WISE recommendations to ensure the safety of injections in diabetes

K. Strauss and WISE Consensus Group

Global Medical Director, BD, Director of Safety in Medicine, European Medical Association, BD, POB 13, Erembodegem-Dorp 86, B-9320 Erembodegem-Aalst, Belgium

Each member of the WISE Consensus Group has seen and approved the submission of this version of the manuscript and takes full responsibility for it.

WISE Consensus Group

<table>
<thead>
<tr>
<th>BELGIUM</th>
<th>SWITZERLAND</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Ken Strauss</td>
<td>Cornelia Mueller</td>
</tr>
<tr>
<td>Dr. Philippe Kiss</td>
<td>Prof. Dr. Andi Wittmann</td>
</tr>
<tr>
<td>Dr. Vincenzo Costigliola</td>
<td>Siegfried Weber</td>
</tr>
<tr>
<td>Els Van Herewegen</td>
<td>ITALY</td>
</tr>
<tr>
<td>CANADA</td>
<td>NETHERLANDS</td>
</tr>
<tr>
<td>Sandra Dudziak</td>
<td>Rosaria Ferranti</td>
</tr>
<tr>
<td>Carrie Taylor</td>
<td>Antonio Caretto</td>
</tr>
<tr>
<td>FRANCE</td>
<td>STEFANO MORACCHIOLLO</td>
</tr>
<tr>
<td>M. Joly</td>
<td>Alexander Ehrenheim</td>
</tr>
<tr>
<td>Mr. Gérard Pelissier</td>
<td></td>
</tr>
<tr>
<td>Prof. Igor Tauveron</td>
<td></td>
</tr>
<tr>
<td>Marcio Coelho</td>
<td>RUSSIA</td>
</tr>
<tr>
<td>Loïc Hervé</td>
<td>Natalia Volkova</td>
</tr>
<tr>
<td>Sophie Cariou</td>
<td>Olga Koteskova</td>
</tr>
<tr>
<td>Nadine Laudette</td>
<td>Andrey Shanchev</td>
</tr>
<tr>
<td>Catherine Almain</td>
<td>SPAIN</td>
</tr>
<tr>
<td>Alexandre Conroy</td>
<td>Marisa Amaya Baro</td>
</tr>
<tr>
<td>Daniel Maleix</td>
<td>Jose Ignacio García Lloret</td>
</tr>
<tr>
<td>Marie-Christine Navailles</td>
<td>FINANCE</td>
</tr>
<tr>
<td>GERMANY</td>
<td>Macarena Candes</td>
</tr>
<tr>
<td>Dr. Ortrud Hamann</td>
<td>SWEDEN</td>
</tr>
<tr>
<td>Dr. Med. Dagmar Korn</td>
<td>Dr. Anders Frid</td>
</tr>
<tr>
<td>Henry Morag</td>
<td></td>
</tr>
</tbody>
</table>

* Correspondence.
E-mail address: kenneth_strauss@Europe.bd.com (K. Strauss).

© 2012 Elsevier Masson SAS. All rights reserved.
Abstract

Aim. – Injections and fingersticks administered to patients with diabetes in health care settings present a risk of blood exposure to the injector as well as other workers in potential contact with sharps. Such exposures could lead to transmission of bloodborne pathogens such as hepatitis and HIV. A recent EU Directive requires that where such risks have been identified, processes and devices must be put in place to reduce or eliminate the risk. The aim of this paper is to provide formal guidelines on the application of this Directive to diabetes care settings. These evidence-based recommendations were written and vetted by a large group of international safety experts.

Methods. – A systematic literature search was conducted for all peer-reviewed studies and publications which bear on sharps safety in diabetes. Initially a group of experts reviewed this literature and drafted the recommendations. These were then presented for review, debate and revision to 57 experts from 14 countries at the WISE workshop in October, 2011. After the WISE meeting, the revised Recommendations were circulated electronically to attendees on three occasions, each time in a new iteration with revisions.

Results. – Each recommendation was graded by the weight it should have in daily practice and by its degree of support in the medical literature. The topics covered include Risks of Sharps Injury and Muco-cutaneous Exposure, The EU Directive, Device Implications, Injection Technique Implications, Education and Training (Creating a “Safety Culture”), Value, Awareness and Responsibility.

Conclusion. – These safety recommendations provide practical guidance and fill an important gap in diabetes management. If followed, they should help ensure safe, effective and largely injury-free injections and fingersticks. They will serve as the roadmap for applying the new EU Directive to diabetes care.

© 2012 Elsevier Masson SAS. All rights reserved.

Keywords: Insulin injection; Fingerstick injury; Muco-cutaneous exposure; Bloodborne pathogens; Health care worker safety; EU directive; Hepatitis B; Hepatitis C; HIV; Review

Résumé

Recommandations WISE pour garantir la sécurité des injections lors du traitement du diabète

Objectif. – Les injections et contrôles glycémiques réalisés chez les patients atteints de diabète dans les établissements de soins présentent un risque d’exposition au sang pour l’injecteur ainsi que pour les autres travailleurs en contact potentiel avec les objets piquants. De telles expositions présentent le risque de transmission d’agents pathogènes comme les virus de l’hépatite et le VIH. Une récente directive de l’Union Européenne (UE) exige que, lorsque de tels risques ont été identifiés, des processus et dispositifs soient mis en place pour réduire ou éliminer le risque. Le but de ce document est de fournir des lignes directrices officielles sur l’application de la directive UE dans les centres de soins du diabète. Ces recommandations fondées sur des publications ont été rédigées et validées par un groupe international d’experts en sécurité des soins.

Méthodes. – Une recherche bibliographique systématique a été réalisée en cherchant les études et publications qui portent sur la sécurité des procédures dans le diabète. Initialement, un groupe d’experts a analysé cette littérature et rédigé des recommandations. Elles ont ensuite été présentées, débattues et révisées par 57 experts de 14 pays durant l’atelier WISE en Octobre 2011. Après la réunion de WISE, les recommandations révisées ont été distribuées par voie électronique aux participants, à trois reprises, à chaque fois dans une nouvelle version.

Résultats. – Chaque recommandation a été classée selon le poids qu’elle devrait avoir dans la pratique quotidienne et par son niveau de preuve dans la littérature médicale. Les sujets couverts comprennent les risques de blessures par les objets piquants et par expositions muco-cutanées, la directive de l’UE, les implications pour les dispositifs médicaux, les implications sur la technique d’injection, l’éducation et la formation (création d’une culture de sécurité), le coût, la sensibilisation et la responsabilité.

Conclusion. – Ces recommandations sur la sécurité fournissent des orientations pratiques et combinent une lacune importante dans la gestion du diabète. Si elles sont suivies, elles devraient aider à garantir la sécurité et l’efficacité d’injections et contrôles glycémiques exempts de blessures. Elles serviront de feuille de route pour l’application de la nouvelle directive de l’UE aux soins du diabète.

© 2012 Elsevier Masson SAS. All rights reserved.

Mots clés : Injection d’insuline ; Blessure par objet tranchant ; Exposition muco-cutanée ; Agents pathogènes transmissibles par le sang ; Sécurité des travailleurs de la santé ; Directive européenne ; Hépatite B ; Hépatite C ; VIH ; Recommandations

1. Introduction

This paper presents new recommendations for ensuring the safety of patients, professionals and all persons in potential contact with sharps used in the treatment of diabetes. A new European Directive has recently come into force which stipulates that wherever there is risk of sharps injury, the user and all healthcare workers (HCW) must be protected by adequate safety precautions, including the use of “medical devices incorporating safety-engineered protection mechanisms” [1].

The new recommendations are intended as a road map for implementing the EU directive in diabetes care settings. The recommendations were informed by the results of a large survey of sharps injuries in European nurses. Over 4 months, from March to July 2011, 634 nurses participated from 13 western European countries and Russia. The results of this survey had...
just become available as the new recommendations were being formulated and are published elsewhere in this supplement.

The initial draft of the new recommendations was presented at the Workshop on Injection Safety in Endocrinology (WISE) which took place from 13-16 October, 2011 in Brussels, Belgium. This high-level forum discussed the application of the new EU Directive on sharps safety to diabetes care. (See a synopsis of the meeting elsewhere in this supplement.) WISE brought together a diverse group of 57 leaders in the field of diabetes safety from 14 countries. The 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 by a number of methods, including use of safety-engineered devices. The new recommendations were significantly reshaped by the collective input of this group.

The present work is based on a review and analysis of all peer-reviewed studies and publications which bear on the subject of sharps safety in diabetes. Articles were searched using Pub Med, Medline and Cochrane Controlled Trials. The search spanned the time period of 1980 through the present and used the terms bloodborne pathogen, hepatitis, HIV, subcutaneous injections, insulin injections, injection technique, lancets and needlestick injury.

Attendees to WISE agreed that for the strength of a recommendation the following scale would be used: A. Strongly recommended. B. Recommended. C. Unresolved issue.

For the scientific support we use this scale:
1. At least one randomized controlled study.
2. At least one non-randomized (or non-controlled, observational) study.
3. Consensus expert opinion based on extensive patient experience.

Thus each recommendation is followed by both a letter and number (e.g. A1). The letter indicates the weight a recommendation should have in daily practice and the number, its degree of support in the medical literature. The most relevant publications bearing on a recommendation are also cited. For each topic, background and introductory information is presented first, followed by the actual recommendations in the shaded text.

2. WISE Recommendations

2.1. Risks

The everyday activities of HCW put them at risk of serious infections with more than 30 potentially dangerous pathogens, including hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV), through injuries with contaminated needles and lancets [2]. More than one million needle stick injuries are estimated to occur in the European Union each year [3].

• Sharp devices used in hospital and other health care settings represent a risk for the transmission of blood-borne pathogens to the user in the event of a needlestick injury (NSI) or muc-cutanous blood exposure [4]. A1
• This risk can extend as well as to “downstream” workers (e.g. technical and kitchen personnel, cleaning persons, rubbish removers, incinerators and the general public) if they receive an accidental NSI or muc-cutanous blood exposure involving infectious material [5]. A1
• Studies have shown that the incidence of NSI among HCW giving injections to patients with diabetes or drawing blood with lancets is just as high, or higher, than workers in other departments or wards [6]. A1
• The prevalence of HBV, HCV and HIV in patients with diabetes is reported to be as high, or higher, than in healthy individuals or in patients with other disease states [7-9]. A1

2.2. European Union Legislation

The majority of NSI are preventable with the provision of effective training, safer working procedures and safety-engineered medical devices that shield or retract the needle after use [10]. The June 2010 publication of EU Council Directive 2010/32/EU, on the prevention of sharps injuries in the hospital and healthcare sector, highlighted the importance of consistently implementing mandatory measures to prevent these potentially fatal injuries [11]. The directive must be implemented in all member states by 11 May 2013 at the latest.

• In accordance with a new EU Directive [12] and its transpositions into member-state legislation, at-risk injections or bloodletting with lancets must be done with safety-engineered devices [13]. A1
• This obligation covers all injections or fingersticks for managing diabetes in the hospital as well as those performed in distributed institutional settings (e.g. nursing homes, ambulatory and emergency clinics, ambulances, schools, prisons, nurseries, 3rd party caregivers in home settings, etc.) [14]. A1
• The use of safety-injection and lancing devices should be considered for certain autonomous home-injecting patients with diabetes (e.g. those known to be positive for HIV, HBV and HCV) as well as for nurses who may visit them to do glucose monitoring or administer insulin injections. B2
• Home-injecting patients with small children, elderly patients with mobility or dexterity limitations, those without appropriate sharps disposal options and those who live far away from a safe sharps disposal facility should also be provided with safety-engineered devices. B2

2.3. Device Implications

Devices designed for different procedures have different injury rates and different transmission rates of bloodborne pathogens. Injection devices (syringe/needle) are the most
common device category associated with NSI [15]. The presence of blood on the needle is a key risk factor determining transmission risk. Studies undertaken in the United States and Italy show that approximately one out of six hypodermic syringes and needles are contaminated with blood [16]. Blood is sometimes present on used injection devices but may not be visible [17]. In the case of highly infectious organisms, e.g. HBV, only minute amounts of infected blood are required for transmission. Multiples of this amount are present within the barrel or on the sides of medical sharps, even in devices not used expressly for blood drawing or vascular access. Lancing devices, by definition, are contaminated with blood after use. Deep injuries incur three times the transmission risk of bloodborne pathogen than superficial ones [18,19].

- Safety-engineered devices, when introduced into health care settings where a “safety culture” has been fostered and appropriate training given, can significantly and sustainably decrease the incidence of NSI [20-26]. A1
- In accordance with the EU Directive HCW should be involved in the evaluation and selection of devices used in their health care setting. Key participants in this evaluation include experienced end users, infection control professionals and occupational health experts [27]. A1
- A safety device for diabetic injections should, if possible, include the features outlined in the Appendix [28]. A1
- Any health care setting which uses insulin pens must follow a strict one-patient / one-pen policy [29]. A1
- When pens are used, the optimal safety device should protect against sharps injury from both the patient and non-patient (cartridge) ends of the needle [30]. A2
- When syringes are used, only safety-engineered ones should be accepted and the protective mechanism must be integral to the device [31]. A1
- HCW must report and manufacturers must assess NSI reported with safety devices for possible device failures, and must design out identified risks and defects. A3
- Performance and reliability data should be made available on each safety device at the time of market introduction. A3

2.4. Injection technique implications

Needle lengths previously recommended for SC injection are now recognized to be too long for many adults (e.g. 12.7 mm) and for most children (e.g. 8 mm). Specifically they increase the risk of intramuscular (IM) injections [32] which can lead to excessively rapid and/or variable absorption of insulin [33]. Two solutions have been proposed for avoiding IM injections: the lifting of a skin fold (into which the injection is given) and/or the use of shorter needles [34]. The lifting of a skin fold puts a HCW at risk of a “through-and-through” NSI, i.e. a NSI to the hand creating the fold from a needle that has entered and exited the skin fold. This risk is higher if a longer needle is used, since its length may exceed the thickness of folded skin.

- Since safety mechanisms will not protect against NSI through skin folds, the use of shorter needles (e.g. 4 and 5 mm pen needles) without a skin fold is recommended [35,36]. Of note, very young children or extremely slim or muscular adults may still need to raise a skin fold [37,38]. A1

2.5. Education and Training (Creating a “Safety Culture”)

The introduction of safety devices must be done within the context of a center-wide, and if possible, region-wide campaign of sensitization of HCW to the risks of NSI and best practices for avoiding them. These procedures and protocols must include the correct and optimal use of products already available to HCW (e.g. gloves, sharps containers, gowns). Emphasis must be given to time-honored practices (e.g. not recapping needles, discarding sharps the moment they are removed from the patient’s body, not overfilling containers) [39]. Political and managerial will, resource allocation, inter-disciplinary cooperation, education and training and visual clues and reminders are all indispensable [40]. Education and training should be given to all new employees and extend to “downstream” workers who may be at risk of NSI from sharps. Manufacturers also have a responsibility to provide training, and it should be mentioned in tenders and contracts.

- NSI awareness campaigns must be carried out regularly and should include all persons in potential contact with medical sharps [41]. A1
- All persons at NSI risk must receive appropriate education and training on ways to minimize risk, including the importance of following optimal injection or lancing techniques, using available safety devices and wearing protective clothing (e.g., gloves) [42]. A1
- Education and training should begin in nursing and medical school and be continued thereafter on a yearly basis. It should be regular, across all shifts, and be repeated to take into account staff turnover [42]. A1
- Needle and lancet recapping must be forbidden. HCW must understand why this is the case and manufacturers should design sharps protection mechanisms which make recapping impossible [43]. A1
- Hospitals must encourage reporting of NSI, near misses and incorrect technique within a “no blame” culture. Central review of these reports must take place regularly to facilitate policy change and assess educational needs. A2
- Review and appraisal of the effectiveness of education and training and of adherence must be performed at regular intervals. A “no blame” reporting system for violations must be put in place, linked where possible into existing adverse event reporting systems. Procedures for what to do following a NSI must be posted in critical locations. A2
- Attention must be paid to proper use of safety devices. If they are not activated because of user inattention, forgetfulness or lack of training, they provide no additional risk reduction over conventional (non-safety) devices [44]. A1
• In all settings suitable sharps disposal containers must be easily reachable and located at the point of care, at or below eye-level. The containers should be emptied or exchanged at frequent intervals and should never be overfilled. Containers should be lockable and single-use devices [45] which bear a warning such as, “Needles can seriously damage the health of others. Please ensure safe disposal”. A2
• Procedures for what to do in the event of a NSI should be clearly communicated. Formal protocols with named clinical care contacts must be available in all areas where sharps are used. A2
• While HBV vaccination should be population-wide, at a minimum it should be a mandatory offering by the employer to all workers exposed to sharps. Vaccination status should be reviewed with each employee and all should be made aware of consequences of non-vaccination [46]. A1
• HBV vaccination should remain individual choice but be available free-of-charge where the work environment places the person at risk. A2

2.6. Value

The initial purchase costs of safety injection devices may be higher than conventional ones, but the significant reductions in NSI and other complications soon offset, and often recover, these costs. In a recent study in Belgium, it was shown that a conversion to safety devices in fact saves money [47]. A more recent study in France [48] comparing safety with non-safety insulin pen needles gave similar results.

• Cost effectiveness studies suggest that the savings from reductions in sharps injuries with safety devices may offset or compensate for the increased price per device. Additional studies, focused on injection and lancing devices for diabetes, should be performed in hospitals, long-term facilities and home settings [49,50]. A1

2.7. Awareness and Responsibility

Every country has its own regulations regarding the disposal of contaminated biologic waste. All stakeholders (patients, HCW, pharmacists, community officials and manufacturers) bear a responsibility for ensuring proper disposal of used sharps.

• Safe sharps disposal processes and systems should be present in each region, should be well known to all persons in contact with sharps and should be enforced consistently. Legal and societal consequences of non-adherence to these regulations should be made known [51]. A1
• Proper disposal and personal responsibility should be taught to patients from the initiation of diabetes injection therapy by dispensing HCW (including pharmacists) and reinforced throughout through literature and personal counselling [52]. A1
• The avoidance of potential adverse events in the patients’ surroundings (e.g. NSI to children, schoolmates, fellow workers) as well as to service providers (e.g. rubbish collectors and cleaners) should be emphasized. A2
• Packaging for sharp devices should carry warnings regarding safe disposal and risks to other people. A3
• Under no circumstance should sharps material be disposed of into the public trash or rubbish. A3

3. Conclusion

Unsafe medical care is a major source of morbidity and mortality throughout the world. Patient safety is the most critical component in the quality of healthcare. But the care of patients with diabetes depends on maintaining a safe working environment for the many workers who provide that care. The purpose of the new EU directive on medical sharps is to ensure that such an environment exists. Innovative medical technologies are available that play an important role in this process, but the issues are far larger than simply devices. An entire culture of safety must be created. The present document is a roadmap for implementing such a culture and each of its recommendations is intended as a signpost. The new recommendations should be read and followed by all persons in contact with medical sharps as well as by those who make policy for diabetes care and those who enforce it.

Conflicts of interest disclosure

KS is an employee of BD.

Acknowledgments

The authors wish to especially thank Dr. Laurence Hirsch for his many invaluable comments and edits.

References

Article 3.2 says that where risk cannot be eliminated the employer shall
PHASE study group (Italy) Rischio biologico e punture accidentali
K. Strauss / Diabetes & Metabolism 38 (2012) S2-S8
Cullen BL, Genasi F, Symington I et al. Potential for reported needle
Adams D, Elliott TSJ. Impact of safety needle devices on occupationally
Yazdanpanah Y, DeCarli G, Migueres B, Lot F, Campins M, Colombo
Prüss-Üstün A, Rapiti E, Hutin Y. Sharps Injuries: Global burden of
Technical Rules for Biological Agents (TRBA 250 Point 4.1.1.4)

[7] Lee JM, Botteman MF, Nicklasson L, Cobden D, Pashos CL. Needle
[16] PHASE study group (Italy) Rischio biologico e punture accidentali
[45] Technical Rules for Biological Agents (TRBA 250 Point 4.1.1.4) published by the German Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (Federal Institute for Occupational Safety and Health, see www.baua.de).
[47] Liesumke D. Safety products, for everyone’s (financial) benefit (Les produits de sécurité, un avantage (financier) pour tous). Study sponsored by and used with kind permission of UNAMEC, The Belgian Association for producers and/or distributors of medical devices.
During use

- The safety feature can be activated using a one-handed technique OR
- Routine use of the device causes the safety mechanism to deploy automatically (i.e. passively) immediately after the sharp has been used
- The safety feature does not obstruct vision of the tip of the sharp
- The device offers a good view of any aspirated fluid
- The safety device does not require more time to use than a non-safety device
- The safety feature works appropriately with a wide variety of hand sizes
- The device is easy to handle while wearing gloves
- The device will work with all required syringe and needle sizes
- The device provides a better alternative to traditional recapping

After use

- There is a clear and unmistakable change (audible and/or visible) that occurs when the safety feature is activated
- The safety feature operates reliably
- The exposed sharp is permanently blunted or covered after use and remains so until and after disposal
- The device is no more difficult to dispose of after use than non-safety devices

Training

- The user does not need extensive training for correct operation
- The design of the device suggests proper use

*These criteria represent optimal target features which may not be achievable in every device; they do not represent an exhaustive list and may evolve over time.