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PRESENTATION

This document is another link in the editorial line of the National Association of Nursing Managers by which we are defining our point of view on different issues we consider to be of interest. We have thus published the following documents that you can find on our website: http://www.ande.org:

- Management of the product of nursing activity.
- Clinical management of nursing care.
- Professionalisation of nursing Management.
- Excellence in nursing care.
- Professional career and skills management.

This document includes the contributions and conclusions agreed in a meeting by a group of experts. The conclusions presented herein are endorsed by the Board of Directors, who have allowed them to be published.

The new European Directive EU 2010/32/EU of 10 May 2010 on the prevention of sharps injuries for healthcare workers requires that all health institutions implement mandatory safety regulations in order to protect health professionals. This directive came into force on 1 June 2010 and must be implemented in the member states of the European Union by 11 May 2013 at the latest.

In order to facilitate the national implementation of this directive, we consider it essential to develop a consensus document on biosafety, supported by the health professions involved and by the different associations, colleges and trade unions that represent these professions, such as La Asociación de Especialistas en Enfermería del Trabajo (AET), La Asociación Nacional de Enfermería Coordinadora de Recursos Materiales (ANECORM), La Asociación Nacional de Directivos de Enfermería (ANDE), El Consejo de Enfermería de la Comunidad Valenciana (CECOVA), El Sindicato de Enfermería (SATSE), La Central Sindical Independiente y de Funcionarios (CSIF) of Seville. We would like to express our gratitude to all of these organisations for their collaboration in defining and establishing its contents.

Jesús Sanz Villorejo.
Chairman of ANDE
INTRODUCTION

The European Union (EU) has published a new directive that is especially designed to help prevent injuries and infections in healthcare caused by sharp objects, such as needles and intravenous catheters. The EU estimates that needlestick injuries “cause more than one million injuries every year”, and therefore the prevention of this kind of injury has become a problem that all European health institutions must address. This directive, which must be transposed into national law in all member states by May 2013 at the latest, deals specifically with the need to “provide medical devices that include safety mechanisms;” since numerous studies have proven their critical role in reducing needlestick injuries.

This directive states that it is the responsibility of companies to protect their professionals from injuries caused by sharp objects. Compliance with the directive is mandatory. Despite the pressure healthcare budgets are under in Europe, many institutions have been able to create a solid financial arguments to include safety devices in healthcare practice. Some of these institutions have already changed to provide a safer working environment, improving the quality of their processes, eliminating the cost from treating these accidents, workplace absenteeism caused by workers trying to avoid such injuries and the costly legal processes.

In Spain, legislation already exists that enforces the use of safety devices in five Autonomous Regions. This legislative initiative started in the Region of Madrid, followed by the Autonomous Regions of Castilla La Mancha, the Balearic Islands, Navarre and Galicia. However, the scope of application of these laws is different in each region. In Madrid, Navarre and Galicia, the Law enforcing the use of safety devices only covers the public health system, whereas in Castilla La Mancha and the Balearic Islands it covers both the public and the private sectors. Likewise, the enforcement of this legislation is also uneven. In Madrid, Castilla La Mancha and the Balearic Islands it is almost completely implemented, whereas in Galicia and Navarre, due to the application terms included in the legislation, it has not yet started.

The lessons learned by some of these regions in needlestick injury prevention and the use of safety devices has inspired much of the content of this consensus document.

We must also consider the commitment of all those who have participated in the drafting of this document to ensure the welfare and the protection of patients and health professionals as well as increasing the economic efficiency of the health institutions they represent.
ADOPTING THE USE OF SAFETY DEVICES: BEST PRACTICES. DEFINITIONS

The generalised adoption of safety devices is only one element of the safety policy intended to radically reduce the incidence of needlestick injuries and infections. There is a recognised hierarchy of priorities regarding the prevention of injuries from sharp objects:

One. It is necessary to eliminate wherever possible and/or otherwise reduce the use of needles and other sharp instruments. Certain procedures contemplate the use of devices without needles and other means for administering medication.

Two. When sharp instruments must be used, measures should be adopted to minimise the risk involved. For example, by using certain devices that feature safety mechanisms, such as caps or withdrawal mechanisms.

Three. Safe professional practices and regular training programmes backed by expert management and prominent figures of the nursing and medical professions are absolutely essential for the safety devices to be used most effectively.

According to the General Secretary of the European Federation of Nursing Associations, independent studies conducted in Europe and elsewhere demonstrate that “a combination of training, safer work practices and the use of medical devices including safety mechanisms can reduce needlestick injuries by 80%.”

Once we accept that the use of safety devices is an essential component in the prevention of accidental needlestick injuries, it is important to promote their universal use in health centres.

In order to guarantee that the investment assigned to this equipment achieves its goal of reducing injuries in health institutions, we must first define exactly what constitutes a safety device and what features and requirements it must meet. Several studies help to specify the characteristics of “safety protection mechanisms”, which are cited in the new EU Directive.2,3,4,5,6,7,8,9,10
REDUCTION OF COSTS DERIVED FROM NEEDLESTICK INJURIES

In the last ten years, there has been some debate and studies on the costs associated with needlestick injuries. Most of these identify the costs derived from needlestick injuries exclusively as the cost of treating the injured person with a general figure ranging between several hundred and several thousand euros.

However, these scientific articles specifically exclude factors such as worker absenteeism, investment in training lost from such absenteeism, as well as the high costs involved in hiring new health professionals. In the event of serious needlestick injury, which can lead to infection by blood-borne pathogens, the costs that can be prevented are much greater, with the National Health Service of Scotland stating that “in such cases, the financial and human costs are high and estimated to range between £10,000 and £620,000.”

Although adopting the use of safety devices requires additional investments, these costs are not excessive. A European study revealed that “the increase in direct costs (from the use of safety devices) was of €0.558 per patient in the emergency room and €0.636 per patient and day in inpatient areas”, and that “the adequate use of safety devices to prevent percutaneous injuries is a very effective measure to prevent these injuries to health professionals.” These studies usually contemplate the adoption of safety devices as a measure that delivers a feasible return on investment, since its use significantly reduces the risk of needlestick injuries and its associated costs, and is more attractive to health professionals who want to work in prestigious institutions with high standards. This has been proven by experience. In Italy, for example, adopting these devices, together with training and awareness-raising, was extremely effective in reducing needlestick injuries - “the reduction ranges from 63% to 100%, depending on the device used”.

In Spain, five Autonomous Regions have already made the use of safety devices a legal requirement. The evidence demonstrating Spain’s leadership in this area comes from a study performed some years ago by the General Nursing Council indicating that the adoption of safety devices would imply estimated savings of 30 million per year.
LEGAL RISK AND COMPENSATION COSTS

Despite some institutions having established partial or total conversion policies on the use of safety devices based on the figures derived from the economic analysis, the financial factor is frequently not the initial factor that leads managers to prioritise the adoption of such devices. Occasionally, the starting point is potentially damaging lawsuits or high compensation rates to be paid for needlestick injuries. It is therefore worth reviewing cases of this kind that have occurred in Europe to understand the threat they pose.

In Italy, the Court of Campobasso passed a ruling awarding compensation of €400,000 to a nurse who suffered an accidental needlestick injury following the administration of an injection to an HCV positive patient and later became infected by the virus, subsequently infecting her baby17. The Court accepted that it was necessary to adopt more effective safety measures in the health centre where the nurse worked. In France, according to Article 452-1 of the Social Security Code, a company is liable for gross negligence for not meeting its obligations regarding safety and results. In the case of gross negligence by the contracting company, compensation awarded to employees increases, and according to Article L452-4 of the Social Security Code, the company is liable for paying additional compensation to the employee from its own capital.

In Germany, within the framework of a regulation called “Biological agents in the health professions and in social service facilities” (TRBA 250), the infringing parties can be sentenced to a maximum of three years in prison.

The UK is the country with the most data on successful claims and compensations, which are generally agreed upon after a trade union becomes involved. Very recently, an important lawsuit set a precedent not only for the physical injury caused by the needlestick injury itself, but also for disorders caused when the responsible health centre did not provide the correct standard of treatment or appropriate care after the injury18.

What compensation would a worker infected with HCV or HIV receive?18 The EU estimates that about 1 million accidental needlestick injuries occur every year. Compensation for damages has little to do with the problem of treatment costs derived from such injuries, which a study undertaken in a European country has calculated to be about €600,000 per year for each healthcare centre19. In Germany, one expert estimates the cost of treatment alone at €40 million, with an additional cost of €130 million for associated costs, without including lost working hours20.
CONCLUSIONS TO THE INTRODUCTION

What might be the conclusion if we consider these different arguments? The legislative apparatus of the EU has been set into motion and cannot be reversed. In less than three years, all European health organizations will be subject to the legal obligation in the new directive, which specifically mentions the need to “provide health devices including safety mechanisms”.

It is also a fact that some health institutions, both public and private, have recognized the influence of the financial arguments to immediately adopt the use of safety devices. In their reasoning they generally combine financial, risk prevention and ethical factors.

They understand that the costs incurred from accidental needlestick injuries can be substantial if we consider the costs for treatment, lost working hours and staff rotation. These institutions have drafted a financial analysis that backs adopting safety devices as a measure that does not reduce profitability; rather, it is in fact more likely to generate savings.

They also wish to avoid damaging lawsuits, high compensation claims and bad publicity, which are elements that divert attention from their main objective: offering high quality healthcare.

Finally, these organizations wish to create an environment for their workers and clinical specialists that offers better protection against injuries which, at the very least, are unpleasant and may even ruin professional careers.

This consensus document has been developed in order to help Spanish and European health institutions to effectively implement systems for the prevention of needlestick injuries in healthcare that are adequately adapted to the new European Directive.

The document introduces key issues regarding needlestick injuries and the use of safety devices. It also includes recommendations to establish an adequate protection system for health professionals.

This document has been drafted with the collaboration of the different associations that participate in the promotion of needlestick injuries within the health institutions: Nurse Directorates, worker health and safety, and preventive medicine departments, the nursing groups dealing with material resources, professional associations and trade unions. The people who participated have great experience and expertise in the development and implementation of healthcare worker safety programmes in their respective health centres.
CONSENSUS DOCUMENT

This document presents the conclusions of the aforementioned working group on the following healthcare worker safety issues:

- The universal and mandatory use of safety devices.
- Selection of the devices to guarantee the successful protection of health professionals and patients.
- Staff training as an essential element to achieve a reduction of needlestick injuries.
- Guarantee to the successful management of safety conversions in healthcare centers.
- Scheduling the dates to start developing healthcare worker safety projects.
- Additional considerations regarding the underreporting of needlestick injuries.
- Healthcare worker safety methodology forum.

THE UNIVERSAL AND MANDATORY USE OF SAFETY DEVICES, ARGUMENTS

The universal use of safety devices in health centres must be mandatory. Partial conversion to safety devices in certain clinical practices or only in certain specialties would lead to serious risks, and we therefore conclude that:

a. The use of safety devices must be universal (when a patient is admitted to a health centre it is impossible to know their risk level a priori), mandatory (as regulated by a European Directive, the Spanish Constitution and the Law on Prevention), ethical (human resources policy) and efficient (cost-benefit ratio).

b. Conventional devices must be withdrawn simultaneously to the implementation of safety devices. The coexistence of both types of devices is not advisable for two main reasons:

   • A misperception exists that there is a lower risk in areas in which the greatest number of accidents occur (with injection systems). The goal of reducing the number of accidents would not be achieved with their discriminate use.

   • It is inappropriate, unfair and ethically incorrect to provide a greater degree of safety to certain healthcare professionals working in areas where safety devices are introduced compared to others working in areas where they are not introduced (ethical and legal liabilities of managers).

c. Health institutions should be entitled to design a feasibility plan that includes different implementation phases per device/department according to their financial resources, size and other variables.
ADEQUATE SELECTION OF DEVICES TO GUARANTEE THE SUCCESSFUL PROTECTION OF HEALTH PROFESSIONALS AND PATIENTS

The selection of health products in general and safety devices in particular must ensure the successful protection of healthcare professionals and patients. It must also be suitable and assessed by a multidisciplinary commission for the selection, assessment and evaluation of health products consisting of:

• Experienced professionals that use the product in its conventional version.
• Professionals with experience in healthcare worker safety, healthcare worker safety materials and their implementation.
• Professionals with experience in the prevention of risks at work.
• Risk prevention officers.
• Supplies and materials resource managers.

The assessment must consider both the quality and safety aspects of the product itself as well as the safety of the new procedures and techniques to be followed by the staff that will be using it. How safe does the healthcare professional feel with regards to the new product and the new technique?

When preparing the tenders, as is the case with any other purchase document, the opinion of health professionals in the multidisciplinary product assessment and selection committee, must be considered and it must reflect the minimum requirements of the current legislation.

The same minimum quality standards must be met whether the purchase is centralised or not. In order to specify the requirements for each medical device it is necessary to develop, within the health centre, a protocol for the selection of safety products based on the Implementation Guide of the European Safety Directive, published by the European Biosafety Network, which defines the criteria for safe medical products.

• The activation of the safety mechanism must be convenient and allow the care-giver to maintain appropriate control over the procedure.
• The safety mechanisms should not be easily reversible once activated.
• The activation of the safety mechanism must manifest itself by means of an audible, tactile or visual sign to the health professional.
• The device must not compromise patient care.
• The safety mechanism must be an integral part of the safety device, not a separate accessory.
• The device must be easy to use and require little change of technique on the part of the health professional.
• The device must perform reliably.
• A single-handed or automatic activation is preferable.
• The device must not create other safety hazards or sources of blood exposure.

It should also enable the adaptation for use by staff with disabilities, including the design of specific training.
It is highly recommended there be an updated and specific healthcare worker safety selection guide in which each product is listed with its detailed technical specifications. If a specific product is not available, it is advisable to select the device that provides most safety and less risk during use, as well as collaborating with medical device suppliers in order to design a specific prototype.

Based on experience it is extremely useful to perform pilot tests in one or several departments before the purchase.

**STAFF TRAINING AS AN ESSENTIAL ELEMENT FOR THE SUCCESSFUL REDUCTION OF NEEDLESTICK INJURIES WITH SHARP DEVICES.**

We consider staff training as an essential element in the successful reduction of needlestick injuries with sharp devices. Training should be regulated and included in the undergraduate training of Health Science degrees with the contribution and participation of the different schools and scientific societies.

We all agree that training must respect the ethical principle of universality and fairness, ensuring that new staff or staff in training practice must receive appropriate training in this regard, since it has been proven that the percentage of needlestick injuries increases with healthcare professionals with less experience.

The training to acquire skills in handling of safety products must be theoretical and practical (including basic healthcare worker safety concepts) and must be provided by the supplier and enforceable in all purchase agreements (not only in public tenders), in order to guarantee its correct use and adaptation to the requirements of the centre (staff rotation, contingencies, etc).

On the other hand, training must be ongoing, regular and mandatory in order to maintain the level of awareness. It is the responsibility of the health centre itself, and not only of the supplier, to ensure compliance with the standards mentioned above through the:

- Assessment of skills.
- Assessment on the correct use of the devices.
- Inclusion in the protocols of the different services and units (general procedure protocols of the institution).
- Monitoring by experts in the centres to reinforce the initial training by the supplier.

The training must consider the following three aspects of professional practice:

- Awareness-raising, which helps to reduce the resistance to change regarding both the healthcare products themselves and the potential change of techniques.
- Effective behaviour/use of the devices and implementation of new techniques.
- Compliance with protocols, their application and maintenance.
ENSURING THE SUCCESSFUL MANAGEMENT OF SAFETY CONVERSIONS IN HEALTHCARE CENTRES

Working teams discussed how to guarantee the successful implementation of healthcare worker safety programmes in health centres. We reached the conclusion that effective safety conversions are the result of a comprehensive project that is led, planned and programmed by the health centre manager and its managing board:

a. A comprehensive project - it does not merely involve the change of conventional medical devices for safety ones. It involves the development and implementation of good healthcare worker safety practices that must be monitored by healthcare centre management.

b. A comprehensive project - it involves critical logistics, purchasing, procedure protocols, training, awareness-raising and the appropriate selection of devices. This is the only way to truly reduce the number of needlestick injuries, as well as obtaining a neutral financial impact or a significant reduction in costs for the institution.

c. The scheduling of the dates and implementation phases must also be performed by the healthcare centre manager together with the managing board, letting each centre define its own development and implementation plans according to the size of the centre, its financial resources and the types of devices, as well as their training requirements.

SCHEDULING THE DATES FOR THE DEVELOPMENT OF HEALTHCARE WORKER SAFETY PROJECTS

Below are different reasons for which healthcare worker safety projects should start immediately, regardless of the fact that each centre may plan its own execution and implementation dates according to the different phases it defines in the previous section, (Section c, according to its size, available resources and other needs):

a. The risk incurred by health professionals is real. Furthermore, there is an unequal use of safety devices in the different specialties and the different health centres, which puts different health professionals at different risk levels. The ethical commitment of health institutions must be to provide safety for both professionals and patients.

b. Health centres will no longer have the choice as to whether or not they want to implement healthcare worker safety programmes based on the new European Directive, which establishes the final deadline for implementation on 11 May 2013.

c. The implementation of safety programmes and corresponding risk assessments, definition of protocols, training, procurement process, logistics, etc are time and resource intensive. It takes several months to effectively implement a safety programme in a healthcare institution.
ADDITIONAL CONSIDERATIONS REGARDING THE UNDERREPORTING OF NEEDLESTICK INJURIES

The underreporting of needlestick injuries in health centres should be considered when measuring results. When performing awareness-raising campaigns on needlestick injury risks, these tend to increase.

We recommend performing information and awareness-raising campaigns to promote the reasons for this change.

HEALTHCARE WORKER SAFETY METHODOLOGY FORUM

We propose creating a healthcare worker safety methodology forum which shares and communicates the synergies relating to risk analysis, assessment tools, technical reports, etc., so that individuals can benefit from the successful implementation of different initiatives and activities carried out elsewhere.
7. ISPESL – Istituto Superiore per la Prevenzione e la Sicurezza sul Lavoro LINEE GUIDA SUGLI STANDARD DI SICUREZZA E DI IGIENE DEL LAVORO NEL REPARTO OPERATORIO, December 2009.
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