European countries and Russia. Once hospitalized, injections were given always by the staff in 31% of cases, by the patient where possible (33%), initially by staff and then the patient takes over (12%) and by both staff and patient throughout the stay (21%). 86% of nurses said their hospitals had a written policy on the prevention of NSI but, where it was available, only 56% were familiar with it. 67% of the nurses had not attended any training on the prevention of NSI and only 13% had attended one in the last year. 7.1% of nurses report recapping needles and 5.9% report storing unprotected needles temporarily on a tray, trolley or cart. 32% of nurses report suffering a NSI in the past while giving a diabetic injection. 29.5% of NSI occurred while recapping a used needle. 57% of nurses unscrew pen needles using their own fingers. In 80% cases the source patient’s identity was known and the sharp item was “contaminated” (known previous percutaneous exposure to patient) in almost half the cases (43%). NSIs were reported to the proper authorities in only 2/3 of cases. Safety devices have been shown to reduce the incidence of NSI and accounted for <2% of NSI in our survey. In conclusion our study shows that frequent NSI occur in European nurses treating people with diabetes in hospital settings. These injuries are a source of possible infection despite the small size of diabetes needles. The introduction of safety-engineered medical devices has been shown to reduce the risk of injury. A new European Directive that has now come into force specifically stipulates that wherever there is risk of sharps injury, the user and all healthcare workers must be protected by adequate safety precautions, including the use of “medical devices incorporating safety-engineered protection mechanisms”. (See full article on this study earlier in this supplement.)

■ GERES studies in France

Mr. Gérard Pellissier (France)

In a one-year (Oct. 1999 - Sept. 2000) retrospective study conducted in 24 sentinel French public hospitals we found that most injection pens used by HCWs were multi-dose pens for insulin administration and required disassembly. We also found that HCWs were mainly injured when they were forced to recap or manually disassemble the needle from the pen in order to store the pen for later use. These pens were associated with a 6-times greater risk of injury than that of disposable syringes [11]. A reduced NSI risk of more than 70% in favor of safety-engineered devices (SED) versus conventional devices emerged in the 2000 survey. An overall low NSI rate of 2.05/100.000 devices in a subsequent 2005-2006 study demonstrated the efficacy of SEDs. We found some SEDs to be more effective than others in preventing NSI: passive devices were safer than active devices and, among active devices, semi-automatic were more effective than top shielding devices (usually require one-handed activation) which were, in turn, safer than sliding shielding devices (usually require two-handed activation).

■ NSI injuries in nursing homes

Dr. Philippe Kiss (Belgium)

Our study’s aim was to describe the causes and circumstances of NSI in nursing homes. We surveyed 45 nursing homes (mean number of beds, 98; range, 30–288 beds), all located in the East Flanders region of Belgium. A total of 162 NSI were reported and registered. Cleaning, technical, or kitchen personnel were involved in 13.0% of all NSI; registered nurses were involved in 55.6%, and 27.8% involved geriatrics helpers. Among nursing personnel (141 injuries), recapping and routine use of insulin pens were reported to be the most important causal acts of NSI (both 21.3% of injuries), followed by sharps disposal—container related injuries (19.9%) and needles that were left in inappropriate places (15.6%). The 3 sharp devices most frequently involved in NSI among nursing personnel were insulin pens (40.4% of injuries), needles for subcutaneous injection (21.3%), and lancet needles (19.9%). Therefore, it is justifiable to state that, in nursing homes, insulin pens are a major source of NSI and should receive appropriate attention in the development of preventive strategies.
2.4. Additional risks: devices, decision-makers, costs and vaccinations

- **Data on performance of safety engineered devices**

  **Dr. Debbie Adams (UK)**

  A four-year prospective study was undertaken at the University Hospital Birmingham, National Health Service Foundation Trust, to evaluate the effect of the introduction of a range of safety hypodermic needle devices on the number of reported NSI. Data on the number of reported NSI for four clinical areas began in 2001. Following an enhanced sharps awareness strategy in 2002, the number of NSI was numerically reduced from 16.9/100,000 devices used in 2001 to 13.9/100,000 devices ($P=0.813$). In 2003, when only standard training was provided, the number of NSI increased to 20/100,000 devices. However, the subsequent introduction of three safety needle devices with concomitant training resulted in a significant reduction in the number of reported NSI to 6/100,000 devices in 2004 ($P=0.045$). User satisfaction and acceptance of the safety needles was also very favourable. These results suggest that when safety needle devices are introduced into the clinical setting and appropriate training is given, a significant reduction in the number of occupationally acquired NSI may ensue. Prior to the introduction of any Safety-Engineered Needle Device (SEND) into the clinical arena it is essential that it be thoroughly evaluated against key criteria to ensure its suitability for safe and effective practice. In a study conducted in 2003 we reported two additional risk factors following the evaluation of three hypodermic safety needles. [12] First, splashing on activation of the safety feature occurred in a limited number of cases with one of the devices. Whereas the risk of transmission of a bloodborne virus via the mucocutaneous route is very low, three cases of occupational transmission of HCV via this route have been reported. [13-15] SENDs should be introduced to reduce the risk of NSI, but it is essential that they do not result in HCWs being exposed to infections via a different route. Potential splashing associated with activation of any SEND should be considered during the assessment period. We reduced the risk of splashing by ensuring training was provided so that the device was activated smoothly. Second, disconnection of a SEND on activation from a slip-lock syringe also occurred in a few cases. To address this concern we specified that needles must be attached using the push-and-twist method, or alternatively LuerLok® syringes were used.

- **A hygienist’s and purchaser’s perspective**

  **Dr. Stefano Morachiello (Italy)**

  An Italian study (SIROH) in 50 hospitals from 1994-2009, which documented 7000 exposures to HCV, found 30 HCV seroconversions – of which 26 were caused by NSI. The same study, during the period from 1986-1996, which documented 2600 HIV exposures, found 5 seroconversions. Before 2000 we estimate the unreported incident rate was 30%; currently, we estimate it to be near 0%. Immediately after an event has been reported an operator interviews the worker and the department manager to understand the details and determine the cause of each accident. Specific biohazard training has been provided since 2006; 750 health workers out of 1650 have been trained (including 93% of nurses, therapists and caregivers). In 2009 we began to purchase insulin syringes with a safety needle. Today we use only insulin syringes with safety needles. In the ten-year period from 2000 to 2010 we had 783 NSI incidents of which 458 occurred in nurses. Ten-year analysis of trends shows that absolute values and rates of occurrence for nurses are decreasing. Safety devices are expensive, but each incident avoided represents a savings equal to the purchase cost of 1900 disposable insulin syringes.

- **Factors influencing the decision to purchase safety pen needles in a hospital**

  **Ms Sophie Cariou (France)**

  Our National French guidelines specify that the Insulin pen be only for self administration by the patient using the rule: ONE PEN = ONE PATIENT. Furthermore there is a prohibition on recapping of used needles. One must use a needle extractor or another instrument to remove the used needles. At Saint Antoine Hospital in Paris we switched to the use of safety pen needles in 2011. Only one accident has been observed since the switch, in September of this year, and that was with an unprotected needle used by a student nurse on the endocrinology service (Fig. 4). The cost for an occupational blood exposure has been estimated at 218 euros at our institution. This includes the costs of tests for viral serologies which yield negative results (i.e. no long-term antiviral treatment is required). The cost of our safety pen needles is 9000 euros/year, a reasonable bargain considering how many occupational exposures we avoid.

![Figure 4. Number of NSI at Saint Antoine Hospital (Paris) with Pen Needles by year with Safety Devices introduced between 2010 and 2011.](image)
Needlestick injuries and HBV vaccination status outside the hospital

Nurse Dieuwke Vos, (Netherlands)

In the Netherlands an estimated 15,000 NSI and accidental exposure to blood occur annually, many are not reported. Insulin pens and lancet pens are involved in many of these accidents in non-hospital settings. Our study’s purpose was to describe the characteristics of NSI occurring to HCW outside the hospital in our region of the Netherlands (Utrecht area) over a period of 12 months. A total of 144 incidents were reported. Of the NSI in nursing assistants, 84% involved an insulin needle or pen. Thirty-five percent of all HCW and 47% of the nursing assistants were not vaccinated against HBV. HBV vaccination status in health care workers outside the hospital should be improved, in particular among nursing assistants.

2.5. Existing laws and guidelines

The Spanish safety law: perspective from diabetes

Dr. Luis Mazón (Spain)

In 2005 the health council of the Community of Madrid approved a pilot project to evaluate biosafety devices. Since 2007, in the Community of Madrid, the use of safety devices in hospitals of the public health network is mandatory. Our study has shown that safety devices reduce the risk of NSI, with an absolute risk reduction of -0.45 (P<0.05) and a number needed to treat (NNT) of 22 (number of persons who must convert to safety to prevent one NSI). A total of 11,886 accidents with biological risk occurred in Madrid region between January 1, 2007 and December 31, 2010 (i.e. after the law was in force). The underreporting rate in this region was nearly 80% before the law. Because of publicity around the law (and the fact that you would only get compensation if you reported a NSI) this fell to less than 20%. Now almost all NSI are being reported. 62% of percutaneous injuries (n = 6269) during this period were caused by conventional devices, compared to 29% with safety ones. This is partly because there were mixtures of safety and conventional devices in the same wards during this time. One’s level of training and experience makes a huge difference with new trainees having far more NSI than experienced ones. We showed that NSI can be dramatically reduced with safety injection devices however NSI cannot ever be reduced to zero. Reported NSI may even rise temporarily after conversion. The reasons include increases in reporting, lack of total conversion to safety and lack of experience and training in the safety device.

AADE recommendations regarding sharps safety

Nurse Rita Saltiel-Berzin (USA)

The 1997 AADE position statement Educating Providers and Persons with Diabetes to Prevent the Transmission of Bloodborne Infections and Avoid Injuries From Sharps states that all patients should be perceived as potentially infectious for blood borne illnesses. It defines high risk situations related to diabetes care and education as capillary blood glucose testing and injecting or infusing insulin. Educators are obligated to teach patients precautions for the prevention of injuries from sharps in both clinical and community settings. As far as HCWs this position statement encourages vaccination against HBV, use of gloves and the reporting and managing of accidental NSI and mucous membrane exposure according to OSHA and Centers for Communicable Disease (CDC) Guidelines. HCW practices should be reassessed regularly. Persons should not share syringes, injection devices, lancets or lancing devices. Used sharps should be treated as medical waste. The 2002 AADE position statement Use of Engineered Sharps Injury Protection Devices to Meet OSHA Regulations recommend that syringes with engineered sharps injury protection (ESIP) be used when the device is different from than that which will be used in the home setting, when patients have limited learning capabilities, or when HCW or patients are experiencing high levels of stress, when patients have reduced vision requiring adapted devices such as magnifiers and when patients have limited manual dexterity.

The TITAN recommendations on safety in diabetic injections

Dr. Ken Strauss (Belgium)

The 2008 TITAN workshop [16] published the following recommendations regarding safety devices in diabetes:

Safety needles should be recommended whenever there is a risk of a contaminated needle stick injury (e.g. in hospital).

Since most safety mechanisms will not protect against needle sticks through skin folds, the use of shorter needles without a skin fold is recommended.

If an IM injection is still a risk, using an angled approach (rather than a skin fold) is preferable.

The following were recommended regarding disposal of used sharps:

All HCPs and patients should be aware of local regulations.

Legal and societal consequences of non-adherence should be reviewed.

Proper disposal should be taught to patients from the beginning of injection therapy and reinforced throughout.

Potential adverse events to the patients’ family (e.g. needlestick injuries to children) as well as to service providers (e.g. rubbish collectors and cleaners) should be explained.

Where available, a needle clipping device should be used. It can be carried in the patient kit and used many times before discarding.

Under no circumstance should sharps material be disposed of into the public trash or rubbish system.
2.6. Safety in diabetes in light of the EU directive

- **Diabetes care safety: A UK clinician’s perspective**

  **Ms June James (UK)**

There are 2.8 million people with diabetes according to the Diabetes UK figures for 2010. This represents 4-5% of the UK population. 8% have Type 1 Diabetes and 92% Type 2. 20-30% of people in the community setting will be insulin-treated. 15-20% of inpatients have diabetes, the majority are insulin treated. Insulin error is common and the potential consequences can be catastrophic. A third of all inpatient medical errors that cause death within 48 hours of the error involve insulin administration. In the National Patient Safety Agency (NPSA) statistics from Nov 2003 to Nov 2009 there were 16,600 reports of incidents involving insulin with 24% reporting harm to the patient – 18 incidents had severe outcomes and there were 6 deaths. The National Diabetes Inpatient Audit (NaDIA) 2010 revealed that 37% of inpatients had at least one medication error (Fig. 5). Those with 1 or more medication errors were twice as likely to experience severe hypoglycaemia (18% vs 8%). To address this problem and because we believe that insulin error is unacceptable, we have developed an E-learning module as a joint collaboration between NHS Diabetes and the University Hospitals of Leicester. The module uses 4 themes: Right insulin; Right dose; Right time; Right way. It takes 45-60 minutes to complete and is easily accessible. It can be dipped into and out at will and has an assessment process and certification at the end. Local completion data can be sent to individuals trusts. So far uptake of the module is excellent and learner feedback good. Module updates and development of new modules will ensure that ALL staff has access to freely available continual professional development.

- **Patient injection training (should they be trained on safety devices?)**

  **Prof. Tauveron (France)**

Are NSI more common when using pens? Our data from the Clinical University Hospital of Clermont-Ferrand showed that in 2010 we had 149 sharp injuries of which 7 (4.8%) were with insulin pens. The French recommendations for general use of insulin pens (AFSSAPS 2007) call out three distinct scenarios, each of which requires (or does not require) the use of an Engineered Sharps Injury Protection (ESIP) device, displayed in Figure 6. Specifically the guidelines state that when pens are used by HCW (in the clinical setting and during teaching) disposable pens should be used instead of pens with cartridges and ESIP needles should be used. Furthermore an appropriate device must be used to unscrew the pen needle and all sharps waste must be put immediately into safety containers. If ESIP needles are not available, traditional syringes may be used but without recapping. One is immediately confronted, when following these guidelines, with the question: Is it consistent with good educational principles to use a different device in the hospital or training setting from the device that the patient will use at home? This is not an easy question to answer and may even be the wrong question to ask. Perhaps the first question should be: In what populations do we have major concerns about injection safety? This will surely

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**Figure 5. Types of Error uncovered by the 2010 UK National Diabetes Inpatient Audit (NaDIA).**

**Figure 6. Proposed scheme for use (or not) of ESIP in three treatment scenarios (adapted from French 2007 AFSSAPS guidelines).**
include those with limited adaptability (e.g. the elderly), limited learning capabilities, reduced vision, limited manual dexterity and major anxiety regarding self injection. But then we must ask the inevitable question: Should these patients be self injecting insulin anyway? My own view is they should not.

■ The view from someone who suffered a NSI

_Nurse Joan Allwinkle (UK)_

The circumstances of my NSI were explained as well as subsequent events, both immediate and long-term. The key lessons learned are: Never take risks! Never think it won’t happen to you! Manufacturers have a responsibility to recognize and resolve product defects – but don’t count on them always doing it! Only use a new device after you have received appropriate training on it.

2.7. Break-out groups
(discussion questions and group conclusions)

■ GROUP 1 scope of the EU directive and applicability to diabetes care

_Moderator: Prof. Dr. Andreas Wittmann; Reporter: Mike Smith_

1. What can be done to ensure the EU Directive is translated into local law in a timely manner and with the full force of the original intent?

The process should be entrusted to persons with an intimate knowledge of relevant existing national laws as well as of the intent and scope of the EU Directive. Provide translators with a “roadmap” for how the transposition should proceed. The fidelity of the translation/transposition must be verified by third parties: experts in the local language as well as the social partners and scientific experts. Then the content and implications of the directive should be communicated directly to appropriate professional and public groups. Consequences of late or incomplete implementation should be made clear.

2. Should hospitals and nursing homes convert to safety diabetes injecting devices immediately or give priority to in-vein devices?

All conventional sharps devices should be converted to safety ones as quickly as possible. A list of these should be provided. To make acceptance easier, the total “value proposition” should be clarified (i.e. costs vs benefits).

3. Besides hospitals and nursing homes, what other arenas should convert to safety? E.g. are there patient populations injecting at home who should use safety devices?

In additional to hospital and nursing home patients, others in specific settings should be provided with safety needles: prisons/police custody; schools; nurseries; patients with immunodeficiencies or on artificial nutrition. For non-self injecting populations we should ensure that all injectors are protected by providing them with safety devices.

4. The EU Directive is focused on sharps injury. How do we ensure that blood splashing and other risks are not ignored?

We should insist that devices that protect against NSI do not splash, splatter or drip blood. Otherwise they do not qualify as safety devices. This should be part of the initial testing process.

■ GROUP 2 building the risk assessment

_Moderator: Dr. Larry Hirsch; Reporter: Dr. Anders Frid_

1. What elements are needed to put together a compelling and powerful risk assessment?

The assessment needs to address each of the key risk factors: the identity and characteristics of the source patient and the victim, virus subtype, viral load, procedure for which the sharp was used and finally, the potential harms from interventions (e.g. side effects of PEP, Quality of life and costs).

2. Do we have data on sharps injuries in diabetes in your specific country/region? If not, how can that be obtained?

NSI data is generally available in every country/region, but it is often not diabetes-specific. While this data might be available in hospitals, it is rarely available in nursing homes or other long-term care facilities. Data on injections is usually more readily available than lancing data.

3. What tools can be used to sensitize professionals in diabetes to safety risks? Who should develop and implement these tools?

Tools should be individualized and, where possible, case-study based. All HCWs should be sensitized and educated as well as ancillary staff. It is the responsibility of the individual institution to ensure that training is performed.

4. Is there a risk hierarchy in which in-vein devices = high risk and injection devices = low risk? If not, how should this issue be addressed?

There needs to be a Zero Risk Tolerance culture because we cannot tell who is a carrier of blood-borne viruses from simple appearances or patient profiling. The severity of the consequences of a NSI trump any “risk hierarchy” arguments based on the low frequency of occurrence. As with biking accidents, a single slip-up and one’s life may be ruined. The risk of disease transmission from NSI is in fact lower for fine, short insulin injection needles than for larger, longer needles used for deep injections and/or blood sampling. But the negative effects of an even-infrequent transfer of a bloodborne illness are so great (the impact is so serious), that the health hazard risk analysis (and the EU Directive) dictates that all possible steps should be taken to avoid such events from happening – and this includes (but is not limited to) use of safety-engineered sharps.
GROUP 3 safety-engineered devices, which ones, for whom and at what cost?

Moderator: Dr. Debbie Adams; Reporter Hilary Witty

1. How do we ensure that the trialing of safety devices includes HCW input and that the choice is based on the most effective and appropriate option?

There is no formula which will work in every setting. There will be countries/centers where only a limited offering of devices exists. But it must be made clear to deciders and payers that if the HCW is involved from the beginning there is a much higher likelihood that effective and appropriate devices will be chosen and that the decision will not have to be revisited later at additional bother and cost.

2. What sort of testing/pre-evaluation should be done before introducing a specific safety device into a health care setting?

Trials should be conducted before any contractual commitment has been made to a specific device. A strongly representative group should be sought to trial the devices. Different specialties should be included, with, at a minimum, the presence of infection control, occupational health and experienced users. A standard, template protocol would be helpful as a starter for trial design. Input from a statistician should be sought to determine sample size and methodology as well as to analyze trial data later. Local results should be compared with data from trials elsewhere.

3. Cost may be an impediment to implementation. How should this be addressed?

We should make clear to all, from the beginning, that safety devices cost more than conventional ones. But, costs of complications-avoided should be part of the discussion at the same time, and the costing out of these by center should be part of the trial and report.

4. Patients in hospital will soon be injected with safety devices. Should they then be trained on other devices (conventional ones) before being sent home or continue using the safety ones after discharge?

This might differ center to center. The issue is larger than just training on safety devices. Patients must be trained on the whole waste disposal process.

GROUP 4 non-device solutions

Moderator: Consultant Nurse Fiona Kirkland; Reporter Dr. David Miller-Jones

1. Sensitization: what is the most effective way of raising concern about NSI in diabetes care without causing unnecessary fear?

First there must be due consideration of the demographics, culture, lifestyle, beliefs and age of those we want to sensitize. Use trusted opinion leaders. Reference cards with a NSI protocol can be displayed on sharps boxes. Manufacturers should consider putting warnings on boxes of sharps stating that “needles can seriously damage the health of others; please ensure safe disposal”. Catchy slogans should be used in awareness campaigns.

2. Education and Training: what are the most effective next steps for training staff in NSI avoidance once awareness is raised?

“Yellow card reporting”: encourage reporting of NSI and near misses and establish a “no-blame” culture. Central review should be done to allow for policy change and assess the need for training.

3. What can be done to increase HBV vaccination coverage?

Whilst HBV vaccination should be population-wide, the minimum standard is the mandatory offering of vaccination by the employer/legislative body to all individuals exposed to sharps (including HCWs, patients, carers, housekeeping and waste disposal workers). Vaccination status should be reviewed annually as part of the appraisal process.

4. What can be done to stamp out needle re-capping?

Caps need to be designed which cannot be “recapped”. Similarly, we should make available safety needles which do not need to be recapped.

5. What can be done to get the sharp into a safety container as soon after use as possible?

Containers must be placed at point of care, beside the patient. Disposal options must be discussed with the patient when needles are dispensed. A container system must be made readily available to them as well as means of collection and disposal. The container must be convenient in size and design. If such systems are not available, safety needles must be provided for patients self-injecting at home.

3. Conclusion

The WISE workshop confirmed that sharps injury and blood exposure risks exist in diabetes treatment in a variety of settings and that, as per the EU Directive, such injuries must be prevented using safety-engineered devices and other preventative measures. The new WISE Recommendations to Ensure the Safety of Injections in Diabetes provides a roadmap for implementing the new EU Directive to diabetes care. They are published earlier in this supplement.

Duality of interest

KS is an employee of BD.

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The Directive specifically requires: “eliminating the unnecessary use of sharps by implementing changes in practice and risks would include the provision by employers of safer needle devices. (Cf. NHS Employers, Implementation advice on sharps agreement, 12th October 2010).”


## Appendix: Biographies of SPEAKERS

### Janine Jagger
Professor of Medicine at the University of Virginia School of Medicine. She is founder and director of U. Va.’s International Healthcare Worker Safety Center. For the past 25 years, she has focused on reducing healthcare workers’ risk of occupational exposure to bloodborne pathogens. In 1988, she and her colleagues were first to introduce design criteria for needles and sharp instruments to reduce risk of sharps injuries to healthcare workers. In 1991, Dr. Jagger developed the EPINet (Exposure Prevention Information Network) surveillance system for healthcare facilities to standardize the tracking of needlestick injuries and blood exposures. EPINet is now used in more than 80 countries. In 1994, Dr. Jagger founded the International Healthcare Worker Safety Center to disseminate the findings from the EPINet research network and to accelerate the transition to safety-engineered needle technology. She was awarded a MacArthur fellowship in 2002 in recognition of this work. She played a pivotal role in the passage of the Needlestick Safety and Prevention Act in the USA on Nov 6, 2000.

**Her topic was, Needlestick risks during injection: an overview from the U.S. 2001-2009**

### Dr. Anders Frid
Practicing endocrinologist at the University Hospital SUS, Malmö, Sweden and is an internationally-recognized expert in insulin injections. He speaks worldwide on this subject and other diabetes-related topics and teaches regularly at the Rashid clinic in Ajman, United Arab Emirates. His hobbies include singing, playing the electric guitar and long-distance biking.

**His topic was, Injections an diabetes, current hospital practice and risks**

### Janine Jason
An epidemiologist and pediatric immunologist specializing in infectious diseases. Dr. Jason was at the U.S. Centers for Disease Control and Prevention for 23 years, in various leadership positions, including Chief of Hemophilia AIDS Surveillance and Epidemiology and Chief of the HIV Immunoregulatory Laboratory. Concurrently, she was an Associate Professor in the Department of Pediatric Immunology, Infectious Diseases, and Epidemiology at Emory University School of Medicine. She now lives a bi-coastal life as CEO of Jason and Jarvis Associates, LLC, a healthcare and epidemiology consulting company. While on the east coast, she also provides medical care at the Volunteers in Medicine Clinic. Dr. Jason has authored over a hundred scientific publications and, in her spare time, a book for parents of premature infants, two novels, and a mildly cynical comic book.

**Her topic was, Determinants of risk of needlestick injury-associated infections**

### Andreas Wittman
Was born in 1975. In 1995 he began his studies in safety engineering at Wuppertal University in Germany. After finishing his Degree in 2003 he worked as assistant to the chair for Occupational Medicine and Infection Control (with Prof. Hofmann). In 2005 he completed his Doctor’s degree on the topic of Needlestick Injuries. During his work with Prof. Hofmann his major focus was scientific research on transferred blood volumes during NSI and on the economic aspects of NSI. In 2010 he was appointed as assistant professor for “Technical Infection Control”. He played a pivotal role in achieving the passage and publication of Directive 2010/32/EU.

**His topic was, The new EU directive 2010/32/EU on sharps safety - and its relevance in diabetes care**

### Ralph Hilberath
A biomedical engineer with a background in implants, stimulation devices and for 15 years in diabetes treatment. He holds several leading positions in international standards development in the medical device field. His professional interests are in risk management and...
the regulation of medical devices and his personal interest is in sailing and restoration.

His topic was, What is a “safety device”? ISO standards (essential components and capabilities)

Chris L. Pashos, PhD earned his PhD (and masters) in public policy at Harvard University, and his BS from the United States Naval Academy, with Distinction. As vice president at United BioSource Corporation (UBC), a global research organization, Dr. Pashos leads international collaborations to assess the burden of disease, and the use, outcomes, and value of healthcare technologies and services to reduce that burden. Previously, Dr. Pashos was on the faculty of Harvard Medical School, where in the 1980s and 1990s, he managed one of the first Patient Outcomes Research Teams (PORTs) sponsored by the US government to study quality of health care. As a Charter Member of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), he has served in various leadership positions, including President for 2008-2009.

His topic was, NSI in diabetic injections in US hospitals

Ken Strauss is an internist and endocrinologist, born in the USA but living in Europe for the last 20 years. He’s Global Medical Director for BD and Director of Safety in Medicine for the European Medical Association. He’s professional interest are patient and health care worker education, training and safety and his personal interest is writing novels.

His topic was, NSI in diabetic injections in European hospitals

Gérard Pellissier is a PhD in biology, born in France. He has worked for the GERES research group, focusing on reducing infectious risks for healthcare workers, since 1996, both as senior scientist and administrative manager. The prevention of Accidental blood exposure and safety engineered devices are major interests.

His topic was, GERES studies in France

Philippe Kiss was born in Ghent, Belgium and graduated as a GP in 1985. He converted to occupational medicine in 1995 and works as an occupational health physician in the Occupational Health Service Securex in Belgium and is also affiliated (on a voluntary basis) to the Department of Public Health of the Ghent University. Together with his colleague Marc De Meester he tries to apply scientific research into daily occupational health practice. He has performed scientific work on cytomegalovirus in kindergarten teachers, fire fighters, computer workers, older workers, the need for recovery and needlestick injuries.

His topic was, NSI injuries in nursing homes

Dr Debra Adams is a Nurse Consultant in Infection Control at an acute care hospital in the United Kingdom and is also an independent Consultant Advisor. Her professional interests include healthcare worker safety and safety engineered needle devices which culminated in her undertaking her PhD in 2006. Her current hobbies include decorating her new property on the beach.

Her topic was, Data on performance of safety engineered devices

Stefano Morachiello is an Engineer and works in the worker’s health and safety sector since 1987. He is director of the Operational Structure “Prevention, Prevention and Environmental Management” of ASS n 4 - Medio Friuli in Udine, including workers Prevention and Protection Office and the Doctor of health monitoring, provided by Italian safety Law (L.D. 81/2008). He is team leader of the regional group of Prevention and Protection manager of health public companies and public hospitals. His professional interest is the health and safety of workers in health care companies, and his personal interests are sailing and playing pop and rock music.

His topic was, A hygienist’s and purchaser’s perspective

Ms Sophie Cariou (France) is a Pharmacist at SAINT ANTOINE Hospital, APHP group, Paris.

Her topic was, Factors influencing the decision to purchase safety pens

Dieuwke Vos is manager infectious disease control and sexual health at the municipal health service (GGD) Midden Nederland. She was born in South Africa but has been living in the Netherlands for 17 years now. Before managing, Dieuwke was a public health nurse, and was also involved in infectious disease research and policy advising. Dieuwke finished her Master’s degree in Public Health in 2005 and likes to observe the behaviour of individuals and groups at work, in society and in a global context.

Her topic was, Needlestick injuries and HBV vaccination status outside the hospital

Luis Mazón is a Specialist in Occupational Health, born in Spain. Currently he is responsible for the Occupational Medicine Unit of the University Hospital of Fuenlabrada. He is head of graduate studies of the specialty of Occupational Medicine in Madrid.

His topic was, The Spanish safety law: perspective from diabetes

Rita Saltiel Berzin is a registered nurse and certified diabetes educator for many years. She has worked in a variety of community and clinical settings as a diabetes educator and clinical nurse specialist working with both adult and pediatric patients. Prior to coming to BD Rita was the director of Joslin Diabetes Centers in New York City and New Jersey. She has been at BD working in Diabetes Care primarily working on educational initiatives for patients and health care professionals. She has sat on several committees for the National Certification Board for Diabetes Educators as well as a long time member of the American Association of Diabetes Educators.

Her topic was, AADE recommendations regarding sharps safety

Ken Strauss

His topic was, The TITAN recommendations on safety in diabetic injections

June James, a Consultant Nurse in Diabetes for the University Hospitals of Leicester represents diabetes specialist nursing on various national committees and is Vice Chair of the Diabetes UK Council of Healthcare Professionals. Committed to ensuring that people with diabetes receive the highest

quality evidence-based care, she has presented on nursing issues, clinical care and non-medical prescribing at national and international meetings and contributes regularly to the world wide literature base. June presented the Janet Kinson Lecture at the Diabetes UK Annual Professional Conference in March 2010. Working in partnership with NHS Diabetes she recently co-authored the National “Safe Use of insulin” e-learning modules.

*Her topic was, Diabetes care safety: a UK clinician’s perspective*

Igor Tauveron is a clinician from France. He is currently Head of the Department of Endocrinology and Diabetes at the Clermont Ferrand University Hospital and is professor at the medical school. He worked on insulin regulation of protein metabolism for his PhD. He presently has an interest in Diabetes Education and was chosen by the French Society of Diabetes as their speaker for this meeting.

*His topic was, Patient injection training (should they be trained on safety devices?)*

Joan Allwinkle has worked in the Royal Infirmary of Edinburgh as a Diabetes Specialist Nurse (DSN) for the last 25 years. She was one of the first DSNs to be appointed in Scotland and pioneered the concept of educating patients at home, saving hospital admissions. Her recent interests have been in the visually impaired patient with diabetes and improving the care of diabetic patients in care homes. She loves to travel and arrived at this meeting from a holiday in Nice.

*Her topic was, The view from someone who suffered a NSI*