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MECOSAN

Direttiva europea sulla tutela dai rischi di infezione di pazienti e infermieri – Intervista con Paul De Raeve, Segretario Generale dell'EFN (European Federation of Nurses Associations)

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Premessa

La tutela della salute, definita come recupero, mantenimento e promozione del benessere fisico e psichico (e si può aggiungere spirituale, in senso laico e religioso), richiede innanzitutto che nei luoghi deputati a perseguire questa finalità, *in primis* ospedali ma anche attività ambulatoriale e assistenza sul territorio e al domicilio dei pazienti, siano adottate tutte le misure per prevenire l'insorgere di malattie. Pazienti, medici, infermieri e altri operatori socio-sanitari di assistenza sono esposti a infezioni derivanti dalle procedure di diagnosi, cura e assistenza, quali prelievi, interventi chirurgici, cateterismi ecc. Tra gli operatori di assistenza, gli infermieri sono sicuramente tra quelli maggiormente esposti e quindi ci è parso opportuno porre al Segretario della Federazione Europea che li rappresenta alcune domande relative alla Direttiva Europea 32/2010. Di seguito si riporta il testo integrale dell'intervista, in inglese per evitare il rischio di tradurre in modo inadeguato il suo pensiero. La conoscenza di termini tecnici da parte degli infermieri non dovrebbe comunque ostacolare la lettura anche a chi conosce in modo limitato la lingua. Con la pubblicazione di questa intervista, *Mecosan* intende stimolare o ravvivare il dibattito sulle politiche di tutela dai rischi di infezioni per i pazienti, medici, infermieri e altri operatori socio-sanitari, rendendosi disponibile a pubblicare articoli di tipo scientifico o che presentano buone pratiche sul tema o a organizzare convegni e seminari con le direzioni delle Aziende Sanitarie e Aziende Ospedaliere, i rappresentanti di medici e del personale sanitario non medico. A tali iniziative potrebbe essere invitato lo stesso Paul De Raeve.

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Premessa

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1. The reasons why specific rules have been defined: what is the evidence on which new rules for patients and nurses safety have been defined?

EFN went in 2004 with 30 nurses to the EP who suffered from sharp injuries. In the EU and Europe, 1 million HCP suffer from sharps injuries, which implies most of the time, being very sick, system failure (liver), family

problems (divorce) and losing your job! This evidence led to an own initiative report by the EP (Liz Lyne and Stephen Huges) pushing the Commission to do something about it!
Result after 6 years: EU legislation with 5-6 key articles! To be implemented in all 28 National legislations. The protection of the HCP workers is an EU competency!
It has been estimated that one million sharps injuries occur in the European Union each year[1]. Sharps injuries – from medical sharps, such as needles and intravenous catheters – are the second most common healthcare injury following back injuries[2] and their impact is not to be underestimated. As well as having a high cost burden for employers[3], a sharps injury can result in possible infection from 30 potentially dangerous blood-borne pathogens and healthcare associated infections, including Hepatitis B, Hepatitis C and HIV. The majority of these injuries are suffered by nurses and occur in patient rooms and the operating theatre, but doctors and other healthcare staff are also victims. Ancillary staff such as hospital porters, cleaners and laundry staff and other downstream workers also suffer sharps injuries because the appropriate boxed to put the needles in are not available[4]. Studies have also begun to highlight the psychological consequences associated with sharps injuries. The distress of having possibly contracted a blood-borne disease can be enough to trigger post-traumatic stress disorder[5] and an injury can cause depression, anxiety and career-limiting fear.
The consequences of a sharps injury can be severe, but most sharps injuries are referred to as zero injuries; i.e. injuries not resulting in sick leave. Sharp injuries are a cause of significant distress as an injured worker can face many months of uncertainty. This can be a huge alarming event when no infection occurs. This can be a major disincentive to a career in nursing. A significant issue as the EU faces increasing shortages of qualified nurses. There are 21 million workers active in the hospital and healthcare sector in Europe. It is estimated that 1 million needle stick injuries occur annually, while from our data of 6.971 professionals, mainly nurses, 41% reported to have suffered a sharp injury incident. This is extremely high, and provides a serious disincentive for a career in nursing.
As such, the prevention of sharps injuries has become a consideration that all healthcare organizations throughout the EU and Europe must address.

2. How have the new rules/ procedures/protocols have been designed and approved? EU legislator, EP, Council – EFN engaging in design.

On 26th October 2009, the European Commission completed a proposal for an EU Council Directive to give legal

[1] EU Commission for Employment, Social Affairs and Inclusion. *New legislation to reduce injuries for 3,5 million healthcare workers in Europe*, 8th March 2010. http://www.saferneedles.org.uk/news/pdf_articles/Directive_press_statement.pdf.
[2] National Audit Office. *A safer place to work – improving the management of health and safety risks in NHS trusts*, 30th April 2003. http://www.nao.org.uk/wp-content/uploads/2003/04/0203623.pdf.
[3] European Biosafety Network. *Prevention of sharps injuries in the hospital and healthcare sector: Implementation guidance for the EU Framework Agreement, council directive and associated national legislation*. http://europeanbiosafetynetwork.eu/EU%20Sharps%20Injuries%20Implementation%20Guidance.pdf.
[4] Ibidem.
[5] Green B., Griffiths E.C. (2013). Psychiatric consequences of needlestick injury. *Occupational Medicine*, 63 (3): 183-188.

effect to the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector, signed on 17th July 2009 by the recognised European Social Partners, HOSPEEM (European Hospital and Healthcare Employers' Association) and EPSU (European Federation of Public Services Unions). The EU-wide agreement was signed following a process of five months negotiations which were undertaken in accordance with article 139 of the EU Treaty. The purpose of the agreement was «to prevent workers injuries with all medical sharps (including needlestick injuries)». This lead to EU-wide legislation on the protection of healthcare workers from injuries with medical sharps.

The EU Sharps Directive establishes a framework that includes measures to address risk assessment, risk prevention, training and information, awareness raising and monitoring and response and follow-up procedures in relation to sharps injuries. The agreement specifies general principles to avoid injuries and is the basis for Council Directive 2010/32/EU implementing the Framework Agreement on prevention of sharps injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU.

3. How will the new rules will be diffused in the European context?

The EU Council Directive on prevention from sharps injuries in the hospital and healthcare sector was adopted by the European Council on 8th March 2010 (Council Directive 2010/32/EU[6]). All EU member states are therefore obliged by EU law (Acquis Communautaire) to incorporate the Directive into national law by 11th May 2013. EU Member States were therefore required to bring into force the laws, regulations and administrative provisions necessary in order for healthcare organisations to comply with the Directive. The Italian Law Decree n. 19 of 19th February 2014 for the implementation of the Directive 2010/32/UE states that the employers have the duty to guarantee the health and safety of all the workers in all aspects concerned with their professional life, including psycho-social factors and work management and they must ensure the following conditions:

a) That the health workers are sufficiently informed and they are given the right resources in order to operate in safety so to avoid injuries and infections caused by sharp devices and needle sticks.
b) To adopt special measures in order to avoid the risk of infections in the workplace by adopting a global policy of prevention that takes into consideration the most advanced technologies, the organisation and work conditions, the psycho-social factors linked to the profession and the influence of the work environment on the employees.
c) To create the conditions for the active participation of the health workers and their representatives to the creation of the prevention policies.
d) To raise awareness by involving both health workers and their representatives.

[6] EU Council Directive 2010/32/EU. http://europeanbiosafetynetwork.eu/OJEU.pdf.

4. What are the expected impacts in term of safety and economics (lower costs for treatment of injuries)?

A large collection of independent studies have shown that a combination of training, safer working practices and the use of safer sharps can prevent more than 80 per cent of sharps injuries[7].
Most discussions and studies identify the costs involved with sharps injuries purely as the cost of treating the injured party, however studies looking at these costs often exclude many key factors, such as:

- the cost of paid leave for the injured party and associated substitute staff costs;
- the cost of resignations as a result of the injury including wasted training investment;
- increased recruitment costs and new staff training expenditure because of staff turnover.

Costs that could be avoided with simple prevention strategies for sharps injuries can be quite high. Despite the exclusion of "hidden" costs, studies still show that a simple process, such as conversion to the widespread use of safety-engineered medical devices in order to prevent sharps injuries, provides a viable return on investment. For example, several studies have shown that the overall cost savings of converting to safety-engineered medical devices far outweigh any additional investment implication they require.

[7] De Raeve P (2013). *Sharps Injuries – Stepping Up to the Challenge in Europe*. http://www.efnweb.be/wp-content/uploads/2013/01/HHE_Sharps_article_Paul-DeRaeve_EFN.pdf.

5. What are the policy and managerial implications of these rules/procedures/ protocols implementation?

This is a European Directive and they are binding requirements that must be met by every Member State. If not, Italy can be brought to Court for non-compliance with EU legislation.
The key requirements of the Directive are:

a) It is required that a formal risk assessment is conducted. Where there is a risk of injuries with a sharp and/or infection, workers' exposure must be eliminated by taking the following measures, without prejudice to their order:
   - Specifying and implementing safe procedures for using and disposing of sharp medical instruments and contaminated waste.
   - Eliminating the unnecessary use of sharps by implementing changes in practice and on the basis of the results of the risk assessment, providing medical devices incorporating safety-engineered protection mechanisms.
   - Banning the recapping of needles.

b) Introduction of safe systems of work, including the use of technology, general working conditions and the working environment and the use of personal protective equipment.

c) Requirements for effective awareness raising and mandatory training (including the correct use of medical devices incorporating sharps protection mechanisms).

d) Employers and workers' representatives shall work together to

eliminate and prevent risks, including consultation on the choice and use of safe equipment, identifying how best to carry out training, information and awareness-raising processes.

e) Provision of appropriate vaccination for workers where such exists (in accordance with national law and/or practice)
f) It is also required that there are policies in place for reporting, response and follow-up in the event of a sharps injury taking place.

The Directive states that employers and workers' representatives should consult about training programmes, changes to operational practices and the choice of safety devices. I have already highlighted the crucial role of awareness-building, information and training of healthcare workers in order to achieve a significant reduction of occupational exposure (even the best technological device is useless if not used properly and for the purposes stated in the relevant operating instructions).

Again, it would be appropriate for the law implementing the Directive to consider and highlight the minimum content required for each proposed training plan. It will also be important to establish criteria for evaluating the adequacy and effectiveness of teaching methods, particularly with reference to continuous medical training objectives.

6. What controls have been envisaged? Commission report.

The Directive sets out rules for its enforcement – EU member states have to lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive, and shall take all measures necessary to ensure that they are implemented. The penalties provided for should be effective, proportionate and dissuasive.

Should EU member states strictly hold non-compliant healthcare organizations to account, they may also hope to see a significant reduction in injuries. Depending on the legislation of each member state, enforceable violations could include, for example, failing to introduce safety-engineered medical devices where reasonably practicable to do so, and failing to include procedures for documenting and reporting incidents. The enforcement of consequences seems an effective way of asserting the importance of compliance in the minds of Directors. It must be remembered that the Directive applies to all environments in which medical sharps are in use, including nursing and care homes, and general practice surgeries.

On 2nd December 2013, the European Biosafety Network held its 4th Summit at the Polish Parliament in Warsaw. Members of the European Biosafety Network and attendees at the Summit have worked for many years to help achieve legislative requirements, and their goal now is to ensure that the EU Directive is effectively applied so that all workers in Europe finally receive the protection that they deserve.

One of the overarching messages from the event is that there is a need for consistency of practices and messaging throughout all healthcare organizations in all member states. Introducing protection measures, risks assessment policies, training information, awareness raising and communica-

tion, monitoring response and follow up are all important elements to be implemented in order to effectively ensure safety.
Interesting to mention:

- And now that the Directive has been implemented in Italy, healthcare contractors and employers should take the time to familiarise themselves with the new legislation to help them understand their legal obligations and the requirements that must be taken to ensure appropriate procedures to prevent sharps injuries. All medical and surgical personnel should make sure that they know their rights and what level of protection, information and training they can expect from their employers.
- Appropriate education, training and communication of the reasons for changes in procedures and devices appear to be vital to ensuring the effectiveness of the new legislation. For example, when introducing safety-engineered medical devices, some devices require manual activation in order for their safety mechanisms to work. The EU Directive states that employers and workers' representatives should be included in consultation on the choice and use of safe equipment, and identify together how best to carry out training, information and awareness-raising processes[8]. However, despite it being a very important element of the solution, in reality training in the use of safety engineered devices is often weak or non-existent. Some manufacturers provide excellent training and other don't. This needs to be taken into account in procurement. Where safety-engineered devices are purchased in accordance with tenders, the tenders should include training and support services as a specific requirement.
- Throughout Europe there also seems to be evidence that the legislation appears not to be being taken sufficiently seriously in long-term care situations. This is an area where increased awareness of the Directive and the new country legislations as well as how to comply with them needs to be addressed.
- Training and use of safety engineered devices is often weak or non-existent, despite it being a very important element of the solution.
- Healthcare organizations should ensure that tenders for procuring safety engineered devices include training and support services as a specific requirement.
- Italy legislation does include information on sanctions for failure to adopt the measures (imprisonment for a period of three to six months, and fines € 2.740 to € 7.014,40) for the employer and the managers – some countries have not included a penalty system.
- Legislative text in Italy states that the implementation of safety measures must be cost neutral. It is unclear as to whether they are advising that this should be the case based on published studies or instructing that safety measures should only be implemented if they are cost neutral. Unfortunately, I suspect that it is the latter. A very confusing signal that is not in accordance with the spirit of the directive.
- Would also be worth mentioning

[8] EU Council. EU Council Directive 2010/32/EU, 2nd May 2010. http://europeanbiosafetynetwork.eu/OJEU.pdf.

that across Europe we are seeing a trend of weak implementation in community care settings.

The Italian Law Decree n. 19 of 19th February 2014 for the implementation of the Directive 2010/32/UE states that employers need to evaluate the risks in the workplace and the evaluation must include the level of risk for contracting infections during work related activities and situations such as injuries and accidental contact with blood and other possible contaminations in the awareness of the importance of working in a safe environment provided with the necessary resources. Wherever the above-mentioned evaluation should point out the risk of injuries caused by sharps and needle sticks the employer needs to adopt specific prevention measures:

- Definition and enforcement of the safe use and disposal of medical devices which carry the risk of infection with
  a) the removal of sharp devices unless strictly necessary;
  b) the adoption of NPDs (Needle stick Prevention Devices);
  c) the forbidding the practice of recapping needles without protection devices in place;
  d) health surveillance;
  e) training in the correct use of NPDs and the procedures to adopt in case of notification, the response and the monitoring post-exposure and its prophylaxis in the case of accidental injuries;
  f) the raising of awareness of promotional activities and material in collaboration with trade unions and the workers representatives;
  g) the preparation for adopting the right procedures in case of accidental injury (post exposure immediate steps and prophylaxis and medical and psychological assistance to the patient);
  h) to promote good practice regarding the recording of incidents/accidents.